



European Translational Information and Knowledge Management Services

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Experiences of Harmonisation of Consortial Agreements in Europe

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Executive Summary

This deliverable was assigned to Work Package 5 in order to document the unexpected challenges encountered when attempting to reach legal agreements between consortia for the management of project research data as envisaged by the original eTRIKS description of work.

For the fullest engagement of eTRIKS' skills in support of a project a general agreement is required between the two consortia. Obtaining legal review and signature of an agreement involving all partners of a consortium has proved to be a challenging and time consuming process.

The learning we have taken from the process has provided a set of template documents that can be used to accelerate the agreement process and suggestions for simpler mechanisms that allow limited, but often sufficient, engagements between eTRIKS and a supported consortium.

Inputs and Outputs from related deliverables

This is a stand-alone deliverable arising from the Mid Term Review.

Description of work achieved

Introduction

Purpose

As set out in the Description of Work, WP5 provides a governance environment for the eTRIKS consortium (hereafter called “*eTRIKS*”) that ensures the delivery of a valued, sustainable platform for the management of Translational Research information for projects sponsored within or external to the Innovative Medicines Initiative Joint Undertaking (IMI).

This document discusses and investigates the challenges inherent in sharing and processing* data between research consortia. Two approaches are discussed and their successes and shortcomings are used to propose a more focussed approach to the contractual framework for data sharing and processing.

Intended audience

The readership of this document is presumed to be familiar with the eTRIKS project and its overall aims.

* ***Data processing/processed data.*** Any operation or set of operations performed upon data, whether or not by automated means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction (adapted from Article 2b of [the European Data Protection Directive 95/46/EC](#)).

Overall description

The eTRIKS project is an IMI project that provides products and services to support information management for exploratory research projects of other consortia (hereafter called “*the Collaborators*”[†]). eTRIKS aspires to create the *de facto* best practices and common technical framework for translational research information management for translational medicine projects conducted in Europe. The eTRIKS project provides an open and collaborative model for scientific knowledge to flourish; and for new approaches for the prevention, diagnosis, and treatment of disease to evolve, ultimately redefining the way biomedical research is translated to better health.

The process of incorporating exploratory data sets into the eTRIKS platform requires quality assessment and, if appropriate, data transformation (i. e. curation[‡]) and mapping of data attributes to the eTRIKS database. In order to deliver support to the Collaborator’s project (hereafter called “*the Project*”) and ultimately open access to the Project data, it is necessary to ensure that the Project data processed by eTRIKS is appropriately protected from both an ethical and a legal viewpoint.

The Challenge

IMI-funded projects must maintain ownership and good governance of their *foreground*. Foreground includes samples and all results and data created or collected in the course of a project. Under the terms of IMI Project Agreements, these remain the property of the consortium member (or members) who created them. Similar rules are in place for other Public Private Partnerships (PPP) translational research projects, such as those funded through the UK Medical Research Council programme.

The agreement that defines the operating context for a new IMI project typically allows for exchange, and cross-management, of foreground among the project partners, but does not generally establish rules for the management of foreground with a third party. Allowing an organisation from outside the project consortium to manage the foreground requires a legal agreement. Typically, a *Material Transfer Agreement* is executed to transfer physical samples to a third party. However, the same principles can be applied when a third party processes data. In dealing with study participant[§]-related personal data^{**} in biomedical projects, an additional layer of complexity is imposed by the

[†] **Collaborators.** One organisation working with one or more other organisations on one or more research projects. Such organisations authorise eTRIKS to process their data in the eTRIKS Platform and/or provide support to help them processing their data themselves.

[‡] **Data curation/ curated data.** Process of cleaning (i.e. removing inconsistency and misspelling, completing), transforming (e.g. converting numerical values with international units), and standardizing data (i.e. reporting, vocabulary and format standards). Curated data are data that have been through the curation process.

[§] **Study participant.** Any person participating in a research study, whether or not a clinical trial. It can refer to patients or healthy volunteers. It does not include health care professionals.

^{**} **Personal data.** Any information relating to an identified or identifiable natural person (data subject); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity (source: Article 2a of the Directive). (...) To determine whether a person is identifiable, account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the said person (source: Rationale 26 of the Directive).

necessity to remain compliant with the terms of national Data Protection legislation, which may differ in detail among the jurisdictions applicable to the collaborating project partners.

The IMI allows considerable latitude in defining processes to manage project data. Although investigators typically view managing data to be less challenging than managing scientific research, making data available, interoperable and usable among partners during and, sometimes, after the project time period is critical to the success of the project-based research.

There are some advantages in having a single organisation managing the entire data landscape of the project as this organization can:

- provide a single consolidated repository for all of the project data,
- facilitate the comparison and combination of data from different partners,
- remove the necessity for maintaining partner-specific data environments that must be secured for access by all other partners,
- reduce the duplication of effort required to maintain multiple data centres,
- provide a consistent, manageable security and access layer.

If the partners in a project cannot fully exploit the project data, then the potential value of the project is put at risk. If there is no project partner capable of providing data management services, then an external organisation needs to be engaged to manage the data on behalf of the project partner(s). Many IMI consortia are established in which a specific partner(s) assumes the responsibility for data management. Other IMI projects, such as ABIRISK decide to engage the services of an external agency (in this case of ABIRISK, the external data management supplier is eTRIKS) to manage their data.

An advantage of engaging an external organisation is that they are able to continue to provide their services beyond the end of the project and therefore offer an opportunity to provide sustainable access to the data after the project has closed. Such an arrangement shifts the long-term responsibility/burden away from the individual partners who ultimately created the data.

The need for a Material Transfer Agreement

Unless otherwise agreed by the Partners, IMI Project Agreements require a Material Transfer Agreement (MTA) whenever a foreground asset of a project is made available to a third party (eTRIKS for example).

For eTRIKS to manage the data of an IMI project, the MTA must meet five requirements.

1. A confidentiality agreement between the Collaborators and eTRIKS;
2. A legal framework in which the Project data can be processed by eTRIKS (including hosting when required by the Collaborators), clarifying the legal status under IMI rules;

Key-coded data (e.g. name, address and social security number of an individual are removed and replaced by a unique random number) or pseudonymised data are personal data.

3. An Intellectual Property (IP) position for curation artefacts, such as transformed data files and database mappings, that are created by eTRIKS during the preparation of the Project data;
4. If needed, set up a joint scientific endeavour that can be used to apply or develop new data management techniques;
5. Set out the roles and responsibilities of the Collaborators and eTRIKS.

The data-oriented MTA that is required does not fit the template for transfer of biological materials

There are many ways in which data processing challenges the standard Material Transfer Agreement written for management and exchange of physical bio-specimens (e.g. MTAs of BBMRI-ERIC^{††})

BBMRI-ERIC typically deals with the provision of physical material from a repository to an individual research group and the agreement must be supplemented to support data transfer. Although MTAs that enable specimen and data transfers can share the same basic templates, there are specific features that are pertinent to MTAs that govern data and information processes by a third party.

- IMI and other PPP consortia are not in themselves legal entities - any collaboration agreement must therefore be agreed by ***all*** legal entities involved.
- The data assets of interest are very easily copied and derivative works are much easier to create and disseminate. Control measures and expectations regarding copies and derived works need to be established.
- Data management suppliers will create derivative works that will be the property of the project owners.
- In cases in which the relationship between the data management suppliers and the project owners is more complicated than basic data processing services (e.g. collaborative in nature), then specialized activities must be carefully defined with respect to IP rights and governance.
- The IMI and other consortial agreements ensure that the project owners maintain the ownership of their IP. Results are *Foreground* and these include derivative works that contain or are produced from the analysis and processing of unrefined datasets. New data management processes and learning that are developed in the act of supplying data management services, however, constitute the foreground of the data management suppliers. Infrastructure (databases and server environments) that contains project data generally becomes the property of the project owners, even if it has been created by the data management suppliers. The processes and tools to create such installations, however, remain the IP of the data management suppliers.
- The IMI allows individual projects to dictate the dissemination rules with respect to the project foreground including the option for commercialization. Some non-IMI consortia restrict the use of materials by for-profit organisations or for for-profit activities.

^{††} <http://bbmri-eric.eu/>

- Pharmaceutical companies, which by definition are partners in all IMI consortia, require anti-bribery and anti-corruption clauses in all agreements. Such clauses are not common in non-commercial agreements and are unfamiliar to many academic and hospital groups.
- The data management suppliers' MTA is a "*Pull*" MTA meaning that the agreement is created and promoted by the data management supplier (e. g. eTRIKS) rather than the project owners. Conversely, most physical sample-based MTAs are created and promoted by the owner(s) of the materials.
- The MTA must, in many cases, address rules governing informed consent, by study participants, with respect to the use of their data for exploratory research. Appropriate use can become a significant issue if data sets contain personal data including pseudonymised data^{††}.

What the MTA needs to cover

The areas that need to be considered, addressed and agreed between eTRIKS and the Collaborator(s) wishing to take advantage of eTRIKS' services may include:

- Definitions of terms used in the agreement
- The scope of the agreement
- Descriptions of the permitted uses of the data sets by each party
- Clarification of ownership of all data entities and software within the scope of the agreement
- Governance of any collaborative activities between the Collaborator(s) and eTRIKS
- Communication processes
- Processes for issue resolution
- Confidentiality
- Publications
- Personal data protection
- Conflict of interest and cross contamination of research
- Liability and indemnity
- Termination
- Anti-bribery and anti-corruption
- Activities covered under the agreement
 - Data de-identification, curation, loading and provenance
 - Data hosting, security, access and release
 - Data visualisation, analysis and export
 - Error reporting and handling
 - Training
- Roles and responsibilities
- Timelines and milestones

^{††} **Pseudonymisation / pseudonymised data.** 'pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person (source: Article 4, paragraph 5 of the [European General Data Protection Regulation](#)).

- Data entities in scope

Options considered for the MTA signatories

There are a number of ways in which an agreement can be reached between the data management suppliers and the project owners (e.g. eTRIKS and the Collaborators, respectively). Each has its merits and drawbacks, which are summarised here.

1 A full MTA among all partners of each consortium

In this case, all partners sign, and are bound by, a single MTA contract.

Pros

The MTA is comprehensive and therefore should, in principle, be the only agreement that needs to be set up between eTRIKS and the Collaborators.

Cons

Both eTRIKS and the Collaborators may be comprised of a substantial number of partners, and all partners must sign the MTA regardless of their role with regard to the data processing activities. The large number of partners may lead to difficult and time-consuming rounds of discussion to reach agreement and obtain authorization among all parties.

2 A Confidential Disclosure Agreement (CDA) signed by all members with an MTA among partners processing the project data

CDAs are typically much more familiar to partners and thus easier to obtain agreement and signature. Collaborative projects often have the capability to assign execution responsibilities of a CDA to a single partner on behalf of all partners provided that no (or minimal) changes to the CDA are requested by the alternate party (i.e. a “Mandate”).

In this case, the confidentiality restrictions apply to all partners of both consortia and become the basis for eTRIKS – Collaborators interaction. However, only those partners having a role in the processing of the Project data need sign an MTA.

Pros

It should be possible to begin activities sooner with this model.

A CDA that is within the remit of a consortium Mandate (if such a mandate exists) requires formal acceptance by each partner but only a single signature by the party responsible for executing the Mandate.

An MTA only between the partners processing the project data is easier to set up, as it involves fewer partners, all of them are engaged directly in the collaboration and therefore are usually motivated to construct the agreement and sign it promptly.

Cons

It requires prior agreement among all partners on the CDA wording.

Not all consortia have a Mandated CDA, so they would need to obtain a full round of signatures for the CDA in addition to the partial set for the MTA.

Even where there are mandated CDAs in both consortia, they may not use the same wording, so a full review and signature will be required by at least one of the consortia. If there were a need to bring in additional eTRIKS partners to manage the processing of the Project data, an amendment to the MTA would be required.

3 Collaboration under a CDA

Pros

Much quicker and easier to set up – it just needs the CDA round as described above.

Cons

Data cannot be processed by eTRIKS under a CDA. Therefore, this option is limited to a collaboration in which eTRIKS provides know-how and support for installation of software and data curation and de-identification on a server under the full control of the Collaborator(s).

4 Individual agreements between partners from each consortium

Pros

Each agreement needs only to involve two organisations, each of them has a vested interest in reaching agreement.

Cons

This solution will only work if there is a single data controller^{§§} on the Collaborator's side and a single eTRIKS partner responsible for the data processing. If there is more than one partner involved from each side the multiplicity of individual contracts will rapidly become intractable.

5 Agreements between a consortium and a single partner

This might be used if the expectation is that only a single partner in the eTRIKS consortium will be handling all aspects of data management or if only a single partner among the Collaborators may act as data controller for the whole consortium.

Pros

Each agreement needs only to involve one consortium and a single partner from the other, all of whom have an interest in reaching agreement.

Cons

If the single partner is in eTRIKS, mirroring the project data in another site of the eTRIKS platform requires a separate agreement for each site.
For a single Collaborator to operate as data controller for the whole of a consortium, this must already be agreed within the consortium.

6 An eTRIKS partner with capacity to provide data processing services joins the Collaborator's consortium

Pros

The eTRIKS partner joins the Collaborator's consortium, and therefore there is no need for any additional CDA or MTAs for them to process the data.

Cons

The Collaborators may be unable or unwilling to admit a new partner.
The acceding partner cannot leverage the skills base of the whole of eTRIKS.

^{§§} **Data controller or controller.** A data controller or a controller is the natural or legal person, or any other body, which alone or jointly with others determines the purposes and means of the processing of personal data (source: Article 2d of the European Data Protection Directive).

The procedural complexity of admitting a new partner in the Collaborators' consortium may exceed that of implementing an MTA.

Options 1, 2, 5 and 6 all offer possible practical options for addressing the need to process data and have been investigated in some form by eTRIKS.

The Process Used

The creation of a full MTA between all partners of each consortium offers the greatest value and flexibility and provides a framework for full scientific cooperation among all partners. Therefore, Option 1 – a general MTA between eTRIKS and the Collaborators - was initially identified as the preferred approach to provide a sufficiently broad and acceptable agreement in a reasonable time frame.

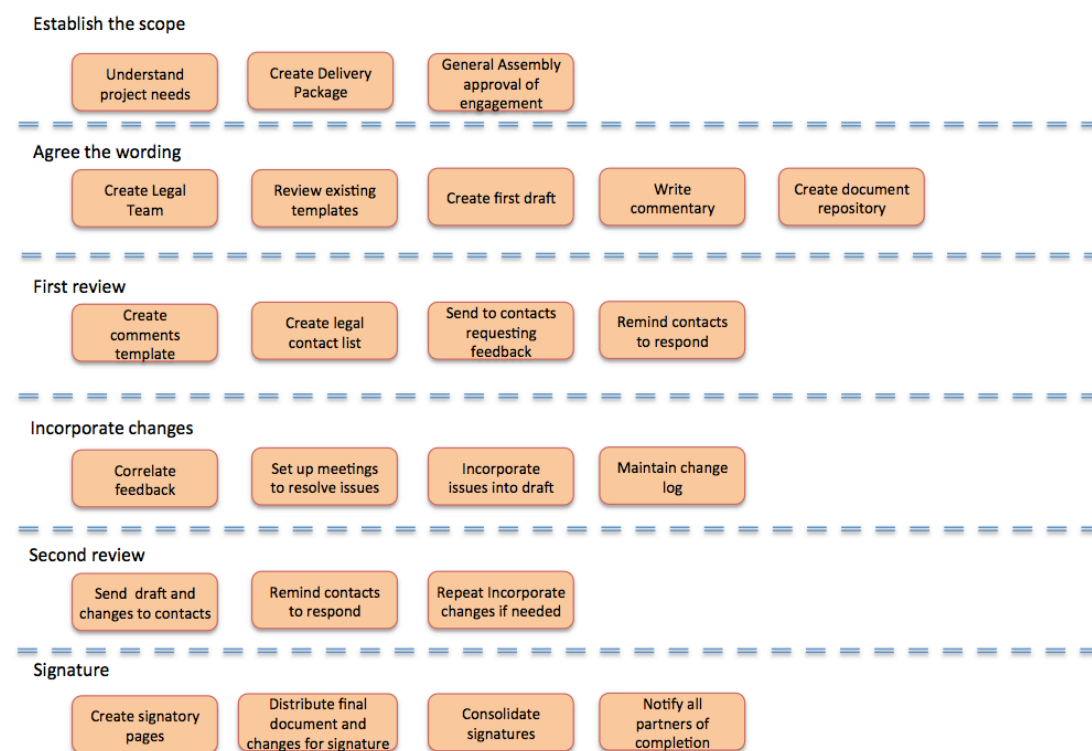
It was further anticipated that the forging of agreements between eTRIKS and ABIRISK would provide a rigorously worded template that could be used substantially unchanged for any future agreements.

Each agreement is divided into two sections.

- 1) The Agreement itself. This is the legal agreement between the two consortia and contains all the clauses that are not expected to vary during the course of the agreement.
- 2) A Task Plan. Each party will likely be responsible for completing certain planned actions as generally dictated in the agreement and described in the appended Task Plan. Such operational responsibilities and the manner of their completion may require amendment during the course of the agreement. The task plan, as a supplement to the main agreement, can be changed by the members of the collaboration team who have been appointed by the consortia without requiring an amendment to the agreement.

Overall process

The approach taken to finalising the agreement corresponds to the process one might expect for any legal discussion, except that it needs to take into account the distributed authorisation processes in a consortium due to the legal entities being the individual consortium partners and not the consortium itself.



Establish the Scope

The degree of interaction between the two consortia can vary from a simple need of information exchange that does not require a MTA to a close scientific relationship in which the consortia are working together, each providing significant resources to the joint endeavour. Agreement on the scope of the relationship must be established early, as this will determine whether a MTA is needed and, if so, set the requirements for the MTA. At a formal level, requests for significant engagement between eTRIKS and the Collaborators must be agreed by the eTRIKS General Assembly before they are begun.

At the beginning of the engagement the high level issues and resources of the engagement are set out in a Delivery Package summary (Appendix 1).

Agree on the Wording

A team of business and legal experts from the two consortia must be established. This team at minimum must include a legal expert and a business expert from each consortia plus the Account Manager, appointed by eTRIKS to work with the Collaborator's consortium. If it is possible for most of the members of the Legal Team to be from organisations that are partners in both consortia this will significantly improve the information flow between the consortia in situations where a CDA is not in place. The legal experts need to be familiar with IMI regulations and general European laws.

At the outset of the negotiations with ABIRISK and OncoTrack, no previous MTA was available as a template. The first task of the Legal Team was therefore to create a document that covered all the issues that need to be considered, and agree among themselves on a first draft of the content. We found that a weekly meeting was necessary to run this process. Not all members of the Legal Team could be present at all meetings, but the frequency was such that continuous progress could be made on the wording.

In addition to agreeing on the wording of the document itself we found it valuable to develop a commentary document that explained the rationale behind some of the wording, particularly where this was not self-evident from the agreement itself and where it would not be normal legal practise to include the descriptions within the legal wording.

First review

It is essential that all partners from both consortia have a chance to comment on and amend the wording. A simple template can be established to capture comments and concerns and to track how the Legal Team addresses them. However, it has been found that many organisations adopt a less structured interaction and it is also necessary to accept comments via email.

The appropriate person to send the Agreement to for review must be identified. The representative of each partner was asked to provide the contact details of a legal representative for their organisation. The Agreement, explanatory notes and comments spread-sheet was sent to each legal contact, and copied to the representative where appropriate. A deadline of 2 weeks seemed appropriate to get back responses, but this proved to be optimistic.

In general, a contact in the legal group was forthcoming for each organisation, but some partners do not encourage their legal groups to interact directly with external teams, and in these cases the documents needed to be sent via the representative. It is our

experience that those organisations that do not allow direct access to their legal counsel are not able to respond as quickly as those that do.

Incorporate changes

Since each partner is reviewing the document independently they do not have access to each other's comments. The next step is therefore to take all of the comments and write them into a second draft. Many of the comments will be minor corrections to text, but some will reflect significant issues that may need lengthy debate. A very valuable step at this time is to invite the legal representatives from organisations with concerns to join with the Legal Team at one or more of the weekly meetings. This may take a number of iterations, particularly if there is a fundamental difference of opinion on a clause between two partners. A single face-to-face or teleconference meeting can resolve problems more effectively than weeks of email exchange.

In this way a new draft of the document can be written that addresses the issues. It is important to keep a change log and/or "before and after" versions of the agreement so that reviewers can see easily what parts have been changed from the first version. Again an explanatory document detailing the reasoning behind any changes is invaluable.

Second review

A second review is conducted using the same process as that for the first, but also including the change log in the distributed document set.

It would be expected that by this stage changes should be minor or for additional clarification. There is a risk, however, that a previously unidentified significant issue is raised at the second review. If that is the case, the review process must be repeated for a third (or more) cycle until the wording is agreeable.

Finally, all agreed changes are incorporated into a final document and a change log created detailing the variations from the previously reviewed version.

This highly managed process is necessary to ensure that all parties have the requisite opportunity to review, comment on and understand the contents of the final agreement before they are asked to sign it.

Signature

A signature page for each partner of each consortium is created. This means that partners who are in both consortia will need to sign twice. This was agreed as several partners pointed out that although they are a single legal entity, the legal groups that deal with different IMI projects could be quite separate from each other. In some jurisdictions, however, (e.g. in France) there are legal statutes that prevent a legal entity from signing a contract twice and effectively concluding a contract with themselves. In such cases, the signature page includes a statement that the single signature indicates acceptance of the agreement for both consortia.

The final document and the final change log together with a covering letter were distributed to each of the legal representatives with the request for immediate attention, signature and return of the agreement. Each partner needed to provide five (5) signed copies of their signature page – one copy each for the Managing Entity and the Coordinator of the two consortia and an additional copy for the IMI. These were sent to the legal counsel for the Coordinator to create a fully consolidated document with all signatures. A return request of four weeks was made as we believed this should allow

for legal representatives to be away, on holiday etc. but still meet the deadline. After receipt of all signature pages, the partners were notified that the agreement process was complete and in effect.

The final step is to consolidate the signature pages into a single, signed version that can be exchanged with the Collaborators and deposited with the IMI.

Case Study 1 – ABIRISK

Background

ABIRISK chose to engage eTRIKS as their primary data management supplier in their initial Project Proposal.

ABIRISK itself is a complex project dealing with diverse data sets from many disease areas and many partner organisations. It was agreed that the flexibility and disease-neutral features of tranSMART^{***} would be well suited to the requirements of the ABIRISK data analysts. At the same time, it was also recognised that this was a novel way to manage the data for the project and that considerable coordination of activities and joint development of data management techniques would be required to ensure a successful partnership.

For this reason it was agreed that the contract between eTRIKS and ABIRISK needed to allow considerable flexibility on how the work was carried out and a joint management structure should be created to manage the combined efforts of the two projects.

A critical feature of the agreement is the recognition that eTRIKS will be much more than a passive data processor^{†††} and host for the ABIRISK data. From the start it was expected that eTRIKS would be actively engaged in advising ABIRISK on good information management practices. The establishment and governance of the joint activities was therefore an important part of the engagement as was the expectation that all partners in both projects could be involved in the joint undertakings even if only in an advisory capacity.

^{***} **tranSMART** (<http://transmartfoundation.org/>). Analytical platform developed for end-users not well versed in informatics, such as biologists or physicians. The tranSMART foundation coordinates the development of tranSMART.

^{†††} **Data processor or processor.** A data processor or processor is a natural or legal person, or any other body, which processes personal data on behalf of the data controller (source: Article 2e of the European Data Protection Directive).

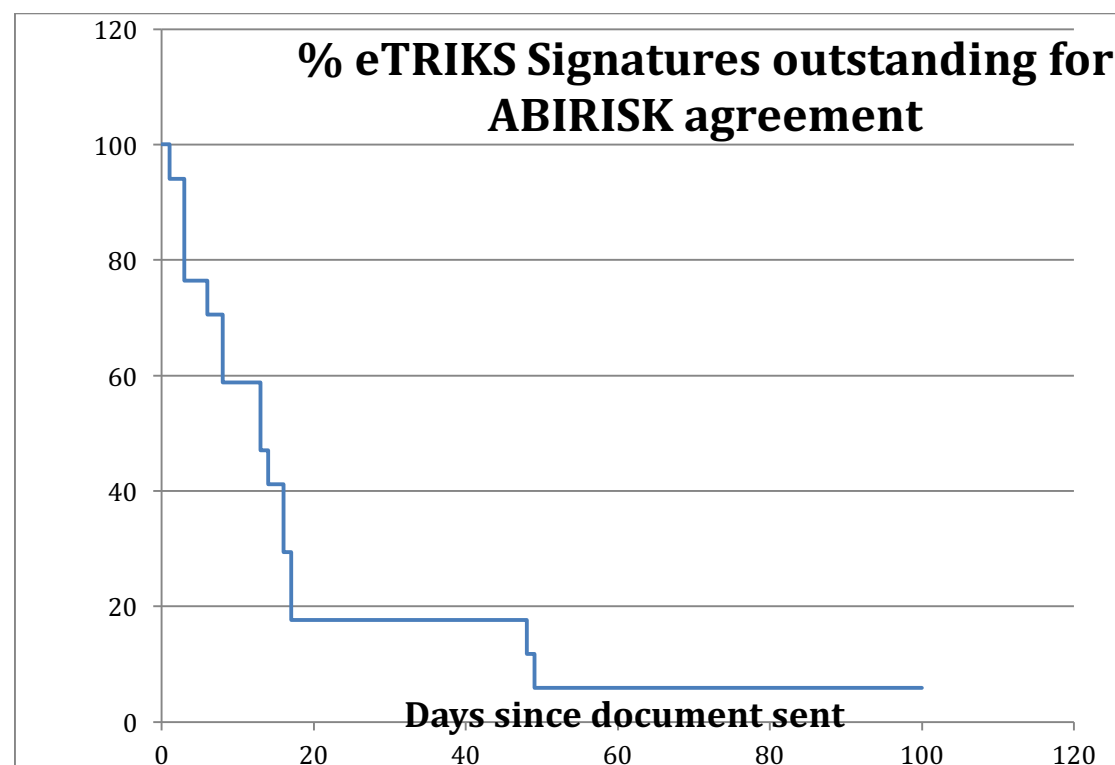
Timelines

Step	Time taken (months)
Establish the scope	2
Agree the wording	3
First review	4
Incorporate the changes	2
Second review	8
Signature	11
Total	30

Signature step

Despite the effort put into the second review to ensure that all partners had a chance to assess and comment on the final wording, the signature process was much slower than we had anticipated. We encountered a number of groups that took over a month to return a signature, and one particular partner from whom a signature was obtained only after 7 months. A question about authority to sign both parts of an agreement arose from a partner who is in both consortia. This further delayed the final signature process.

The attached “Kaplan Meier” like plot shows the rate at which signatures were received.



ABIRISK case review

As the first and most complex example of creating a data transfer agreement it was expected that ABIRISK would provide a challenging case. However, we did not

anticipate the extreme delays that would be encountered in reviewing and agreeing the document wording, nor the time it would take to secure the final signatures.

As understanding of the relationship between eTRIKS and the supported consortia has matured it has become clear that this form of all-encompassing agreement is not favoured by most Collaborators' consortia, so while we will maintain a general template version of it, it is deemed unlikely that this will be used for any future agreements.

Case Study 2 – Oncotrack

Background

OncoTrack provided a different set of challenges. The project already had a data management partner and a database providing access to all data collected by the OncoTrack partners. The data base system was not, however, designed to provide a user interface for exploration and analysis such as that provided by the tranSMART core. OncoTrack's motivation to complete this agreement was to provide a user interface, for non-informaticians, to mine the available data and develop new hypotheses. Furthermore, the data are maintained in pseudonymised form, and crucially, the wording of the patient consent form used by the clinical data controllers meant that a considerable amount of legal activity needed to be carried out inside the project before the data could be released for hosting by eTRIKS.

The outcome of the process is a much simpler Data Processing Agreement (DPA) that requires signature only from the Oncotrack clinical data controller and the partners in eTRIKS. There is no generation of shared foreground or other IP, and therefore no need for a collaborative research engagement between the two consortia.

Issues encountered

A major roadblock that delayed the early phase of this agreement process was the recognition of an issue with the wording of the consent agreement at one Oncotrack clinical site that considerably reduced the latitude available for data transfer. This led to the decision to use a Data Processing Agreement between eTRIKS and the OncoTrack Data Controller. Transfer and processing of the data within the OncoTrack consortium is regulated by the terms of the Project Agreement and by a separate DPA between the OncoTrack Data Controller and the partner responsible for maintenance of the OncoTrack consortial database.

Timelines

Step	Time taken (months)
Establish the scope	2
Agree the wording	4
First review	5
Incorporate the changes	2
Second review	2
Signature	3+
Total	18+

OncoTrack case review

The OncoTrack data processing agreement is in the signature phase at time of writing, with 2 signatures outstanding.

Issues encountered and possible solutions

A number of issues were encountered during the creation of the ABIRISK and OncoTrack agreements that appear likely to be encountered in future collaborations. These are summarised below with suggestions for how they might be mitigated in future agreements.

Issue	Description	Probability	Impact	Mitigation
No response from a partner	This is most likely a symptom of another underlying problem.	High	High	<p>Look for the reason for lack of response.</p> <p>Most frequently, this is probably a consequence of “partner representatives have no mechanism to hurry their legal teams”</p> <p>Remind partner representatives that they are responsible for their organisations behaviour towards the consortium – but this is a tricky proposition if in the institution in question “partner representatives do not have good communications with their legal departments”</p>
Not all partners see the need for the agreement	If a partner is neither supplying data directly, nor processing the Project data, then their interest in the agreement is minimal	High	Medium	<p>A solid story to explain the value of the agreement to the whole consortium</p> <p>Last resort: by signing up to the consortium they have agreed to behave in the interests of the consortium as a whole</p> <p>There can be a legitimate case made for a partner not signing on to an MTA due to concerns about research contamination (see below)</p>

				There may be a legitimate case to conclude an MTA among only those partners directly involved in the exchange and processing of the Project data (see Summary)
Partners do not have good communications with their legal departments	In order to get a sound legal view on the implications of the agreement it is essential that each partner's legal team reviews it. This can be a challenge in organisations with central or very busy legal teams.	Medium	High	There doesn't seem any easy way to mitigate this problem except discussion with the partner representative and/or the consortium coordinator
Partners have no mechanism to hurry their legal teams	Typically, legal teams address the highest priority issues for their organisation. If there is a lack of belief of the value from the partner, then there may be no incentive to push the legal team.	High	High	There don't seem any easy way to mitigate this problem except discussion with the partner representative and/or the consortium coordinator
No ability to speak directly with the partner's legal team	Some legal teams do not want to engage directly with external organisations. This causes delay and risks misunderstanding	Medium	Medium	Explain value of direct engagement of the legal team to the partner representative, but ultimately this is an internal decision with the organisation.
Sharing of documents between the consortia	Practically, it can be hard to ensure that each partner has an up to date version of the document	High	Medium	This could be taken care of through a shared document environment like Teamwork or GoogleDocs. But some organisations require considerable time to grant access to these.

IMI Consortia are not legal entities	Any agreement must be reviewed and agreed by all partners individually.	High	High	This general problem is being actively worked on at IMI in the context of revised templates of the Project and Grant Agreements for IMI2 calls.
Fundamentally differing views on a clause	It can occur that two partners, either in the same consortium or different ones have strongly held but incompatible views on a feature of the agreement	Low	High	Only solution is to seek a compromise. Run frequent and regular legal teleconferences throughout the negotiations and invite any and all legal teams who may have an issue. Be prepared to hold ad hoc calls if there is a particularly difficult issue to agree. Try to have a “neutral” view on the issue available
Partners who are in both consortia may not be able to sign both parts of the contract separately	In some legal jurisdictions (e.g. France) it is not legally permitted to sign a contract with yourself. This needs to be considered to ensure that appropriate wording is included for the signatures of partners that are in both consortia	High	Medium	Ensure that all partners common to both consortia are familiar with the law on multiple signature of an agreement in their country of incorporation.
Different views from academic and EFPIA ⁺⁺⁺ partners	The outlook and priorities from EFPIA and academic or clinical organisations can be very different. Typically, EFPIA partners are more experienced in dealing with international contracts. Academic ones are usually more familiar with the local	High	High	This is really a sub-set of the point raised above. The differing priorities of the partners lead to “incompatible views on a feature of the agreement”. The most effective approach is to arrange frequent and regular teleconferences to discuss the issues

⁺⁺⁺**EFPIA**. The [European Federation of Pharmaceutical Industries and Associations](#).

	legal landscape. Also specific issues, such as anti-bribery and anti-corruption clauses may be unfamiliar to clinical groups. Academic groups are often deeply concerned to protect their IP.			
Changing lawyers at partners needing to be re-briefed	Over the course of a prolonged negotiation like this it is possible that the legal contacts in some partners will change. This results in the need to inform them of the background and reason for the agreement and may result in sudden new requests for changes	High	Medium	Try to maintain a “briefing status” summary of the discussions and salient points to share with any new legal contacts. This is also useful in the case above where there may be a deeply held difference of opinion encountered some time into the discussions
Very late requests for change	Even after 2 rounds of review it is possible that one partner will request a change to a part that was thought to be agreed already	Medium	High	The best mitigation for this problem is to have all the parties at the table from the start – which is nigh on impossible if you are dealing with 30+ partners in two consortia. An alternate solution would be to have templates that are an integral part of the Grant or Project Agreement so that the changes can be kept to a minimum.
No standard wording to start from	Without a standard template to start from there was no bedrock of common understanding between the legal teams. The entire agreement had to be created from scratch	High	High	With the ABIRISK agreement and the alternative of the Data Processing Agreement in the works for OncoTrack, we have created ‘standard’ wording of sorts for the future.
Most partners do not commit legal resource to IMI projects	The legal consultation comes from legal teams of the partners. They are not able to have a full commitment to the negotiations and need to	High	High	Partners should include allowance for some legal time within their resources for an IMI project

	balance it with other activities. This can mean that legal support is not always available when you most need it. There is no IMI legal department that can be used.			
The agreement may need to be reshaped as the relationship progresses	The nature of the relationship between the consortia is expected to be collaborative and evolving. As such, it is not possible to exactly define every detail of the relationship at the beginning. It is necessary to provide some mechanism in the contract to agree changes that do not change the material outcome without needing a complete re-negotiation and re-signing by all partners	Medium	Medium	<p>The Parties can amend any contract if circumstances demand it. They simply have to agree on the changes and exchange written documentation of an amendment to the contract.</p> <p>Modification to the Task Plan is foreseen in the MTA agreements (§2.6 Modification) and requires only written agreement.</p>
Clear, standard definition of datasets	Although there are definitions (e.g. Dublin Core) for data sets, they do not match the variety of data and images that will fall into the scope of an MTA involving clinical, imaging and bio-molecular data.	High	Low	We now have a definition in the ABIRISK agreement that is compatible with IMI foreground rules.
The data management needs to be different for pseudonymised data	Anonymised data can be managed relatively straightforwardly as it is not personal data. This is not the case for pseudonymised data. The exact status of this is still in discussion and varies between states. Therefore, the latitude of the agreement is significantly curtailed when managing pseudonymised data.	Medium	High	The eTRIKS WP7 “Data Ethics and Protection” established a data ethics and privacy framework that facilitates data sharing and processing between eTRIKS and the Collaborators. Moreover, the new European Data Protection Regulation addresses the issue of pseudonymised data.

Some partners may have concerns with IP contamination and wish to opt out of an agreement	The risk of compromising of research by having access to data under CDA from another consortium is an issue.	Medium	Medium	This needs to be addressed through appropriate clauses in the contract and may exclude one or more partners as signatories to an agreement
Correlating change requests from multiple partners	There are multiple partners each potentially wanting to make changes, especially in the early stages of the negotiations. Different changes may be requested simultaneously to the same clause and need to be correlated	High	Medium	This makes for a lot of coordinating work, but cannot be avoided.
No IMI Legal counsel	Where there are issues that go between or across projects, there is no centre of legal advice in IMI that can be called on to offer guidance	High	High	

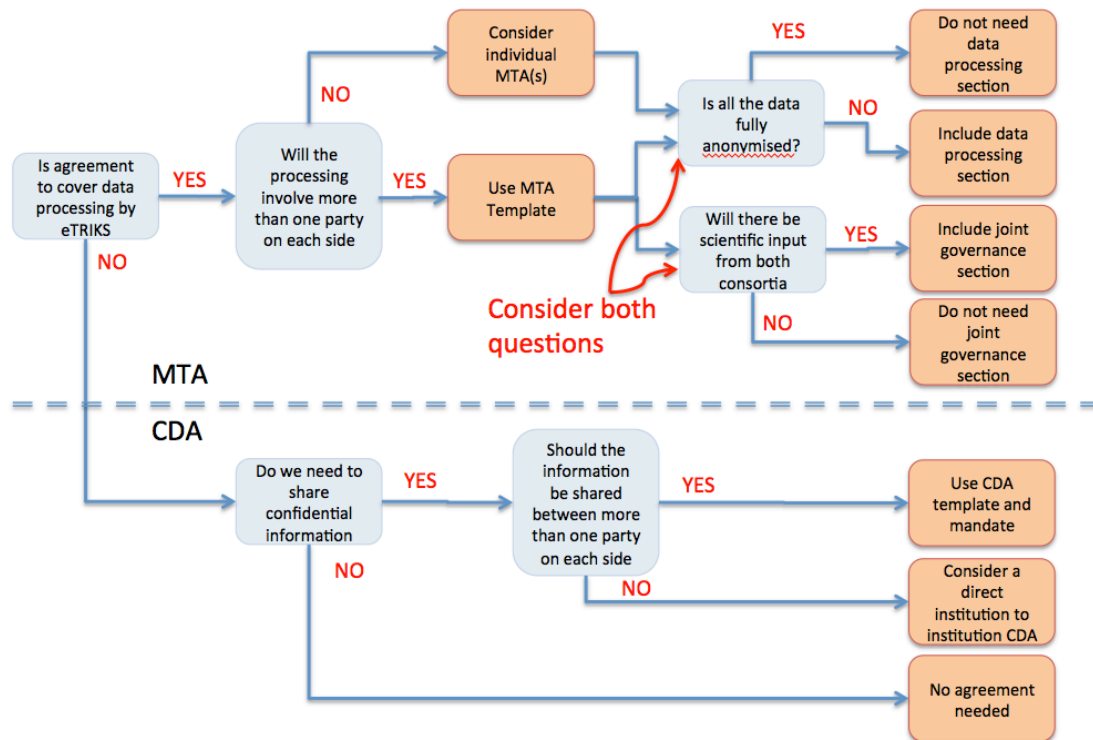
Creating generally applicable templates

From the activities on the two projects it has been possible to create templates that can be tailored to fit many likely situations. As previously stated, it is not possible to make this a standard part of a mandated legal agreement as partners are always going to need to review the details of exactly what data is being considered. But it does provide starting points in which the majority of the text has been reviewed, understood and accepted by the legal departments of each of the partners. We can therefore concentrate discussion on each case on the details rather than the overall structure of the agreement.

The first step when considering a material transfer relationship between eTRIKS and the Collaborators is to establish what type of agreement is required. This will inform the decision as to whether the requirement is specifically for a CDA (outside the scope of this report), a full MTA or a more restricted Data Processing Agreement (DPA).

Selecting the right project agreement format

Project Agreement Decision Tree



Once the decision has been reached as to the nature of the engagement the appropriate template (Template for eTRIKS MTA – Appendix 2 or Template for Data Processing – Appendix 3) can be used. In either case a Task Plan also needs to be created (Appendix 4).

These templates can form the basis of the agreement, but as noted above in almost all circumstances they will need to undergo several rounds of editing to meet the specific needs of the relationship and activities to be carried out.

Towards a more streamlined agreement model

We have observed that partners not directly involved in the collaboration are most likely to delay the process by failing to respond to requests for review or signature. Thus, even the process for obtaining full signatures on a DPA has proved prohibitively time consuming. To address this we have looked at the possibility of creating an agreement that requires only the signatures of those IMI partners directly involved in provided services and activities in support of the collaboration.

It may provide a significantly quicker process because only those parties actively involved in the collaboration need to review and sign the agreement. We have made progress on a form of wording that could be used for such an agreement, but it has not been tested in a live situation (Appendix 5).

Beyond this we have also explored the option of direct partner-to-partner agreements. These do not fall within the remit of the eTRIKS project, nevertheless we have provided an example template that might be used to facilitate the creation of an appropriate

agreement (Appendix 6). As previously noted this approach will rapidly lead to an intractable proliferation of cross-partner agreements if more than one partner from each consortium is involved. However, it does potentially offer a rapid way for a limited engagement to be initiated and would not prevent the later conclusion of a wider agreement between the consortia.

Summary

Sustainable exploitation and management of data is a critical component of the value of IMI funded collaborative research. A corpus of data that can be built up during the course of the project, accessed through a common universal interface, and that remains accessible after the project has concluded is a lasting asset to researchers. eTRIKS was set up to help to provide an environment and meet this need as it was recognised that many IMI projects did not have the capacity within the project to do this.

The structure of PPP funded projects makes the creation of project-to-project agreements challenging. The relationship required for eTRIKS to manage another project's data is more complex than a normal Data Processing or sample-based Material Transfer Agreement. It needs to recognise the foreground ownership needs of each consortium, consider the creation of derivative works and may also include joint research activities, e.g. to manage new data types.

Bringing full consortium-to-consortium agreements to signature has proved to be prohibitively time consuming. Firstly the involvement of multiple partners makes finding a fully acceptable form of words a challenge, but this is compounded by the time taken to get all partners to sign the agreement. There is no practical way to compel swift response. Completion of an agreement requires all parties to sign and we have found serially slow organisations that consistently hold up the process.

Two options appear possible as partial solutions to the problem.

- Use agreements that only cover those organisations that are directly involved in the joint activities.
- Ensure that new grant and project agreements include a mandated CDA and, when possible, an MTA template for data processing is agreed as part of the project agreement proposal.

Of these the most likely to garner immediate value is to limit agreements to only those partners of the consortia who are actively engaged in the collaborative activities, combined with a CDA that allows these groups to leverage appropriate support from the rest of the consortium. This is the approach we are investigating and recommending in eTRIKS.

Appendix 1

The DPDD Template document

Delivery Package Name:

Purpose of this document

This document outlines the objectives, deliverables and teams for an eTRIKS Delivery Package as agreed at the outset of the Delivery Package. It includes a breakdown of the activities and the estimated effort required to deliver each portion. The document is to be completed before the work begins and will form part of the work prioritisation process for eTRIKS.

Objective of This Delivery Package

Project(s) Impacted by Delivery Package

Scope

Data Entities

Priority

Start Date of Delivery Package

End Date of Delivery Package

Stakeholder Work-Packages

eTRIKS Resources

Project Manager

Account Manager

Others ...

Agreed Delivery components – these will form the “Sprint Card” stack for the DP

Component name	WP	FTE estimate (people months)	Due date
<add new lines as required>			
	Total		

Other DP and WP Dependencies

Activity	Nature of Dependency	Impact
<i><add new lines as required></i>		

Key Risks

Risk	Impact	Probability	Mitigation
<i><add new lines as required></i>			

Appendix 2

A general template for eTRIKS MTA

eTRIKS - PROVIDING PROJECT DATASETS AND IMAGES TRANSFER AND COLLABORATION AGREEMENT

This Datasets and Images Transfer and Collaboration Agreement (the “**Agreement**”) is made effective as of the [number] day of [month] 201[x] (the “**Effective Date**”) by and between

- (1) **ASTRAZENECA AB**, a company incorporated in Sweden under no. 556011-7482 with offices at S-151 85 Södertälje, Sweden (“**AZ**”); acting in its capacity as coordinator under the agreement entitled “European Translational Information & Knowledge Management Services” (IMI grant agreement No. 115446) and
- (2) **IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE**, whose administrative offices are at Exhibition Road, South Kensington Campus, London, SW7 2AZ, UNITED KINGDOM (“**ICL**”) acting in its capacity as Managing Entity under the agreement entitled “European Translational Information & Knowledge Management Services” (IMI grant agreement No. 115446)

WHEREAS AZ, ICL and the other eTRIKS participants listed below and any future eTRIKS participants that join the eTRIKS consortium, which shall be notified by the eTRIKS coordinator promptly upon such accession, are hereinafter collectively referred to as the “**eTRIKS Participants**”:

University of Luxembourg, Luxembourg Centre for Systems Biomedicine (UL), whose administrative offices are at 7 avenue des Hauts-Fourneaux, L-4362 Esch-sur-Alzette, LUXEMBOURG;

ID Business Solutions Limited (IDBS), whose administrative offices are at 2 Occam Court, Surrey Research Park, Guildford, Surrey, GU2 7QB, UNITED KINGDOM;

BioSci Consulting (BSC), whose administrative offices are at Weg naar Geneuth 95, 3631 Maasmechelen, BELGIUM;

Centre National de la Recherche Scientifique (CNRS), whose administrative offices are at Campus Gérard-Mégie, 3 rue Michel-Ange - F-75794, Paris cedex 16, FRANCE;

CDISC Europe Foundation (CDISC), whose administrative offices are at 141 rue Saint-Lambert 1200 Woluwe-St Brussels, Belgium;

Janssen Pharmaceutia NV (JANSSEN), whose administrative offices are at Turnhoutseweg 30, B-2340 Beerse, BELGIUM;

F. Hoffman-La Roche Limited (Roche), whose administrative offices are at Grenzacherstrasse 124, CH-4070 Basel, SWITZERLAND;

GlaxoSmithKline Research & Development Limited (GSK), whose administrative offices are at 980 Great West Road, Brentford, Middlesex, TW8 9GS, UNITED KINGDOM;

Sanofi-Aventis Recherche & Développement (SARD), whose administrative offices are at Avenue Pierre Brossolette 1, Chilly-Mazarin 91385, FRANCE;

Bayer Pharma AG (Bayer), whose administrative offices are at Mullerstrasse 178, D-13353, Berlin, GERMANY;

Merck KGaA (ME), whose administrative offices are at Frankfurter Strasse 250, 64293 Darmstadt, GERMANY;

Pfizer Limited (Pfizer), whose administrative offices are at Ramsgate Road, Sandwich, Kent, CT13 9NJ, UNITED KINGDOM:

Eli Lilly and Company Limited (LLY), whose administrative offices are at Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, UNITED KINGDOM;

H. Lundbeck A/S (LUB), whose administrative offices are at Ottiliavej 9, Valby DK-2500, DENMARK

THE CHANCELLOR MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD (UOXF), whose administrative offices are at University Offices, Wellington Square, Oxford, Oxon OX1 2JD, United Kingdom

On the one hand

And

- (3) **PROVIDING PROJECT COORDINATOR** <Insert full name, abbreviation and address of Providing Project Coordinator> acting in its capacity as coordinator under the agreement entitled “<insert full project title>” (IMI grant agreement No. xxx)
- (4) **PROVIDING PROJECT MANAGING ENTITY** <Insert full name, abbreviation and address of Providing Project Managing Entity> acting in its capacity as Managing Entity under the agreement “<insert full project title>” (IMI grant agreement No. xxx)

WHEREAS PROVIDING PROJECT COORDINATOR, PROVIDING PROJECT MANAGING ENTITY, and the other PROVIDING PROJECT participants listed below are hereinafter collectively referred to as the “**PROVIDING PROJECT Participants**” <Insert list of PROVIDING PROJECT Participants here>

On the other hand

The eTRIKS Participants and PROVIDING PROJECT Participants are hereinafter individually (or collectively) referred to as a “Party” (or the “Parties”)

Recitals

WHEREAS, the Innovative Medicines Initiative (“IMI”) is a public-private partnership between the pharmaceutical industry represented by the European Federation of Pharmaceutical Industries and Associations (“EFPIA”) and the European Union represented by the European Commission.

WHEREAS, the eTRIKS consortium was formed under the IMI for the purpose of undertaking the project entitled “European Translational Information & Knowledge Management Services” (IMI grant agreement No. 115446) (the “eTRIKS Project”). AZ is the coordinator of the eTRIKS Project and ICL the Managing Entity of the IMI JU.

WHEREAS, PROVIDING PROJECT consortium was formed under the IMI for the purpose of undertaking the project entitled “<insert full project title>” (IMI grant agreement No. xxx) (the “PROVIDING PROJECT Project”). PROVIDING PROJECT COORDINATOR is the coordinator of the PROVIDING PROJECT Project and PROVIDING PROJECT MANAGING ENTITY the Managing Entity of the IMI JU.

WHEREAS, each of the PROVIDING PROJECT Participants owns or otherwise controls (either alone or jointly with certain other PROVIDING PROJECT Participant(s)) the Datasets and Images (as defined below); and is willing to furnish the eTRIKS Participants with such Datasets and Images upon the terms and conditions set forth herein for the sole purpose of completing the collaborative project (the “Collaboration Project”) outlined in Schedule 1 to this Agreement.

Agreement

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

1 Definitions

Unless otherwise specifically provided in this Agreement, the following terms shall have the following meanings:

2 “Affiliate” means any corporation, partnership or other legal entity that directly or indirectly controls, is controlled by, or is under common control, with a Party. For the purposes of this definition only, the term “control” means (i) beneficial ownership of at least 50% of the voting securities of a corporation or other business organization with voting securities (or such other percentage as required to establish control in the relevant jurisdiction); (ii) a 50% or greater interest in the net assets or profits of a partnership or other business organization without voting securities (or such other percentage as required to establish control in the relevant jurisdiction); or (iii) the ability, via contract or otherwise, to direct the affairs of any such entity.

3 “Background Intellectual Property” has the meaning given such term in Section 2.7.

1.3 “Collaboration Project” is the set of activities as outlined in the Task Plan in Schedule 1 on which participants of both Consortia work together.

1.4 “Consortium” means the whole group of participants working on eTRIKS or PROVIDING PROJECT, as the context requires, and “Consortia” means jointly the eTRIKS and PROVIDING PROJECT consortia.

1.5 “Datasets” means collections of data of the PROVIDING PROJECT Consortium intended by the PROVIDING PROJECT Consortium to be useful for machine processing that are transferred to the eTRIKS Participants by the PROVIDING PROJECT Participants and any derivations, improvements and results generated in the course of or as a result of the Collaboration Project, provided that they fall within the scope of the Project Objectives of the PROVIDING PROJECT Project.

1.6 “Images” means visual representations other than text that are transferred to the eTRIKS Participants by the PROVIDING PROJECT Participants and any derivations, improvements and results generated in the course of or as a result of the Collaboration Project, provided that they fall within the scope of the Project Objectives of the PROVIDING PROJECT Project.

1.7 “Project Objectives” shall mean the objectives as defined in the full project proposal which is part of the grant agreement among the Participants for each Consortium.

1.8 “Researchers” means all employees, and any person working for a Party who are engaged in carrying out the Collaboration Project.

1.9 “Subcontractor” means a third party which has entered into an agreement on business conditions with one or more Participants, in order to carry out part of the work of the Task Plan on behalf of the said Participant(s).

1.10 “Task Data” means any information, data, know-how, inventions, and other developments made or discovered for the data process during the course of the Collaboration Project in accordance with the Task Plan referred to in Schedule 1 of this Agreement, which includes, without limitation, programmatic scripts, algorithms, and software of data transformation and analysis, but which are not Datasets nor Images.

1.11 “Task Plan” means those activities set forth in Schedule 1 hereto.

4 Conditions of Datasets and Images Transfer and Collaboration Project Scope

5 Transfer of Datasets and Images. PROVIDING PROJECT Participants agrees to transfer to the eTRIKS Participants the Datasets and Images to allow the eTRIKS Participants to carry out the Collaboration Project as outlined in the Task Plan in Schedule 1 of this Agreement.

6 Permitted Use of Datasets and Images. The Datasets and Images transferred pursuant to this Agreement (a) shall be used by the eTRIKS Participants only for the Collaboration Project (b) shall not be used by or delivered by the eTRIKS Participants to or for the benefit of any third party without the prior written consent of PROVIDING PROJECT Participants; and (c) shall

not be used by the eTRIKS Participants in any product for commercial use or distribution without the prior written consent of PROVIDING PROJECT Participants.

7 **No Sale or Transfer.** The transfer of the Datasets and Images by PROVIDING PROJECT Participants to the eTRIKS Participants shall not constitute a sale of the Datasets and Images or an option or license in or to any rights, title or interest in or to the Datasets and Images.

8 **Scope.** The Task Plan shall set forth, as applicable, (i) the goals and objectives of the Collaboration Project, (ii) the methodology and processes required to complete the Collaboration Project, (iii) the roles and responsibilities of the Parties carrying out the Task Plan, (iv) an approximate timetable/milestone delivery chart for the work in regard to the Collaboration Project, (v) a list of all results, deliverables, reports, studies, and other information and documentation expected to be produced in regard to the Collaboration Project, (vi) the timing and frequency of any reporting obligations, (vii) the respective financial responsibilities of the Parties with respect to activities performed in connection with the Collaboration Project, provided that the financial responsibilities fall wholly within the eTRIKS and PROVIDING PROJECT Project agreements (viii) activities with respect to licensing of the background technology of the Parties, (ix) activities with respect to compliance with ethical business practices and applicable laws, rules and regulations, (x) activities to meet the wind-down and wind-up obligations of the Parties upon the completion or termination of the Collaboration Project, (xi) activities to address conflict of interest of eTRIKS and/or PROVIDING PROJECT Participants, and (xii) any other information as the Parties may determine. Each Party should use reasonable efforts to perform their allocated tasks in accordance with the Task Plan.

9 **Existing Obligations.** The Task Plan shall be consistent with the terms of the eTRIKS Project agreement with respect to any eTRIKS Participants engaged in the Collaboration Project, and shall be consistent with the terms of the PROVIDING PROJECT Project agreement with respect to any PROVIDING PROJECT Participants who are engaged in the Collaboration Project.

10 **Modification.** Unless and to the extent expressly set forth in the Task Plan, the Task Plan may not be modified, supplemented or amended except with the written consent of the Parties.

11 **Background Intellectual Property.** For the avoidance of doubt, all intellectual property, Datasets and Images and know-how existing as of the Effective Date, or developed or acquired outside of the scope of this Agreement (“*Background Intellectual Property*”), that is used in connection with the Task Plan shall remain the property of the Party introducing the same. Nothing in this Agreement shall transfer any rights in such Background Intellectual Property to the other Parties.

12 **Ownership of Datasets and Images.** PROVIDING PROJECT Participants shall own and retain all right, title and interest in and to the Datasets and Images in accordance with the agreement(s) among them. The eTRIKS Participants shall (a) transfer or allow transfer, as

applicable, of such Datasets and Images to the PROVIDING PROJECT Participants and (b) assign all right, title and interest in and to them, and any intellectual property rights associated therewith to the PROVIDING PROJECT Participants, and execute, or cause to be executed, all papers necessary or useful to vest all right, title and interest in and to such Datasets and Images, and any intellectual property rights associated therewith, in PROVIDING PROJECT Participants, without additional consideration. The PROVIDING PROJECT Participants accept such transfer and assignment.

13 Ownership of Task Data. Any Task Data developed or created by the eTRIKS Participants as part of the Task Plan shall be owned by the eTRIKS Participants in accordance with the agreement(s) among them. Any Task Data developed or created by the PROVIDING PROJECT Participants as part of the Task Plan shall be owned by the PROVIDING PROJECT Participants in accordance with the agreement(s) among them. The PROVIDING PROJECT Participants hereby grants to the eTRIKS Participants a non-exclusive, world-wide, perpetual, royalty-free license to use the Task Data owned by the PROVIDING PROJECT Participants for any purpose.

14 Software License. Any license to any software, and ownership of such software or any improvements or other modifications not incorporating Datasets and Images to such software required as part of the Task Plan, shall be governed by a separate agreement between the eTRIKS Participants and the owner of the software, which agreement shall be consistent with the terms of the eTRIKS Project agreement.

15 Collaboration Project Governance.

16 Task Committee. The Governing Committees will oversee the formation of a Collaboration Project governance committee (the “*Task Committee*”), which will work to ensure that the Collaboration Project is aligned with the applicable Task Plan and otherwise successfully conducted. For clarification, the Task Committee will not be an independent decision-making body and, other than as expressly set forth herein, shall have no authority to make decisions in respect of the Collaboration Project.

17 Governing Committees. The eTRIKS general assembly and the PROVIDING PROJECT <insert name of governing committee> (each, a “*Governing Committee*” and collectively, the “*Governing Committees*”) will be advised by the Task Committee with respect to the Collaboration Project. The Governing Committees shall have final approval authority with respect to (i) the termination of the Collaboration Project, (ii) any material alterations to the Task Plan, (iii) any publication plan, and (iv) any other matters relating to the Collaboration Project as a whole. The mutual decision of the Governing Committees with respect to the foregoing (which decision shall be made in accordance with the terms of the eTRIKS Project agreement, in the case of the eTRIKS Governing Committee, or the PROVIDING PROJECT

Project agreement, in the case of the PROVIDING PROJECT Governing Committee) shall be binding on the Parties.

18 **Task Committee Composition.** The Task Committee will be comprised of: (i) one (1) overall task leader appointed by each Governing Committee (both such leaders, individually, the “*Task Leader*” or collectively, the “*Task Leaders*”), (ii) representatives of the Parties responsible for the tasks defined in the Task Plan, and (iii) to the extent specified in the Task Plan, or as otherwise jointly approved by the Task Leaders on an *ad hoc* basis, the representatives for Intellectual Property matters.

19 **Task Committee Functions.** The Task Committee will meet at least every three (3) months (and more frequently if jointly approved by the Task Leaders) to (i) review and monitor the progress of the Task Plan, (ii) approve for submission to the Governing Committees any significant alterations to the Task Plan, (iii) develop and approve for submission to the Governing Committees any publications plan, (iv) identify issues for resolution, (v) provide advice and feedback to the Governing Committees and obtain any necessary approvals therefrom, and (vi) any other functions as may be identified in the Task Plan, in each case in accordance with the eTRIKS Project agreement and the PROVIDING PROJECT Project agreement, as applicable. On a quarterly basis, the Task Leaders will alternate responsibility for arranging meetings of the Task Committee and for documenting and distributing English-language minutes from these meetings, which shall be circulated to each member of the Task Committee within seven (7) working days after each meeting. The Task Committee will then circulate such minutes to each Party. Unless otherwise set forth in the Task Plan, any decisions or resolutions of the Task Committee shall be by unanimous agreement of the Task Committee members.

20 **Communicating Progress.** The Task Leaders will take responsibility for communicating progress to the PROVIDING PROJECT and eTRIKS Coordinators and Managing Entities on a monthly basis. Communicating progress to IMI Scientific Officer responsible for the eTRIKS project will be in accordance with the eTRIKS project agreement. This will take the form of a brief update email that outlines progress and issues and the plans to resolve them. Comments raised will be discussed and resolved by the Task Committee.

21 **Confidentiality.**

22 **Confidentiality - General.**

23 A Party (the “*Disclosing Party*”) may disclose certain information or materials (including Datasets and Images) which such Disclosing Party considers proprietary or otherwise wishes to remain confidential (“*Confidential Information*”) to a Party of the other Consortium (the “*Receiving Party*”) in connection with the Collaboration Project. Confidential Information shall include only such information or materials (i) marked or identified in writing as confidential or proprietary at the time of disclosure, or (ii) if disclosed orally or in other intangible form, that are identified as confidential at the time of disclosure and summarized in writing and marked as confidential within thirty (30) days of such disclosure.

24 During the term of this Agreement and for a five (5) year period thereafter, each Receiving Party shall maintain all Confidential Information of the Disclosing Party in strict confidence and with at least the same degree of care it uses to protect its own confidential or proprietary information of a similar nature or sensitivity (but no less than reasonable care under the circumstances) and not to disclose Confidential Information to any other party without the prior written approval of the Disclosing Party. The Receiving Party shall use the Confidential Information only for the purpose of fulfilling the Receiving Party's obligations in connection with the Collaboration Project as set forth in the Task Plan and in accordance with this Agreement, and for no other purpose.. The Receiving Party shall be responsible for informing those of its employees, officers, Subcontractors and other representatives who have access to the Disclosing Party's Confidential Information of the confidential nature thereof and the Receiving Party's obligations under this Agreement. The Receiving Party agrees not to disclose any of the Confidential Information, except to such employees, consultants, contractors, advisors and agents of the Receiving Party and its affiliates who need to know the Confidential Information and who are bound by obligations of non-use and non-disclosure substantially similar to those set forth herein. The Receiving Party shall be responsible for any disclosure or use of the Confidential Information by such employees, officers, Subcontractors and other representatives. The Receiving Party may also disclose Confidential Information to its Affiliates provided that each such Affiliate agrees to confidentiality and non-use obligations at least equivalent as those set forth in this Agreement. The Receiving Party's obligations under this Section 4.1 with respect to any portion of the Confidential Information shall cease when such portion of the Confidential Information becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Receiving Party or any of its Affiliates, employees, officers or other representatives. Confidential Information shall not include information or material that: (a) is or becomes publicly known through no fault of the Receiving Party; (b) was rightfully in the Receiving Party's possession or known by the Receiving Party before receipt from the Disclosing Party as shown by written records; (c) becomes rightfully known to the Receiving Party without confidential or proprietary restriction from a source other than the Disclosing Party who does not owe a duty of confidentiality to the Disclosing Party with respect to such information; or (d) is independently developed by the Receiving Party without any use of, reliance upon or reference to the Confidential Information of the Disclosing Party as shown by written records.

25 The obligations of the Parties under this Section 4 are expressly in addition to, and not in lieu or limitation of, the confidentiality and other obligations to which the Parties are subject under the eTRIKS Project agreement or the PROVIDING PROJECT Project agreement. In the event of any conflict between the confidentiality obligations of a Receiving Party hereunder and the confidentiality obligations of such Receiving Party under the eTRIKS Project agreement or PROVIDING PROJECT Project agreement, as applicable, the most restrictive confidentiality obligations shall prevail.

26 Authorized Disclosure. Notwithstanding Section 4.1.2, the Receiving Party may disclose Confidential Information of the Disclosing Party to the extent reasonably necessary to comply

with law, regulation or lawful court orders by a court of competent jurisdiction; provided that (a) prior to any such compelled disclosure, the said Receiving Party shall give the Disclosing Party reasonable advance written notice of any such disclosure and shall cooperate with the Disclosing Party's reasonable efforts to protect against any such disclosure and/or obtaining a protective order narrowing the scope of such disclosure, and (b) the disclosure and/or use of such Confidential Information shall be to the minimum extent permissible pursuant to such compelled disclosure.

27 Confidentiality of Agreement. Subject to Section 4.1, and subject to approval by the eTRIKS coordinator and PROVIDING PROJECT coordinator any Participant may issue press releases or other public communications concerning the existence, nature and participants of the Collaboration Project; provided that the applicable participants will have the right to review and approve any such communications, such approval not to be unreasonably withheld.

28 Publications. The Task Committee will, if appropriate, oversee the development and execution of a strategy and plan for joint publication, to be approved by the Governing Committees (the "*Publication Plan*"). The Publication Plan will be consistent with the publication policy, guidelines, strategies and review practices of each of the Consortia and will recognize the common objective of the Consortia to disseminate the results of the Collaboration for public benefit. The Task Committee will be responsible for identifying potential scientific and technical publications based on the Task Data, and identify potential target journals for these publications. The Task Committee will be responsible for identifying other potential publications and communications of a more general nature relating to the Collaboration Project, including press releases. Authorship credit for any publications shall be determined by the Task Committee as applicable. Final and complete drafts of all documents (including, without limitation, manuscripts, abstracts and posters) considered part of the Publication Plan, as well as any proposed press releases, should be circulated, at least thirty (30) calendar days prior to the planned submission date, to all Parties, the Task Committee, and the Governing Committees for final approval before submission. No such manuscripts, abstracts, posters or press releases may be submitted for publication prior to the approval of each of the foregoing. Any Party may reasonably object to such publication on the grounds that (a) such publication contains the Confidential Information of such Party, (b) contains information materially harmful or detrimental to such Party or (c) contains patentable Task Data, and in such event the publishing Party will extend the review period and delay the proposed publication pending resolution of such reasonable objection or to permit the filing of patent applications, this period not to exceed sixty (60) days. Such objection will be discussed by the Task Committee with the other Parties. If any objection that such publication contains the Confidential Information of the objecting Party is not withdrawn, or any objection that such publication contains information materially harmful or detrimental to such Party is upheld by the Task Committee, the publishing Party will modify the publication as reasonably requested by the objecting Party for scientific or patent reasons and/or delete the objectionable information or Confidential Information from the publication draft. Any such revised draft shall be recirculated to the Task Committee, and the Governing

Committees for final approval before submission. Any publication or dissemination activity arising from the Collaboration Project shall include the eTRIKS logo and the PROVIDING PROJECT logo, each displayed with equal prominence.

29 **Compliance with Personal Data Protection Regulations and Guidelines.** Each Party acknowledges and agrees that, in connection with the Collaboration Project, it shall fully comply with any applicable laws and regulations governing protected health information and other personal data (collectively, “*Privacy Laws*”). Notwithstanding anything to the contrary herein, any protected health information or personal data that should be distributed, transferred, shared or otherwise made available to the eTRIKS Participants for the performance of the Task Plan shall be anonymised pursuant to the rules and regulations of applicable Privacy Laws by the PROVIDING PROJECT Participants prior to being distributed, transferred, shared or otherwise made available to the Researchers hereunder.

eTRIKS Participants also agree (1) not to try to re-identify the patient in the original data set, (2) not to disclose or allow disclosure of the personal data to any third party unless authorised in writing by the Party providing the personal data or if compelled by law, (3) to inform the Party providing the personal data within 24 hours if it learns of any loss or unauthorised access, use or disclosure of personal data and take all necessary corrective actions to remedy the causes and (4) in the absence of specific written instructions from the Party providing the personal data, to take technical and organisational measures appropriate to the sensitivity of the personal data to protect the data against accidental or unlawful destruction or accidental loss or damage, alteration, unauthorised disclosure or access and against all other unlawful processing.

30 **Conflict of interest and Intellectual Property cross-contamination.** eTRIKS Participants who have access to or in contact with PROVIDING PROJECT Datasets and Images certify that this access to or contact with PROVIDING PROJECT Datasets and Images will only be used for the purpose of this Agreement. If an eTRIKS Participant believes that such access to or contact with PROVIDING PROJECT Datasets and Images might conflict or compete with its own interest or project developed outside the scope of this Agreement the eTRIKS Participant shall immediately refrain from accessing the said Datasets and Images and send a written notice to the Task and Governing Committees, and its contact or access to PROVIDING PROJECT Datasets and Images will be immediately ceased.

31 **Representations and Warranties.**

32 **Representations and Warranties.** Each Party hereby represents and warrants that: (i) it is duly organized and validly existing under the laws of its jurisdiction of formation and has the authority and power to enter into, execute and deliver this Agreement on its own behalf, (ii) the execution, delivery and performance of this Agreement will not violate any provision of the eTRIKS Project agreement or PROVIDING PROJECT Project agreement, as applicable, require it to obtain any further consent from, approval of or action by any third party, conflict with or result in any material breach or violation of any agreement by which it is bound, or

violate any law applicable to or covering it and (iii) this Agreement constitutes its legal, valid and binding obligation.

33 **PROVIDING PROJECT** Participants represent and warrant to the eTRIKS Participants that **PROVIDING PROJECT** Participants have the required consents from the subjects to transfer the de-identified Datasets and Images to the eTRIKS Participants under this Agreement for the activities intended under the Task Plan and that any such transfer is in accordance with applicable law.

34 **Disclaimer.** Except as expressly set forth herein or in the Task Plan outlined in Schedule 1, and to the maximum extent permitted by applicable law, all technology, Datasets and Images, information, materials and Confidential Information provided by any Party hereunder or under a Task Plan are provided “as-is” and each Party expressly disclaims any and all warranties of any kind, expressed or implied, statutory or otherwise, including without limitation any warranties of design, quality, merchantability, fitness for a particular purpose, or non-infringement of the intellectual property rights of any Party, Consortium or third party, or arising from a course of dealing, usage or trade practices.

35 **Limitation of Liability; Indemnification.**

36 **Limitation of Liability.**

37 In no event shall any Party be entitled to recover from any other Party any special, incidental, consequential, or punitive damages in connection with this Agreement. Nothing in this Section 6.1 shall restrict, modify or condition any provisions applicable to any Party under the eTRIKS Project agreement and/or PROVIDING PROJECT Project agreement, as applicable or limit the liability for any breach of the representations and warranties in section 5.2 by PROVIDING PROJECT Participants.

38 No eTRIKS Participant shall be responsible for the acts or omissions committed by any other eTRIKS Participant performing work under this Agreement. Furthermore no eTRIKS Participant shall be responsible for any defect or other issues related to any products or services created by another eTRIKS Participant under this Agreement, including, for instance, anomalies in the functioning or performance thereof.

6.1.3. In any event the maximum liability of any Party to any other Party under or otherwise in connection with this Agreement or its subject matter in respect of any one claim or series of connected claims shall not exceed that Party’s share of the total costs of the eTRIKS or ABIRISK Project as determined in the provisions of the applicable Project and Grant Agreements.

39 **Indemnification.**

40 Each eTRIKS Participant separately hereby agrees to defend and indemnify each PROVIDING PROJECT Participant and its respective directors, officers, employees and agents (each, a “*PROVIDING PROJECT Indemnatee*”) from and against any damages and losses actually incurred by such PROVIDING PROJECT Indemnatee to the extent arising out of a breach by such eTRIKS Participant of its obligations under Sections 4.1 (Confidentiality-General) and 4.2 (Authorized Disclosure) of this Agreement. The PROVIDING PROJECT Indemnatee will promptly and in writing notify the eTRIKS Participant upon the occurrence of an event triggering the indemnification referenced above and will take and continue to take all reasonable steps to mitigate its loss. The eTRIKS Participant will be entitled to take over the conduct of any matter triggering the indemnification, including appointing legal counsel reasonably satisfactory to both Parties.

41 Each PROVIDING PROJECT Participant hereby agrees to defend and indemnify each eTRIKS Participant and its respective directors, officers, employees and agents (each, a “*eTRIKS Indemnatee*”) from and against any damages and losses actually incurred by such eTRIKS Indemnatee to the extent arising out of a breach by such PROVIDING PROJECT Participant of its obligations under Sections 4.1, 4.2 and 5.2 of this Agreement. The eTRIKS Indemnatee will promptly and in writing notify the PROVIDING PROJECT Participant upon the occurrence of an event triggering the indemnification referenced above and will take and continue to take all reasonable steps to mitigate its loss. The PROVIDING PROJECT Participant will be entitled to take over the conduct of any matter triggering the indemnification, including appointing legal counsel reasonably satisfactory to both Parties.

6.2.3 For the avoidance of doubt, nothing in this Section 6.2 creates any obligations with respect to indemnification among eTRIKS Participants, nor among PROVIDING PROJECT Participants, which are separately addressed in the eTRIKS Project agreement and PROVIDING PROJECT Project agreement, respectively.

42 General.

43 Term of Agreement; Termination.

44 Except to the extent set forth in a Task Plan or as otherwise agreed in writing by the Parties, this Agreement shall commence on the Effective Date and continue in full force and effect until the Collaboration Project is completed; provided that, the Parties acknowledge and agree that eTRIKS and the PROVIDING PROJECT coordinators may each, with the prior consent of its Governing Committee, and in accordance with the respective Project agreements and with no less than thirty (30) days prior written notice to the other Parties, terminate this Agreement.

45 In the event that, at any time during the term of this Agreement, any entity that is an eTRIKS Participant or PROVIDING PROJECT Participant ceases to be a participant in eTRIKS Project or a participant in PROVIDING PROJECT Project as applicable, this Agreement shall be deemed to be, and shall be terminated as to such entity.

46 Subject to the foregoing, upon the termination or expiration of this Agreement, each Receiving Party shall return all Confidential Information to the applicable Disclosing Party, or upon request by such Disclosing Party, destroy such Confidential Information and notify such Disclosing Party in writing of the destruction thereof. In addition, upon termination or expiration of this Agreement, any licenses or other rights granted to any Party hereunder or under the Task Plan shall expire unless expressly provided herein or in such Task Plan.

47 Notwithstanding the termination or expiration of this Agreement, any obligation under this Agreement or any Task Plan which is intended by their terms to survive shall so survive (including, without limitation, any terms and conditions applicable to any rights in and to Task Data). In addition, and without limiting the generality of the foregoing, Sections 2.3, 4, 5.2, 5.3, 6 and 7.3 shall survive any termination or expiration of this Agreement.

48 Governing Law. This Agreement will be governed by, and construed and enforced in accordance with, the laws of Belgium, without giving effect to any conflicts of law principles that require the application of the laws of a different jurisdiction.

49 Dispute Resolution.

50 Except as and to the extent provided in the Task Plan:

For any dispute, the Party or Parties involved in such dispute shall initially attempt to resolve the dispute through good faith negotiations. Any dispute that remains unresolved for twenty (20) days following the commencement of such good faith negotiations shall be escalated to the Governing Committees. If the dispute remains unresolved for twenty (20) days thereafter, the dispute shall be referred to the executive director of IMI, who will discuss the dispute and suggest proposals for resolution.

If the dispute remains unresolved for twenty (20) days after referral to the executive director of IMI pursuant to Section 7.3.1(a), and one or more Parties involved in such dispute wish to pursue the matter, the dispute shall be finally resolved by arbitration under the rules of arbitration of the international chamber of commerce ("*ICC Rules*"). The number of arbitrators shall be three (3). In accordance with ICC Rules, the eTRIKS Participant(s) that is (are) involved in the dispute shall, by mutual agreement, select one arbitrator and the PROVIDING PROJECT Participant(s) that is(are) involved in the dispute shall, by mutual agreement, select one arbitrator. The two arbitrators selected by the Parties shall then select a third arbitrator. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed in accordance with ICC Rules. The place of the arbitration shall, unless otherwise agreed by the Parties involved in such dispute, be: Brussels, Belgium. The language of all proceedings and communications of the arbitration shall be English. Any Party involved in a dispute may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Any Party involved in a dispute also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending

the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Any such Party seeking injunctive or provisional relief in such circumstances shall not be deemed to have breached its agreement to arbitrate or to have affected the powers reserved to the arbitrations. The decision of the tribunal shall be final and binding. The Parties waive any right to appeal the arbitration award to the maximum extent permitted by applicable law. The Parties involved in such dispute agree that they shall share equally the cost of any such arbitration. Each Party involved in such dispute shall bear its own attorneys' and expert fees and all associated costs and expenses.

51 For the avoidance of doubt, this Section 7.3 only applies to any dispute, difference, controversy or claim arising out of or relating to this Agreement between one or more eTRIKS Participants and one or more PROVIDING PROJECT Participant. Any dispute, difference, controversy or claim arising out of or relating to this Agreement among only eTRIKS Participants shall be settled in accordance with the eTRIKS Project agreement, and any dispute, difference, controversy or claim arising out of or relating to this Agreement among only PROVIDING PROJECT Participants shall be settled in accordance with the PROVIDING PROJECT Project agreement.

52 Waiver; Amendment. No failure or delay on the part of any Party to exercise any power, right, privilege, or remedy under this Agreement will operate as a waiver of such power, right, privilege, or remedy, in whole or in part, in that or any other instance. No Party will be deemed to have waived any claim arising from this Agreement, or any power, right, privilege or remedy under this Agreement, unless such waiver is expressly set forth in a written instrument executed by the relevant Party and any such waiver will have no effect except in the specific instance in which it is given. Other than with respect to the Task Plan as set forth in Section 2.6, this Agreement may not be amended, modified, altered or supplemented other than by means of a written instrument duly executed and delivered by each Party.

53 Assignment. Except as expressly provided hereunder, neither this Agreement nor any right or obligation hereunder may be assigned or otherwise transferred by any Party without the prior written consent of the Governing Committee of the other Consortium; provided, however, that a Party may assign this Agreement and its rights and obligations hereunder without the consent of the Governing Committee of the other Consortium: (a) in connection with the transfer or sale of all or substantially all of such Party's business to a third party, whether by merger, sale of stock, sale of assets or otherwise; or (b) to an Affiliate; provided, in either case, that (i) the assignee shall have executed and delivered to the Governing Committees its express written agreement to abide by all terms and conditions of this Agreement, and (ii) no such assignment shall relieve the assigning Party of its duties and obligations hereunder. The rights and obligations of the Party shall be binding upon and inure to the benefit of the successors and permitted assigns of such Parties. Any assignment not in accordance with this Section 7.5 shall be void.

54 **Subcontractors.** Where an eTRIKS Participant intends to subcontract its share under the Task Plan to a Subcontractor, such eTRIKS Participant shall be liable for the acts and omissions of its Subcontractor as if those acts and omissions have been performed by such eTRIKS Participant and, as such, shall remain responsible for the implementation of such share and for the satisfaction of all obligations relative to such share arising out of or in connection with this Agreement.

55 **Severability.** If any provision of this Agreement is determined to be invalid, unlawful, void, or unenforceable by a court of competent jurisdiction, the remainder of this Agreement will not be impaired or otherwise affected and will continue to be valid and enforceable to the fullest extent permitted by law.

56 **Relationship of the Parties.** The status of a Party under this Agreement shall be that of an independent contractor. Nothing contained in this Agreement shall be construed as creating a partnership, joint venture or agency relationship between the Parties or, except as otherwise expressly provided in this Agreement, as granting either Party the authority to bind or contract any obligation in the name of or on the account of the other Party or to make any statements, representations, warranties or commitments on behalf of the other Party.

57 **Anti-Trust.** The Parties acknowledge and agree that the activities under this Agreement shall be conducted in compliance with the provisions of Schedule 2 attached hereto.

58 **Ethical Business Practices; Compliance With Law.** The Parties acknowledge and agree that the activities under this Agreement shall be conducted in compliance with ethical business practices and in accordance with all applicable laws, rules and regulations, all of the foregoing as more specifically set forth in the Task Plan.

7.11 Anti-Bribery and Anti-Corruption

7.11.1 Each Party acknowledges receipt of the ‘Prevention of Corruption – Third Party Guidelines’ (contained in Schedule 3 of this Agreement) and agrees to perform its obligations under the Agreement in accordance with the principles set out therein.

7.11.2 Each Party shall comply fully at all times with all applicable anti-corruption laws of the territory in which each Participant conducts business under this Agreement.

7.11.3 AZ, PROVIDING PROJECT COORDINATOR, ICL and PROVIDING PROJECT MANAGING ENTITY (the “*Managing Organisations*”) acting together shall be entitled to terminate the participation of a Party in the Collaboration Project on written notice with immediate effect, if a Party fails to perform its obligations in accordance with this clause 7.11. A Party shall have no claim against the Managing Organisations or the other Parties for compensation for any loss of whatever nature by virtue of the termination of their participation under this Agreement in accordance with this clause 7.11. To the extent (and only to the extent) that the laws of the territory provide for any such compensation to be paid to a Party upon the

termination of their participation under this Agreement, each Party hereby expressly agrees to waive (to the extent possible under the laws of the territory) or to repay any such compensation or indemnity.

7.11.4 Each Party hereby certifies that it will not and, to the best of its knowledge, has not employed or otherwise used in any capacity hereunder the services of any person or entity debarred or otherwise convicted of medical malpractice, corruption, organized crime, fraud, money laundering or terrorism under applicable law. Each Party shall notify the Managing Organisations in writing immediately if any such debarment or conviction occurs or comes to its attention, and shall, with respect to any person or entity so debarred promptly remove such person or entity from performing any service, function or capacity related to the Collaboration Project. The Managing Organisations shall inform the other Parties promptly of such notification. The Parties shall be entitled to amongst themselves agree that the Managing Organisations should terminate the participation of a Party in the Collaboration Project, if such Party fails to perform its obligations in accordance with this clause 7.11.4. In the event that the Parties do not act swiftly to resolve the matter by causing the Party which fails to abide by the provisions of this clause 7.11.4 to remove such person or entity from performing any service, function or capacity related to the Collaboration Project, or by terminating the participation in the Collaboration Project of the Party which fails to abide by the provisions of this clause 7.11.4, any Party may in such case, and with immediate effect, terminate its participation under this Agreement at its sole discretion upon written notice to the Managing Organisations and without prejudice to any other remedies that may be available to such terminating Party.

7.12 Notices. Any notices or other communications required or permitted to be delivered to any Party under this Agreement must be in writing and will be deemed properly delivered, given and received when delivered (by hand, by registered mail, by courier or express delivery service or by facsimile) to the address or facsimile telephone number set forth below (or to such other address or facsimile telephone number as may have specified by such Party in a written notice given to the other Parties):

If to the eTRIKS coordinator or any eTRIKS Participants:

ASTRAZENECA AB, S-151 85 Södertälje, Sweden

If to the PROVIDING PROJECT coordinator or any PROVIDING PROJECT Participants:

<Insert address of PROVIDING PROJECT COORDINATOR>

Each of the eTRIKS and the PROVIDING PROJECT coordinators shall promptly communicate to its respective participants a copy of all notices or other communications received hereunder.

7.13 English Language. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between or among the Parties regarding this Agreement shall be in the English language.

7.14 Entire Agreement. This Agreement sets forth the entire understanding of the Parties relating to the subject matter hereof and supersedes all prior agreements and understandings among or between any of the Parties hereto relating to the subject matter hereof.

7.15 Counterparts This Agreement may be executed in any number of counterparts, each of which will be deemed an original document and all of which, when taken together, will constitute one agreement.

Signature Pages Follow

PROVIDING PROJECT SIGNATURES

**Authorised to sign on behalf of:
PROVIDING PROJECT COORDINATOR**

Signature

Name

Title

Date

**Authorised to sign on behalf of:
PROVIDING PROJECT MANAGING ENTITY**

Signature

Name

Title

Date

Stamp (if applicable)

**Authorised to sign on behalf of:
Provide one additional page for each PROVIDING PROJECT Participant**

Signature

Name

Title

Date

Stamp (if applicable)

eTRIKS SIGNATURES

Authorised to sign on behalf of:

AstraZeneca AB (AZ)

Signature

Name

Title

Date

Authorised to sign on behalf of:

IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE (ICL)

Signature

Name

Title

Date

Authorised to sign on behalf of:

University of Luxembourg, Luxembourg Centre for Systems Biomedicine (UL)

Signature

Name

Title

Date

Authorised to sign on behalf of:

ID Business Solutions Limited (IDBS)

Signature

Name

Title

Date

Authorised to sign on behalf of:

BioSci Consulting (BSC)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Centre National de la Recherche Scientifique (CNRS)

Signature

Name

Title

Date

Authorised to sign on behalf of:

CDISC Europe Foundation (CDISC)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Janssen Pharmaceutia NV (JANSSEN)

Signature

Name

Title

Date

Authorised to sign on behalf of:

F. Hoffmann-La Roche Limited (Roche)

Signature

Name

Title

Date

Authorised to sign on behalf of:

GlaxoSmithKline Research & Development Limited (GSK)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Sanofi-Aventis Recherche & Développement (SARD)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Bayer Pharma AG (Bayer)

Signature

Signature

Name

Name

Title

Title

Date

Date

Authorised to sign on behalf of:

Merck KGaA (ME)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Pfizer Limited (Pfizer)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Eli Lilly and Company Limited (LLY)

Signature

Name

Title

Date

Authorised to sign on behalf of:

H. Lundbeck A/S (LUB)

Signature

Name

Title

Date

Authorised to sign on behalf of:
Oxford e-Research Centre (UOXF)

Signature

Name

Title

Date

Schedule 1 - Task Plan

[Please specify the Datasets and Images to be transferred and provide any other relevant specifications. If supporting documentation is required that should also be specified.]

[Please specify the scope of the Collaboration Project as outlined in Section 2.4 of the Agreement e.g. activities to be undertaken by the eTRIKS Participants, the objectives of the Collaboration Project, maximum term of the Collaboration Project, frequency and content of reports etc.]

Schedule 2–Anti-Trust Statement

Meetings of Parties in connection with this Agreement or the Collaboration Project shall not be occasions where such Party's representatives or other invited participants:

- exchange or discuss proprietary business information that is not necessary to the activities of the Consortia, such as pricing policies, terms and conditions of sale, marketing or product plans, costs of production and distribution issues;
- confer about division or allocation of sales territories or customers;
- establish blacklists or boycotts of suppliers, purchasers or competitors;
- coerce members to implement particular programs or policies; or
- resolve problems unique to a single member or a small, select group of members.

Because the Parties represent a substantial segment of the pharmaceutical industry, each Consortium should avoid any activity that forecloses business opportunities of non-members or stifles innovation by the Parties. The Consortia should not exercise control over its participants' independent business activities.

Schedule 3 Prevention of Corruption – Third Party Guidelines

Each Participant agrees that the conduct of the Project requires compliance with the highest ethical standards and all anti-corruption laws applicable in the countries in which the Participant conducts business under this Agreement (including as appropriate, the provisions of the U.K. Bribery Act and the U.S. Foreign Corrupt Practices Act). In particular all Participant employees and any third party acting for or on behalf of a Participant must ensure that all dealings with third parties, both in the private and government sectors, are carried out in compliance with all relevant laws and regulations and with the standards of integrity required for IMI project. Each Participant values integrity and transparency and has zero tolerance for corrupt activities of any kind, whether committed by employees, officers, or third-parties acting for or on behalf of the Participant.

Corrupt Payments – the Participant's employees and any third party acting for or on behalf of the Participant, shall not, directly or indirectly, promise, authorise, ratify or offer to make or make any "payments" of "anything of value" (as defined in the glossary section) to any individual (or at the request of any individual) including a "government official" (as defined in the glossary section) for the improper purpose of influencing or

inducing or as a reward for any act, omission or decision to secure an improper advantage or to improperly assist the company in obtaining or retaining business.

Government Officials – Although this policy prohibits payments by a Participant or third parties acting for or on its behalf to any individual, private or public, as a “quid pro quo” for business, due to the existence of specific anticorruption laws in the countries where we operate, this policy is particularly applicable to “payments” of “anything of value” (as defined in the glossary section), or at the request of, “government officials” (as defined in the glossary section).

Facilitating Payments – For the avoidance of doubt, facilitating payments (otherwise known as “greasing payments” and defined as payments to an individual to secure or expedite the performance of a routine government action by government officials) are no exception to the general rule and therefore prohibited.

GLOSSARY

The terms defined herein should be construed broadly to give effect to the letter and spirit of the ABAC Policy. Each Participant is committed to the highest ethical standards of business dealings and any acts that create the appearance of promising, offering, giving or authorising payments prohibited by this policy will not be tolerated.

Anything of Value: this term includes cash or cash equivalents, gifts, services, employment offers, loans, travel expenses, entertainment, political contributions, charitable donations, subsidies, per diem payments, sponsorships, honoraria or provision of any other asset, even if nominal in value.

Payments: this term refers to and includes any direct or indirect offers to pay, promises to pay, authorisations of or payments of anything of value.

Government Official shall mean: Any officer or employee of a government or any department, agency or instrument of a government; Any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; Any officer or employee of a company or business owned in whole or part by a government; Any officer or employee of a public international organisation such as the World Bank or United Nations; Any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or Any candidate for political office.

Appendix 3

A general template for an eTRIKS Data Processing Agreement

Data Processing Agreement

by and between

<Insert name and address of data controller>

- hereinafter „**Controller**“ -
- <use an appropriate abbreviation for the organisation name in place of
“Controller” throughout the document>

and

the participants of the Innovative Medicines Initiative (“IMI”) eTRIKS consortium
listed in **Appendix 1**
and any future eTRIKS participants,
whose accession will be communicated to Controller promptly upon such accession

- hereinafter collectively „**Contractors**“ -

Preamble

WHEREAS, Controller is a participant of the IMI <or other funding body as appropriate> <insert name of project> consortium and owns or otherwise controls certain collections of data and visual representations other than text, hereafter referred to as Datasets and Images (as defined below).

WHEREAS, Contractors are participants of the IMI eTRIKS consortium, which is led by a coordinator and a managing entity as indicated in **Appendix 1**, and are each independent contractors; Contractors have developed certain software for the eTRIKS platform in the IMI eTRIKS consortium and have expert knowledge in the use of this newly developed platform.

WHEREAS, Controller wishes to have Contractors undertake activities in connection with the eTRIKS platform using the Datasets and Images.

THEREFORE, the parties agree as follows:

Section 1 Definitions

1. “Datasets” means collections of data owned or controlled by Controller that are transferred to one or more Contractors by Controller and their derivations, improvements and results, excluding any Task Data, generated in the course of or as a result of this agreement.
2. “Images” means visual representations other than text that are transferred to one or more Contractors by Controller and their derivations, improvements and results generated in the course of or as a result of this agreement.
3. “Task Data” means any information, data, know-how, inventions, and other developments made or discovered for the data process during the course of the Services as set forth in Appendix 2, which includes, without limitation, programmatic scripts, algorithms, and software of data transformation and analysis, but which are neither Datasets nor Images.

Section 2 Subject of the Agreement

1. Contractors shall undertake reasonable efforts to perform the activities as set forth in **Appendix 2, Description of Services** (hereinafter “eTRIKS Activities”).

For the avoidance of doubt, when in this agreement (including but not limited to its annexes) an obligation is assigned to “Contractors” to perform the eTRIKS Activities or abide by certain standards in that regard, such obligations shall vest only in those Contractors which are assigned to perform the eTRIKS Activities.

2. The eTRIKS Activities include in particular:
 - a) provision of web-based access to computer and software systems to enable and sustain secure storage, access, and use/re-use of Datasets and Images by Controller.
 - b) deliverables as defined Appendix 2, including but not limited to:
 - Curation and loading of Data Sets and/or Images
 - <insert summaries of other agreed tasks as appropriate>
3. The Contractors responsible for the relevant activities shall undertake reasonable efforts to perform the eTRIKS Activities within the timelines set forth in **Appendix 2**. In the event Contractors expect a delayed performance, Contractors through their coordinator and managing entity shall inform Controller in writing of such delay and the underlying reasons and shall suggest possible remedy.
4. *Contractors shall report on a regular basis to Controller in writing setting out the progress of the eTRIKS Activities.*

Section 3

Third parties

1. Controller or a third party working on behalf of Controller shall contact the coordinator and the managing entity of IMI eTRIKS regarding questions and instructions in connection with the conduct of the eTRIKS Activities as set forth in **Appendix 2**.
2. Any subcontracting or any assignment of any of Contractors’ obligations under this Agreement to a third party requires prior written approval by Controller at Controller’s sole discretion. Contractors shall provide name and address of the subcontractor and the scope of Services to be performed by the third party.
3. In case Contractors subcontract all or part of the eTRIKS Activities, they shall ensure that such subcontracted activities shall be performed in accordance with the terms of this agreement.

AA) Section 4

BB) Cooperation by Controller; Material Transfer

1. Controller or a third party working on behalf of Controller shall provide to Contractors the Datasets and Images, which are needed to perform the eTRIKS Activities as described in **Appendix 2**.
2. Contractors shall undertake reasonable efforts to review the Datasets and Images received from Controller as to possible deficiencies in consideration of the intended purpose and inform Controller of any deficiencies found.
3. Contractors shall use the Datasets and Images solely for the purpose of the eTRIKS Activities. Contractors shall not make the Datasets and Images available to any third party (except in case of subcontracting under Section 3). Contractors shall limit access to the Datasets and Images to those employees who are involved in the performance of the eTRIKS Activities, imposing on them restrictions on disclosure and use equivalent to those set out herein.
4. At any time upon request of Controller, Contractors shall return to Controller such Datasets and Images.
5. Contractors agree that the Datasets and Images are and shall remain the sole property of Controller. Nothing in this Agreement shall be construed as a grant to Contractors of any rights in the Datasets and Images other than expressly herein provided.

Section 5

Changes in capacity, surplus and deficient performance

Changes and additions regarding the scope of eTRIKS Activities are only binding, if the parties have agreed upon them in writing.

Section 6

Consideration

Contractors provide the eTRIKS Activities under this agreement without any compensation by Controller.

Section 7

Results / Warranty / Defects

1. Controller and Contractors agree that all Datasets and Images shall be the exclusive property of Controller.
2. Controller and Contractors agree that any Task Data developed or created by Contractors shall be owned by Contractors in accordance with the agreement(s) among them.
3. Contractors and Controller agree to comply with all applicable laws, governmental regulations and guidelines applicable to the eTRIKS Activities. Controller and Contractors agree to the terms set forth in **Appendix 3** relating to

the anti-trust principles, **Appendix 4** relating to the prevention of corruption – third party guidelines and **Appendix 5** relating to data protection processing. It is hereby expressly agreed that the terms and conditions in the data protection processing agreement as set forth in Appendix 5 shall take priority over this Agreement. <Insert this section and Appendix 5 if the data includes any Personal Data>

CC) Section 8

DD) Confidentiality

1. Each party possesses information of a secret and confidential nature which information is regarded by such party as an asset of considerable value. With respect to Controller this includes, without limitation, the Datasets and Images (hereinafter “Controller Information”). With respect to Contractors this includes all proprietary information relating to the eTRIKS platform and Task Data owned or controlled by Contractors (hereinafter “Contractors Information”; Controller Information and Contractors Information hereinafter collectively the “Information”).
2. The receiving party agrees to treat all Information of the disclosing party strictly confidential both during the cooperation and after the expiration of this Agreement. The receiving party (i) shall not use the Information for its own purposes or those of any third party, (ii) shall not disclose the Information to any other third party without obtaining the prior written consent of the disclosing party, (iii) shall provide access to the Information only to such minimum number of its or its Affiliates’ employees, or permitted subcontractors with a need to know the Information for the purpose of this Agreement imposing on them restrictions on disclosure and use equivalent to those set out herein and (iv) except if otherwise provided herein, shall not transfer the Information to any third party without the prior written consent of disclosing party. For the purposes of this Agreement, “Affiliates” shall mean with respect to a party, any person, corporation, firm, joint venture or other entity which, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such party. As used in this definition, “control” means possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of the outstanding voting securities or by contract or otherwise. Such Affiliates will only use the Information in accordance with this Section 7.
3. The obligation of confidentiality and non-use does not apply to Information which:
 - a) is available to the public at the time of receipt by the receiving party from the disclosing party; or
 - b) becomes public knowledge other than through a breach of this Agreement by the receiving party of the Information; or
 - c) the receiving party (this includes any Affiliate) can prove was known to the receiving party before the date of its disclosure by the disclosing party; or
 - d) the receiving party (this includes any Affiliate) has legally obtained from a third party that does not owe a duty of confidentiality, whether expressly or indirectly, to the disclosing party; or

- e) was independently developed by the receiving party (this includes any Affiliate) without reference to or use of the Information.
- 4. Furthermore, the parties may disclose Information to the extent that such disclosure is required to comply with law or an enforceable judicial order, provided, however, that the receiving party shall give reasonable advance notice, as legally permissible, to the disclosing party and, at the so informed disclosing party's request, shall cooperate to seek a protective order or other appropriate remedy. The receiving party shall use its reasonable efforts to secure confidential treatment of any Information that will be disclosed.
- 5. Information shall not be deemed to be public knowledge merely because any part of such Information is contained in general disclosures or because individual features of the Information are known or become known to the public.
- 6. On completion of the Agreement, completion of the eTRIKS Activities or at any time at the disclosing party's request, the receiving party shall return to the disclosing party any Information or, at the disclosing party's option and cost, destroy such Information and promptly confirm destruction in writing. Return or destruction of the Information shall not affect the receiving party's obligation to keep the Information confidential pursuant to this Section 7.

Section 9

Term and Termination

- 1. The term of this Agreement shall commence effective upon last signature hereof and shall last until completion of the eTRIKS Activities or expiration or early termination of the OncoTrack Project Agreement, whichever is earlier.
- 2. *Controller may terminate this Agreement without cause in parts or in its entirety at the end of every month upon giving three (3) months notice. In the event of termination, Contractors shall inform Controller in writing about the remainder of any and all eTRIKS Activities already commenced. Contractors shall perform these in accordance with the conditions set forth in this Agreement.*
- 3. The terms set forth in Sections 7, 8, 9 and 10 shall survive any termination or expiration of this Agreement.

Section 10

Miscellaneous

- 1. This Agreement may not be assigned or otherwise transferred - in parts or in its entirety - by either party without the prior written consent of the other parties.
- 2. This Agreement sets forth the entire understanding and agreement of the parties relating to the subject matter hereof. No modification or amendment to this

Agreement will be effective unless in writing and signed by both parties. Any notice to be given by either party under this Agreement shall only be effective if in writing.

3. The invalidity of a particular provision of this Agreement shall not affect the validity of the remaining provisions. The parties shall replace the invalid provisions with a valid provision that comes closest to effectuating the intent of the parties at the time of the Agreement's execution. This shall also apply if the provisions of this Agreement should be found to be incomplete.
4. The following appendices shall form an integral part of this Agreement:
 - a) Appendix 1: List of participants of the IMI eTRIKS consortium
 - b) Appendix 2: eTRIKS Activities
 - c) Appendix 3: Anti-trust Principles
 - d) Appendix 4: Prevention of Corruption – Third Party Guidelines
 - e) Appendix 5: Data Protection Processing Agreement

Section 11

Governing law / Place of proceedings

This Agreement shall be governed by, subject to and construed in accordance with the laws of <insert name of governing legal jurisdiction> without reference to its conflict of laws provisions. Any legal action arising under this Agreement shall be instituted in <insert location of governing legal jurisdiction>.

(The remainder of this page is intentionally left blank.)

Signed for and on behalf of:

Controller

Date:.....

eTRIKS SIGNATURES

Authorised to sign on behalf of:

AstraZeneca AB (AZ)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Imperial College of Science, Technology & Medicine (ICL)

Signature

Name

Title

Date

Authorised to sign on behalf of:

University of Luxembourg, Luxembourg Centre for Systems Biomedicine (UL)

Signature

Name

Title

Date

Authorised to sign on behalf of:

ID Business Solutions Limited (IDBS)

Signature

Name

Title

Date

Authorised to sign on behalf of:

BioSci Consulting (BSC)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Centre National de la Recherche Scientifique (CNRS)

Signature

Name

Title

Date

Authorised to sign on behalf of:

CDISC Europe Foundation (CDISC)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Janssen Pharmaceutia NV (JANSSEN)

Signature

Name

Title

Date

Authorised to sign on behalf of:

F. Hoffmann-La Roche Limited (Roche)

Signature

Name

Title

Date

Authorised to sign on behalf of:

GlaxoSmithKline Research & Development Limited (GSK)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Sanofi-Aventis Recherche & Développement (SARD)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Bayer Pharma AG (Bayer)

Signature

Signature

Name

Name

Title

Title

Date

Date

Authorised to sign on behalf of:

Merck KGaA (ME)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Pfizer Limited (Pfizer)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Eli Lilly and Company Limited (LLY)

Signature

Name

Title

Date

Authorised to sign on behalf of:

H. Lundbeck A/S (LUB)

Signature

Name

Title

Date

Authorised to sign on behalf of:

Oxford University (UOXF)

Signature

Name

Title

Date

Appendix 1: List of participants of IMI eTRIKS consortium

AstraZeneca AB, a company incorporated in Sweden under no. 556011-7482 with offices at S-151 85 Södertälje, Sweden (“**AZ**”); acting as coordinator under the agreement entitled “European Translational Information & Knowledge Management Services” (IMI grant agreement No. 115446)

Imperial College of Science, Technology & Medicine, whose administrative offices are at Research Office, Level 5 Sherfield Building, Exhibition Road,, South Kensington Campus, London, SW7 2AZ, UNITED KINGDOM (“**ICL**”) acting as Managing Entity under the agreement entitled “European Translational Information & Knowledge Management Services” (IMI grant agreement No. 115446)

University of Luxembourg, Luxembourg Centre for Systems Biomedicine (UL), whose administrative offices are at 7 avenue des Hauts-Fourneaux, L-4362 Esch-sur-Alzette, LUXEMBOURG;

ID Business Solutions Limited (IDBS), whose administrative offices are at 2 Occam Court, Surrey Research Park, Guildford, Surrey, GU2 7QB, UNITED KINGDOM;

BioSci Consulting (BSC), whose administrative offices are at Weg naar Geneuth 95, 3631 Maasmechelen, BELGIUM;

Centre National de la Recherche Scientifique (CNRS), whose administrative offices are at Campus Gérard-Mégie, 3 rue Michel-Ange - F-75794, Paris cedex 16, FRANCE;

CDISC Europe Foundation (CDISC), whose administrative offices are at 141 rue Saint-Lambert 1200 Woluwe-St Brussels, Belgium;

Janssen Pharmaceutia NV (JANSSEN), whose administrative offices are at Turnhoutseweg 30, B-2340 Beerse, BELGIUM;

F. Hoffman-La Roche Limited (Roche), whose administrative offices are at Grenzacherstrasse 124, CH-4070 Basel, SWITZERLAND;

GlaxoSmithKline Research & Development Limited (GSK), whose administrative offices are at 980 Great West Road, Brentford, Middlesex, TW8 9GS, UNITED KINGDOM;

Sanofi-Aventis Recherche & Développement (SARD), whose administrative offices are at Avenue Pierre Brossolette 1, Chilly-Mazarin 91385, FRANCE;

Bayer Pharma AG (Bayer), whose administrative offices are at Mullerstrasse 178, D-13353, Berlin, GERMANY;

Merck KGaA (ME), whose administrative offices are at Frankfurter Strasse 250, 64293 Darmstadt, GERMANY;

Pfizer Limited (Pfizer), whose administrative offices are at Ramsgate Road, Sandwich, Kent, CT13 9NJ, UNITED KINGDOM:

Eli Lilly and Company Limited (LLY), whose administrative offices are at Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, UNITED KINGDOM;

H. Lundbeck A/S (LUB), whose administrative offices are at Ottiliavej 9, Valby DK-2500, DENMARK

The Chancellor Masters and Scholars of the University of Oxford (UOXF), whose administrative offices are at University Offices, Wellington Square, Oxford, Oxon OX1 2JD, UNITED KINGDOM

Appendix 2: Description of Services

<Insert or attach full list of agreed services and activities here>

Appendix 3: Anti-trust principles

Meetings of parties in connection with this Agreement or the eTRIKS Activities shall not be occasions where such party's representatives or other invited participants:

- exchange or discuss proprietary business information that is not necessary to the activities of the Consortia, such as pricing policies, terms and conditions of sale, marketing or product plans, costs of production and distribution issues;
- confer about division or allocation of sales territories or customers;
- establish blacklists or boycotts of suppliers, purchasers or competitors;
- coerce members to implement particular programs or policies; or
- resolve problems unique to a single member or a small, select group of members.

Because the parties represent a substantial segment of the pharmaceutical industry, each party should avoid any activity that forecloses business opportunities of non-members or stifles innovation by the parties. The parties should not exercise control over the other parties' independent business activities.

Appendix 4: Prevention of Corruption – Third Party Guidelines

Each party agrees that the conduct of the eTRIKS Activities requires compliance with the highest ethical standards and all anti-corruption laws applicable in the countries in which the party conducts business under this Agreement (including as appropriate, the provisions of the U.K. Bribery Act and the U.S. Foreign Corrupt Practices Act). In particular all party employees and any third party acting for or on behalf of a party must ensure that all dealings with third parties, both in the private and government sectors, are carried out in compliance with all relevant laws and regulations and industry and professional codes of practice and with the standards of integrity required for an IMI project. Each party values integrity and transparency and has zero tolerance for corrupt activities of any kind, whether committed by employees, officers, or third-parties acting for or on behalf of the party.

Corrupt Payments – the party’s employees and any third party acting for or on behalf of the party, shall not, directly or indirectly, promise, authorise, ratify or offer to make or make any “payments” of “anything of value” (as defined in the glossary section) to any individual (or at the request of any individual) including a “government official” (as defined in the glossary section) for the improper purpose of influencing or inducing or as a reward for any act, omission or decision to secure an improper advantage or to improperly assist the company in obtaining or retaining business.

Government Officials – Although this policy prohibits payments by a party or third parties acting for or on its behalf to any individual, private or public, as a “quid pro quo” for business, due to the existence of specific anticorruption laws in the countries where we operate, this policy is particularly applicable to “payments” of “anything of value” (as defined in the glossary section), or at the request of, “government officials” (as defined in the glossary section).

Facilitating Payments – For the avoidance of doubt, facilitating payments (otherwise known as “greasing payments” and defined as payments to an individual to secure or expedite the performance of a routine government action by government officials) are no exception to the general rule and therefore prohibited.

GLOSSARY

The terms defined herein should be construed broadly to give effect to the letter and spirit of the ABAC Policy. Each party is committed to the highest ethical standards of business dealings and any acts that create the appearance of promising, offering, giving or authorising payments prohibited by this policy will not be tolerated.

Anything of Value: this term includes cash or cash equivalents, gifts, services, employment offers, loans, travel expenses, entertainment, political contributions, charitable donations, subsidies, per diem payments, sponsorships, honoraria or provision of any other asset, even if nominal in value.

Payments: this term refers to and includes any direct or indirect offers to pay, promises to pay, authorisations of or payments of anything of value.

Government Official shall mean: Any officer or employee of a government or any department, agency or instrument of a government; Any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; Any officer or employee of a company or business owned in whole or part

by a government; Any officer or employee of a public international organisation such as the World Bank or United Nations; Any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or Any candidate for political office.

Appendix 5: Data Protection Processing Agreement

between

<Insert full name and address of data controller>

- hereinafter referred to as “Controller” -

and

the participants of the Innovative Medicines Initiative (“IMI”) eTRIKS consortium listed in **Appendix 1** and any future eTRIKS participants, whose accession will be communicated to Controller promptly upon such accession

- hereinafter collectively “Contractors”

Controller and Contractors are individually referred to as “Party” and collectively as the “Parties”.

Contractors and Controller have entered into a Data Processing Agreement dated [Date to be inserted] under which Contractors perform certain activities (“eTRIKS Activities”) for Controller as described in that agreement (“Data Processing Agreement”).

In connection with the eTRIKS Activities, Controller will transfer to certain Contractors Datasets and Images which may include personal data within the meaning of the EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (to the extent such Datasets and Images include personal data, including information regarding the health of patients, “Personal Data”).

This Agreement specifies the obligations of the Parties with respect to the storage, use and processing by Contractors of the Personal Data provided by Controller under the Data Processing Agreement (“Processing”).

This Agreement governs the actions aimed to ensure that Controller's and Contractors' Processing of the Personal Data meet the requirements for the protection of personal data stipulated in the EU Directive 95/46/EC as implemented for <insert national implementation of EU Directive as appropriate> (the "Act"). and other applicable laws implanting such Directive.

1. Contractors will perform Processing of the Personal Data as part of the eTRIKS Activities under the Data Processing Agreement as data processor on behalf of Controller. The Processing of Personal Data shall only take place on servers located in the European Economic Area and Data may not be transferred to any location outside the European Economic Area (EEA) without the approval of Controller and provided that an agreement with the company in a third country in accordance with the rules on standard contractual clauses for the transfer of personal data as set forth in the decision of the European Commission dated 5 February 2010 (2010/87/EU) is concluded..
2. Controller continues to be the data controller of the Data Sets and Images and will remain responsible for protecting the rights of the data subjects and thus for determining whether the Processing of their personal data is admissible. Both Parties will ensure compliance with the requirements for the protection of personal data stipulated in the EU Directive 95/46/EC and the applicable laws implanting such Directive. To this, Controller shall provide Contractors with identity and the location of the organizations that Controller will allow to process the Data Sets and Images hosted in the eTRIKS platform (hereafter called "the Organizations"). However, only Controller will ensure compliance with the Act and any other applicable data protection regulations, especially the EU Directive 95/46/EC when Controller or the Organizations use Data Sets and Images on the eTRIKS Platform and export(s) the Data from the eTRIKS platform and process(es) them outside the eTRIKS platform.
3. Controller shall provide the Personal Data to Contractors complete, accurate and up to date and in such form as is necessary for Contractors to process the Personal Data in accordance with the Data Processing Agreement.
4. Controller warrants that it is entitled to provide the Personal Data under this Agreement under applicable laws regulations and that all relevant consents and approvals in connection herewith, if required, have been obtained.

5. Contractors will perform Processing of the Personal Data only in accordance with the instructions of Controller for those purposes which are specified in the Data Processing Agreement.
6. The Contractors who will perform the eTRIKS Activities confirm that they have implemented the technical and organizational measures designed to meet the specific requirements of data protection in accordance with EU Directive 95/46/EC. For that purpose such Contractors have created their internal organization in a way that it complies with the requirements of data protection and privacy. Contractors ensure that technical and organizational measures for adequate security against misuse and loss of the Personal Data within the eTRIKS platform are maintained, in particular:
 - a) to prevent unauthorized persons from gaining access to data processing systems for processing or using data (access control),
 - b) to prevent data processing systems from being used without authorization (access control),
 - c) to ensure that persons authorized to use a data processing system have access only to the data they are authorized to access, and those data cannot be read, copied, altered or removed without authorization during processing (access control),
 - d) to ensure that data cannot be read, copied, altered or removed without authorization during electronic transfer or transport or while being recorded onto data storage media, and that it is possible to ascertain and check to which bodies data is intended to be transferred using data transmission facilities (disclosure control),
 - e) to ensure that it is possible after the fact to check and ascertain whether personal data have been entered into, altered or removed from data processing systems and if so, by whom (input control),
 - f) to ensure that data processed on behalf of Controller are processed strictly in compliance with Controller's instructions (job control),
 - g) to ensure that data are protected against accidental destruction or loss (availability control),

h) to ensure that data collected for different purposes can be processed separately.

One measure in accordance with the sub-paras. a) to d) is in particular the use of the latest encryption procedures.

7. With respect to the Processing of Personal Data, Contractors agree to engage only those individuals who are obliged to maintain the confidentiality of the Data pursuant to EU Directive 95/46/EC. Contractors shall designate an appropriate number of employees to supervise and monitor the use of the Personal Data left in their care.
8. Contractors shall notify Controller in the event of an interruption in processing, a suspected breach of the data protection provisions or any other irregularity involving the processing of Controller's data. Controller shall notify Contractors without delay if Controller becomes aware of any errors or irregularities, including, without limitation, those ascertained while reviewing results.
9. Contractors agree to respond to any and all reasonable requests and enquiries made by Controller relating to the Processing of the Personal Data. Contractors will maintain the Personal Data on their data processing systems and have to check periodically whether the obligations under No. 6 are fulfilled.
10. In case Controller is required under applicable data protection law to provide information regarding the Data Processing towards a data subject, Contractors will provide the necessary information (if required) to Controller within a reasonable period of time. In case a data subject approaches Controller regarding a correction or deletion of Data, Controller will immediately inform Contractors, and the Parties will discuss in good faith, taking into account applicable data protection law, how to deal with any such request.
11. Controller will periodically check that Contractors maintain the technical and organizational measures pursuant to No 6. Contractors acknowledge and agree that the authority responsible for monitoring Controller's protection of personal data may also monitor Contractors' operations to the extent permitted by law.

12. The Parties will provide to each other the name of the Privacy Officer taking care of the technical and organizational measures pursuant to No 6, as applicable.
13. Contractors may only engage a subcontractor for the performance of Processing Data with the prior written consent of Controller (a “Subcontractor”).
14. In case Subcontractors are engaged, Contractors shall procure in their agreement with such subcontractors that the requirements for confidentiality, data protection and data security correspond to the regulations in this Agreement. Contractors shall procure that Controller has the same control rights over the subcontractors as provided for in this Agreement.
15. This Agreement has the same term as the Data Processing Agreement and the respective termination provisions apply accordingly. Following expiration of this Agreement Contractors shall (1) immediately stop any Processing of Data, (2) delete any Personal Data on its IT systems and (3) procure that Subcontractors shall immediately stop any Processing of Personal Data and delete any Personal Data on their IT systems.
16. Capitalised terms not defined in this Agreement shall have the meaning as set forth in the Data Processing Agreement.
17. This Agreement is governed by the laws of <insert name of governing legal jurisdiction> As regards any disputes arising under or out of this Agreement the Parties herewith submit exclusively to the jurisdiction of the courts of <insert location of governing legal jurisdiction>.
18. Unless otherwise regulated in this Agreement, the terms of the Data Processing Agreement shall apply. In case of any discrepancy between this Agreement and the Data Processing Agreement, this Agreement shall prevail.

Appendix 4

A general template for eTRIKS MTA Task Plan

Schedule 3

Task Plan

Glossary

- Project is the <PROVIDING PROJECT> Project, as defined in the document "e-TRIKS- <PROVIDING PROJECT> DATASETS AND IMAGES TRANSFER AND COLLABORATION AGREEMENT"
- Lab.: laboratory
- eCRF: electronic case report forms
- ED: Effective Date of agreement of the Task Plan
- TM: tranSMART
- eTM: eTRIKS production TM
- eTM UI: eTM user interface
- <PROVIDING PROJECT> data: data that are anonymized and reconciliated by <PROVIDING PROJECT>, and are sent from <PROVIDING PROJECT> to eTRIKS. Those data are considered as "raw", since they have not been curated within eTRIKS yet.
- Content: <PROVIDING PROJECT> data that have been curated within eTRIKS. Once curated, they are intended to be loaded into the Project eTM DW.
- eTM DW: eTM data warehouse
- Project eTM DW: the Project instance of the eTM DW that contains the Content.
- Data labels: (also called variables in data management) descriptions of data (often names; in a table they are column headers)
- Data label tree: the study representation at the data label level in the eTM UI
- eTRIKS WP1: eTRIKS work package 1 dedicated to Platform Service Delivery
- eTRIKS WP2: eTRIKS work package 2 dedicated to Infrastructure Platform Design and Development
- eTRIKS WP3: eTRIKS work package 3 dedicated to Standards Research and Development
- eTRIKS WP4: eTRIKS work package 4 dedicated to Analytics Research and Data Curation
- eTRIKS WP7: eTRIKS work package 7 dedicated to Ethics
- TC: Task Committee.

Aim and mutual understanding of the collaboration

The overall goals of the collaboration between the two consortia <PROVIDING PROJECT> and eTRIKS (www.etriks.org) are

1. to enable and sustain secure storage, access, and use/re-use of <PROVIDING PROJECT> Datasets and Images for the <PROVIDING PROJECT> consortium participants within the requirements of international and national patient

privacy and confidentiality rules during the collaboration project (hereafter called “the Project”);

2. to make the contributions of the consortia be beneficial in the research activities of the consortia. Moreover, since the main mission of eTRIKS is to enable translational research for the benefit of not only the <PROVIDING PROJECT> participants but also the whole scientific community, the consortia agree to reach an agreement on the conditions of the <PROVIDING PROJECT> Datasets and Images release beyond the <PROVIDING PROJECT> project end date no more than 18 months after the effective date of the Agreement.

To reach the Project goals, contributions and responsibilities of both consortia are required and shared as described in detail in the following sections. Although both consortia have clear visions and work plans, it is expected that they will gain novel insights during the collaboration period, that will require adaptation of their activities and resource in order to reach the collaboration goals and milestones.

Overview of <PROVIDING PROJECT> data

<Insert 0.5 – 2 page description of project’s data>

Scope of the Schedule

The collaboration will cover the following areas, for which detailed information is given in the following sections:

<add or delete scope elements as necessary in this section and appropriate longer descriptions below, typical examples are given here>

- Knowledge transfer
- Data curation, loading, and provenance
- Data hosting, security, and release
- Data visualization, analysis, and export
- Error reporting and eTM feature requests
- Training

Knowledge transfer

This section describes the processes that will be required to manage any exchange of knowledge between <PROVIDING PROJECT> partners or their third parties and eTRIKS that is required to understand the current data management environment and processes in use in <PROVIDING PROJECT>.

<PROVIDING PROJECT> and/or their data management third party will provide to eTRIKS details of the existing and historic data curation, loading and provenance processes used by <PROVIDING PROJECT> in sufficient detail that eTRIKS can reproduce or transfer the process to any hosted environment.

Teleconferences, presentations, system demonstrations and site visits will be arranged as required to provide eTRIKS with the fullest necessary knowledge of the current data environment.

<PROVIDING PROJECT> and/or their data management third party will provide such assistance as is necessary to ensure the smooth transfer of data from existing environments to the eTRIKS hosted environment.

Data curation, loading, and provenance

Data curation and loading process

This section describes the eTRIKS WP3, 4 and 7 standard practice for all collaborative projects.

eTRIKS will help <PROVIDING PROJECT> to curate its data and load the Content into the Project eTM DW according to eTRIKS curation guidelines and process (see the document in the section 14.2) in the following steps of the data curation and loading process.

- i. Based on all the information <PROVIDING PROJECT> will provide to eTRIKS (e.g. ethics committees' approvals, study design, number of cohorts, number of patients per cohort, assays used, list of variables/data labels per cohort, used semantic standards, format(s) of the source data files) at least 2 months before the curation pipeline launch date, eTRIKS will check the <PROVIDING PROJECT> procedures for the data anonymisation, and will define the data label tree in the eTM UI, and the curation and loading parameters (i.e. data cleansing, conversion, standardization, transformation, loading file formats, and the mapping files) at least one month before the curation pipeline launch date;
- ii. Based on the eTRIKS curation process (see the document in the section 14.2) and the curation parameters defined in the previous step (see point 5.1 i), eTRIKS will build/adapt the curation pipeline (i.e. the curation and loading scripts/tools will be written and/or modified), and test it on a subset of <PROVIDING PROJECT> data;
- iii. Once the curation pipeline is launched, eTRIKS will train <PROVIDING PROJECT> curators to curate <PROVIDING PROJECT> data and load the Content into the Project eTM DW.

Notes:

- eTRIKS is authorized to curate and load only anonymized data into the Project eTM DW. Therefore, <PROVIDING PROJECT> can submit only anonymized data to eTRIKS.
- The setting of eTRIKS data curation and loading process is specific to a data label tree. Thus, if 2 studies have different data label trees, then the setting of eTRIKS data curation and loading process is different between the 2 studies.
- The eTRIKS curation and loading process has 2 phases: an implementation phase and a production phase. In the implementation phase, all the needed material, resource, and procedures are put in place, the curators are in a learning phase, and thereby the process is not at its maximal speed. The length of the implementation phase period highly depends on
 - 1) the completeness of the documentation/information that <PROVIDING PROJECT> sends to eTRIKS
 - 2) the standards to put in place

- 3) the data label tree
- 4) the diversity of the <PROVIDING PROJECT> data file formats.
- In the production phase, the curation and loading process speed depends on the completeness and cleanness of the received data: the cleaner the data are in the source files, the faster the data are curated and loaded into Project eTM DW.

Data migration/load from IDBS-tranSMART

This section describes requirements and practices specific to the eTRIKS-<PROVIDING PROJECT> Project.

The <PROVIDING PROJECT> datasets that are currently hosted in the IDBS-TM DW instance will be loaded by eTRIKS into Project eTM DW. Since the IDBS-tranSMART and eTM instances are 2 different TM versions, the following procedure will be put in place.

- <PROVIDING PROJECT> will provide all the technical information regarding the curation and loading procedures that IDBS has put in place for <PROVIDING PROJECT>, the source data files, the standard format data files (used by the loading procedures), error reports and the mapping files, as well as the documentation related to the ethic committee's approval and the anonymization procedures at least 2 months before eTRIKS starts supporting the <PROVIDING PROJECT> data curation and the Content loading into Project eTM DW.
- eTRIKS will review the provided documentation related to the curation workflow/pipeline (scripts, reports, source data files, curated data files), and will take part in knowledge transfer workshop(s) organized by IDBS.
- eTRIKS will provide IDBS with access to Project eTM DW as well as a virtual machine where IDBS will test the loading procedures into Project eTM DW and the eTM features.
- eTRIKS will test/modify loading procedures when receiving IDBS-TM-loaded data subset representative of all IDBS-TM-loaded datasets;
- eTRIKS will load the IDBS-TM-loaded datasets once eTRIKS has performed the above steps.
- <PROVIDING PROJECT> will check the accurateness of the Data label tree design as well as eTM functions when using the IDBS-TM-loaded datasets.

Data provenance

This section describes the eTRIKS WP4 standard practice for all collaborative projects. To guarantee the data provenance, eTRIKS applies the following principles (as described in the eTRIKS data provenance guidelines (under release process)).

- Data files that have been received or generated by eTRIKS are registered in the <PROVIDING PROJECT>-dedicated eTRIKS repository (hereafter called the Project landing space) when eTRIKS repository is built, and are never modified or erased. When a modification or update needs to be done in a file, another file is created with a new file identifier.

- Source data files have unique identifiers that describe the investigation name (e.g. <PROVIDING PROJECT>), study location (eg: Karolinska Institute), the data type (eg: RNA-Seq), Version_<date in yyyyymmdd format> (e.g. Version_20130822)
- Data files generated from source data files along the curation process also have unique identifiers derived from the unique identifiers of the source data files.

Those principles will be implemented when the eTRIKS repository is built. Before the eTRIKS repository is built, the data files will be maintained in the Project landing space (see its description in the section 6.1.1) and managed by the Task Committee.

Resource and contribution

This section describes the eTRIKS WP4 standard practice for all collaborative projects.

eTRIKS will provide hardware, software, configuration, installation of hardware or software, and/or expertise to support the <PROVIDING PROJECT> data curation and the Content loading activities (a maximum of 0.5 FTE of eTRIKS WP4 per year). However, <PROVIDING PROJECT> will curate most <PROVIDING PROJECT> data and load the Contents. Moreover, <PROVIDING PROJECT> expertise in its domains remains essential at each step of the data curation and loading process. More specifically this means that:

- eTRIKS will provide <PROVIDING PROJECT> with a curation pipeline (i.e. a package of curation/loading tools or scripts) that will enable <PROVIDING PROJECT> curators to curate <PROVIDING PROJECT> data and load the Contents into the Project eTM DW. To this eTRIKS will develop and test the curation pipeline on a <PROVIDING PROJECT> data subset;
- eTRIKS will train <PROVIDING PROJECT> curators on how to use the curation pipeline and curate <PROVIDING PROJECT> data according to the eTRIKS curation guidelines;
- eTRIKS will provide <PROVIDING PROJECT> with programming support when curation pipeline needs to be changed or fixed;
- eTRIKS will provide <PROVIDING PROJECT> with data standards support when data standardization issues occur (a maximum of 0.1 FTE of eTRIKS WP3 per year);
- <PROVIDING PROJECT> will provide eTRIKS with the information/documentation needed for the setting and implementation of the data curation and loading process (see the eTRIKS curation guideline document in the section 14.2 for details);
- <PROVIDING PROJECT> will be responsible for the completeness, the cleanness, the consistency, the anonymization, and the reconciliation (i.e. clinical with lab data) of its data;
- <PROVIDING PROJECT> will contribute to the establishment of annotations guidelines (MIG) by assigning <PROVIDING PROJECT> domain experts (data type, assay) who will be asked to give their inputs on MIG documents written by eTRIKS about those domains;
- <PROVIDING PROJECT> will provide curator(s) who will curate most <PROVIDING PROJECT> data and load the Contents.

Data hosting, security, and release

Data hosting

Hosting spaces

This section describes the eTRIKS WP1 standard practice for all collaborative and eTRIKS-hosted projects.

eTRIKS will host <PROVIDING PROJECT> Datasets and Images files. Data hosting needs depend on the data characteristics and their use, and are summarized in the section 14.2. The Project runs 3 kinds of activities: 1) data curation and loading; 2) testing the Content that has been loaded into the Project eTM DW 3) working on the Content through the eTM UI. To avoid these 3 main activities interfering with each other, eTRIKS will dedicate one space per activity to the Project:

- the Project landing space is dedicated to the curation activities, and hosts the <PROVIDING PROJECT> data files, the curation-generated data files, and the curation and loading scripts/software. The new dataset that includes new, modified and/or deleted data are loaded from the Project landing space into the Project eTM DW that is used by the eTM of the Project testing space;
- the Project testing space is dedicated to test the new Content through the UI of the last eTM version;
- the Project working space is dedicated to read and work (i.e. analyze, visualize, and export) on the previous and new versions of the tested Content through the eTM UI.

For each type of data that <PROVIDING PROJECT> will bring to the eTRIKS platform or that will be generated by the curation activities in the eTRIKS platform, eTRIKS will allocate the proper storage space, provided the resource is available (a maximum of 1.5 PB of disk storage, 13 vCPU, 52 GB RAM).

Back-up/replication solutions

This section describes the eTRIKS WP1 standard practice for all collaborative and eTRIKS-hosted projects.

- eTRIKS hosts, mirrors, and backs up the <PROVIDING PROJECT> Datasets and Images and eTMs on three hubs: CC-IN2P3/CNRS (CC) of Lyon, Imperial College of London (ICL), and University of Luxembourg (UL). If this back up/replication is not implemented on the effective date, then eTRIKS will provide a temporary solution of back-up at CC.
- The backup and replication frequencies are agreed upon between <PROVIDING PROJECT> and eTRIKS, and depend on the type of data. Software deployed on the master platform that is hosted at CC is replicated to ICL and UL sites at any new release or bug fix.
- All the <PROVIDING PROJECT> data are replicated once, and new curation-generated data are replicated with a frequency of once a day or higher if needed.
- For the Content the synchronization is done automatically every time a change is made (insertions, deletions, and/or modifications).
- For the testing and working spaces, the transient outputs of the <PROVIDING PROJECT> user jobs are saved for a predefined time period depending on the size of the outputs and on the allocated user storage space. It is the responsibility of the

users to export and save their definitive outputs (e.g. when users finish their analysis) on their own home file spaces.

Data security and access

This section describes the eTRIKS WP1 standard practice for all collaborative and eTRIKS-hosted projects.

- The servers/machines of the 3 eTRIKS hubs are exclusively dedicated to the eTRIKS platform and the collaborative projects such as the eTRIKS-<PROVIDING PROJECT> Project.
- The Project landing and testing spaces are exclusively accessed by the Task Committee (see definition in the section 10.1), while the working space is dedicated to <PROVIDING PROJECT> users and the Task Committee.
- <PROVIDING PROJECT> Datasets and Images and virtualized servers are isolated logically from all other eTRIKS collaborative projects, and are exclusively available to the Task Committee and <PROVIDING PROJECT> users through customized access permissions.
- <PROVIDING PROJECT> source data files are transferred from original data storage space to the parking space of the Project landing space through an encrypted communication channel. This encryption is to be negotiated between both parties.
- Only the eTRIKS administrator is authorized to update eTM in the Project testing space.
- The tested Content is frozen between its 2 versions, and <PROVIDING PROJECT> users can only read it through the eTM UI in the Project working space. Only the eTRIKS DataBase administrator has the right to delete the tested Content in the Project working space. To do it, the eTRIKS DataBase administrator must receive written authorizations from both Task Committee Leaders, which may happen after each release of a new tested Content in the Project working space.
- The Content access can be restricted only at the study level. Access restriction at lower level (e.g. an arm/cohort of a study) is not possible with the current version of eTM (postgresql eTM version 1.1).
- Access accreditations are given only by the eTRIKS security administrator only when the eTRIKS security administrator receives written approvals from both Task Committee Leaders.

The following sections (6.2.1-3) describe requirements and practices specific to the Project.

Project landing space

- Only curators of the Task Committee will be accredited to log into the Project landing space.
- <PROVIDING PROJECT> study owners will be authorized only to up-load new <PROVIDING PROJECT> source data files in the parking space of the Project landing space, and will not be authorized to access to the rest of the Project landing space unless they also are curators of the Task Committee.

- Curators of the Task Committee will be authorized to generate the curation data files from the <PROVIDING PROJECT> source data files remotely in the Project landing space.
- Curators of the Task Committee will not be authorized either 1) to modify <PROVIDING PROJECT> source data files existing in the Project landing space, or 2) down-load source or curation data files into a local machine(s).

Project testing space

- Only the Task Committee members, the eTRIKS developers, and the eTRIKS administrator will be accredited for testing the Content and the features of the eTM versions in the Project testing space.
- Only 2 master curators of the Task Committee will be authorized to load the Content from the Project landing space into the Project testing space.

Project working space

- The Task Committee members and the eTRIKS developers will be accredited for testing the Content and the features of the eTM versions in the Project working space, if needed.
- <PROVIDING PROJECT> users may be accredited by <PROVIDING PROJECT> for accessing data only from some <PROVIDING PROJECT> studies (e.g. the multiple sclerosis study) when using the Content and the eTM versions in the Project working space.

Project workflow

This section describes the eTRIKS WP1/2/4 standard practice for all collaborative and eTRIKS-hosted projects.

The Project workflow and update/release cycles are shown in the Figure 1. **Very importantly the cycles of the eTM releases and the Content updates are independent.** The goal of its workflow is to update and test the versions of the Content and eTM without interfering with users' activities.

- eTRIKS updates, upgrades, fixes, and tests its TMs (DW and/or applications) in its own development environment. Once passed the test the eTRIKS TM is released as a new production version of eTRIKS TM (eTM). Releases of new eTM versions are scheduled according to the eTRIKS roadmap.
- Once a new version of eTM is ready for release, users and Task Committee Leaders are notified on a date for this new release. If there is no veto to the release is raised, the release is installed by the eTRIKS administrator in all the project spaces and the new release is made available as the standard platform. If needed, the corresponding Content is released as well. The previous release will be kept available for users for a short time to be defined.
- The curators of the Task Committee provide new dataset that is transferred from the Project landing space to Project eTM DW of the Project testing space. The Content (i.e. the loaded dataset) updates in the Project testing space is scheduled by the Task Committee Leaders.

- Once the Content (and eTM features if it is a new eTM version) pass(es) the tests, the Content (and eTM if it is a new eTM version) is/are updated/released in the Project working space. The update/release date is scheduled by the eTRIKS administrator and the Task Committee Leaders, and is communicated by eTRIKS to all authorized <PROVIDING PROJECT> users. The previous Content remains accessible in the Project working space for the 3 months following the Content update date in order to let the authorized <PROVIDING PROJECT> users finish their analyses. The access rights and credentials to both Content versions remain unchanged in the Project working space.

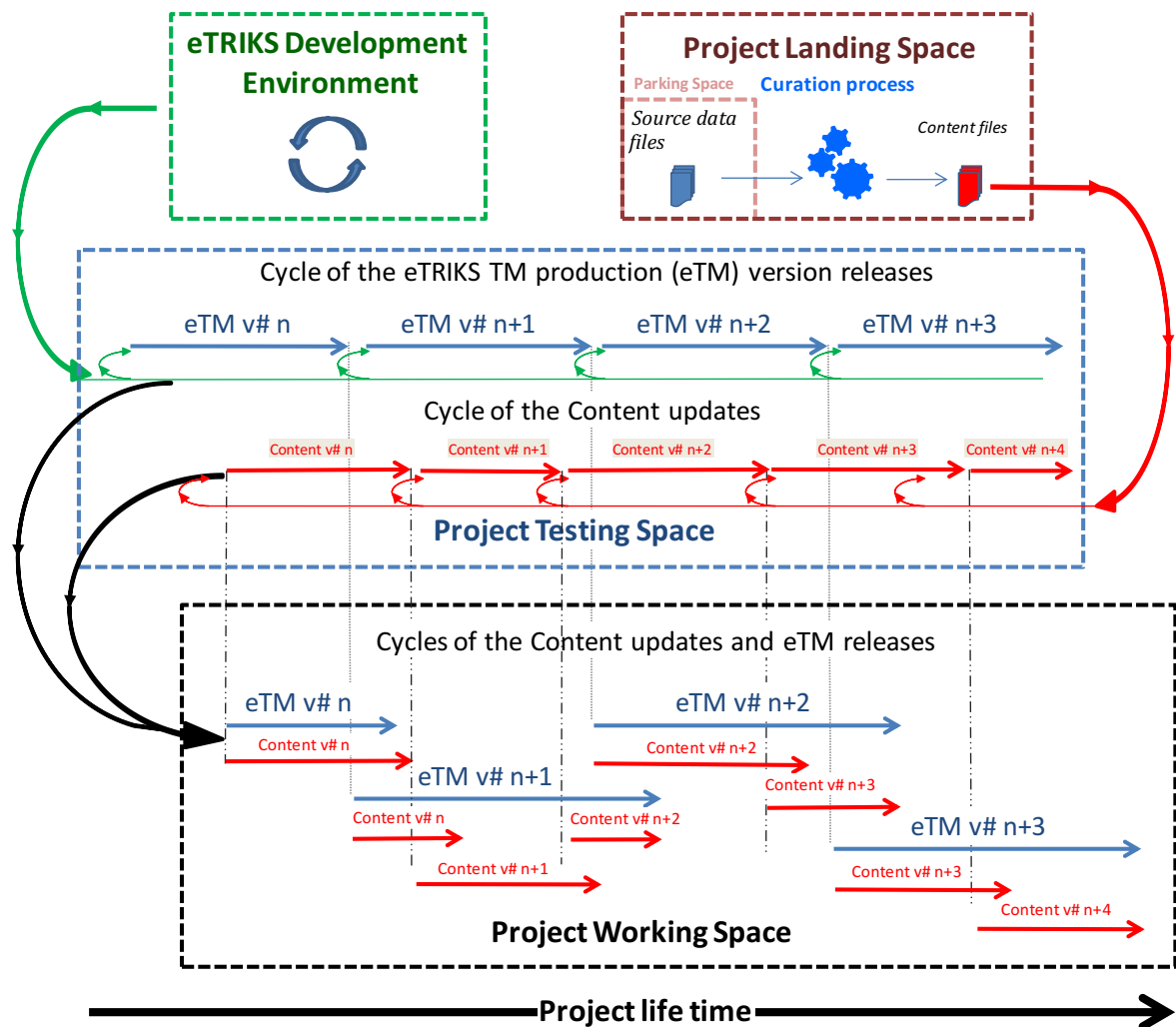


Figure 1: Project workflow. The cycles of the eTM releases and the Content updates are independent. The eTM releases depend on eTRIKS, while the Content updates depend on the Project.

Requirements specific to the Project:

The periodicity of the Content releases in the Project working space will be about 3 months.

Resource and contribution

This section describes the eTRIKS WP1/2 standard practice for all collaborative and eTRIKS-hosted projects.

- eTRIKS provides hardware, software, hardware configuration, software installation, expertise, and resource (a maximum of 0.2 FTE per year) to support the above described activities on data hosting, security, and release.
- <PROVIDING PROJECT> provides eTRIKS with the information needed for the estimation of space sizes (the types of data (e.g. raw, output of curation, user data) and files (e.g. text or flat files, binary, image)).
- The Task Committee members and the <PROVIDING PROJECT> authorized users use the Content and eTM versions in the Project testing and/or working space(s), and may provide eTRIKS with feedback (errors reports or feature requests) as described in the section 8.

Data visualization, analysis, and export

As eTRIKS WP1/2/4 standard practice for all collaborative projects, eTRIKS provides <PROVIDING PROJECT> with eTM versions that enable <PROVIDING PROJECT> authorized users to access and export <PROVIDING PROJECT> and public data, and to use some analytical and visualization tools. If <PROVIDING PROJECT> needs new analytical and/or visualization tool(s), then <PROVIDING PROJECT> sends a feature request to eTRIKS as described in the section 8.2.

Requirements specific to the Project:

<PROVIDING PROJECT> users who are not members of the Task Committee will be able to visualize, analyze, and/or export only data for which they have authorized accesses in the Project working space (for details on the data access, see section 6.2.3).

Error reporting and eTM feature requests

Error reporting

As eTRIKS WP1 standard practice for all collaborative projects, eTRIKS provides a help desk system (5/7d, 8-17h00 CET on working days) to which the Task Committee members and <PROVIDING PROJECT> authorized users can send a ticket and report any type of error they found when using the eTM versions (e.g. data access, visualization, analyses, and export). After ticket reception either the incident can be solved by the level 1 support or it will be escalated to the relevant level 2 expert (platform administrators, curators, developers, etc...). In any case, acknowledgement of the reception and of the escalation is done within one working day. The time due to provide a solution to the problem depends on the type of incident or request. The user is informed on the issue.

eTM feature requests

This section describes the eTRIKS WP2/6 standard practice for all collaborative projects.

- eTRIKS provides new or improved TM features based on the schedule of its own eTM development roadmap that is defined according to IMI project needs and feedback that eTRIKS has collected. Therefore, if <PROVIDING PROJECT> needs a new feature, then <PROVIDING PROJECT> has to send a feature request to the Task

Committee Leaders who will transmit it to eTRIKS. Then, the feature request passes through the established eTRIKS procedures, and, if eTRIKS considers it as a relevant for most collaborative projects, then eTRIKS will include it in its next eTM development roadmap.

- If an eTM feature urgently needed for <PROVIDING PROJECT> work is missing or defective, then eTRIKS evaluates the resource cost and time for its implementation. If the eTRIKS resource and time are available, then eTRIKS informs <PROVIDING PROJECT> of an implementation date. Otherwise, <PROVIDING PROJECT> is invited to provide resource for the implementation of the required feature, and is informed that the required feature will be included in the next eTM versions, and its code is free and open source.

Training

This section describes the eTRIKS WP6 standard practice for all collaborative projects. eTRIKS provides <PROVIDING PROJECT> with all training and tutorials needed to perform <PROVIDING PROJECT> tasks: these will be done either by webinars, teleconferences, and/or in face to face meetings. Several types of training are provided:

- eTM training aims to train <PROVIDING PROJECT> authorized users and trainers on how to use the eTM UI;
- Personal Data Protection training aims to make <PROVIDING PROJECT> users be aware of the European Regulations and Guidelines regarding Personal Data Protection;
- Curation training aims to train <PROVIDING PROJECT> members on how to curate <PROVIDING PROJECT> data and/load the Contents according to the eTRIKS curation guidelines and process;
- Error reporting training aims to train <PROVIDING PROJECT> authorized users and trainers on how to use the help desk system.

The consortia will agree on a certain number of training sessions after evaluation of the <PROVIDING PROJECT> needs.

The following sections (10-15) describe requirements and practices specific to the Project.

Task Committee

- The Task Committee (TC) will consist of <PROVIDING PROJECT> and eTRIKS members (i.e. Task members) who will work together on the Project activities such as 1) ethics and ownership, 2) data collection, 3) data standards, 4) data curation, loading and provenance, 5) data hosting, security, and release, 6) Error reporting, 7) eTM feature requests, and 8) Training. Some Task members are Task leaders (see definition in the Collaboration Agreement sections 3.3, 3.4), or Task representatives.
- A Task representative will run and be responsible of one Project activity. To this, each Task representative will receive resource from the WPs of eTRIKS and/or <PROVIDING PROJECT>, and will manage and lead the received resource who will become TC members.

- The names of the Task representatives may change during the Project life time, while the names of the organizations that are responsible for the Project activities remain unchanged (for details on their roles and responsibilities, see section 11).
- The Task representatives will discuss/report progress and/or issues to the Task Leaders at the TC meeting (TCM) that will occur every 2 weeks or on the Task Leaders' demand.
- The Task Committee Leaders will present the Project progress and/or issues bi-weekly at <PROVIDING PROJECT> Work Package 4 (WP4) team meetings and at the monthly eTRIKS Delivery Package meeting.
- The Project issues will be brought to:
 - the <PROVIDING PROJECT> WP4 meetings, and escalated to the <PROVIDING PROJECT> Level 2 sponsors or the <PROVIDING PROJECT> Executive Project Management Team (EPMT) as needed.
 - the eTRIKS Delivery Package meeting, and escalated to the eTRIKS Work Package Leader Group or the Executive Committee (ExCom) as needed.
- eTRIKS may invite <PROVIDING PROJECT> TC members to work with other TC members of other IMI projects on topics that are common between IMI projects such as ethics or standards, and need inputs from all the concerned IMI projects.

Roles and Responsibilities

TC representatives will lead and be responsible for the Project activities. The below table describes the roles and responsibilities of the TC representatives and their organizations in the Project.

Consortium	Collaborator's organization	Function	Role in the frame of/for the Project
<PROVIDING PROJECT>		<PROVIDING PROJECT> Sponsor	Organizes the support and contribution of <PROVIDING PROJECT> for the Project.
<PROVIDING PROJECT>		Task Representative - Master Users	Leads the master user group, collects users' and master users' feedback and requests, attends the TC meeting, and reports to Task Leaders.
<PROVIDING PROJECT>		Task Representative - data submission	Leads the activities and resource related to data collection, anonymization, and cleaning within <PROVIDING PROJECT> and before submission to eTRIKS, attends the TC meeting, and reports to Task Leaders.
<PROVIDING PROJECT>		Task Representative - ethics and privacy	Co-leads eTRIKS WP7 which supports <PROVIDING PROJECT> consortium in complying with Ethics and Privacy rules, attends the TC meeting when needed, and reports to Task Leaders.
<PROVIDING PROJECT>		Data manager	Leads the technical discussions on behalf of <PROVIDING PROJECT> to agree the information organization and structure
<PROVIDING PROJECT>		Data manager	Leads technical discussion on behalf of <PROVIDING PROJECT> to understand the current data management environment including the role of any third parties
<PROVIDING PROJECT>		Task Leader	Leads the Task Committee, facilitates information exchange and operational tasks between the consortia, reports issue and progress to the relevant WPs of both consortia.
eTRIKS		Task Representative - data standards	Leads the activities and resource related to the construction of the data label tree and data standards, attends the TC meeting, and reports to Task Leaders.
eTRIKS		Task Leader	Leads the Task Committee, facilitates information exchange and operational tasks between the consortia, reports issue and progress to the relevant WPs of both consortia.
eTRIKS		Task Representative - Training	Leads the activities and resource related to trainings, attends the TC meeting when needed, and reports to Task Leaders.
eTRIKS		Task Representative - error reporting system	Leads the activities and resource related to error reporting system of eTRIKS, attends the TC meeting, and reports to Task Leaders.
eTRIKS		Task Representative - data hosting, mirroring, back-up, security, and eTM release	Leads the activities and resource related to hosting, mirroring and backing-up <PROVIDING PROJECT> data submitted to eTRIKS in the CC-IN2P3/CNRS site, as well as the data security, and release of eTMs, attends the TC meeting, and reports to Task Leaders.
eTRIKS		Task Representative Deputy - ethics and privacy	Co-leads eTRIKS WP7 which supports <PROVIDING PROJECT> consortium in complying with Ethics and Privacy rules, attends the TC meeting when needed, and reports to Task Leaders.
eTRIKS		Transition Lead, Business Analyst	Facilitates the technical transition between IBS and eTRIKS and the technical/IT discussions between the consortia, inform issues or request to Task Leaders, attends the TC meeting, and reports to Task Leaders.
eTRIKS		eTRIKS Sponsor Level 1	Organizes the support and contribution of eTRIKS for the Project.
eTRIKS		Task Representative - eTM feature requests	Leads the activities and resource related to the requests of eTM features and their implementation (testing including), attends the TC meeting when needed, and reports to Task Leaders.
eTRIKS		Task Representative - data hosting, mirroring and back-up	Leads the activities and resource related to hosting, mirroring and backing-up <PROVIDING PROJECT> data submitted to eTRIKS in the ICL site, and reports to Task Leaders.
eTRIKS		eTRIKS Sponsor Level 1	Organizes the support and contribution of eTRIKS for the Project.

eTRIKS		Task Representative - ethics and privacy	Co-leads eTRIKS WP7 which supports <PROVIDING PROJECT> consortium in complying with Ethics and Privacy rules, attends the TC meeting when needed, and reports to Task Leaders.
eTRIKS		Task Representative - data curation, loading, provenance, hosting, mirroring and back-up	Leads the activities and resource related to the curation, loading and provenance of <PROVIDING PROJECT> data submitted to eTRIKS as well as their hosting, mirroring and back-up in the UL site, attends the TC meeting, and reports to Task Leaders.

Timelines and milestones

Timetable/milestone delivery chart

Milestone	Delivery date
Migration or existing curated data from <PROVIDING PROJECT> TM instance	
First data sets accessible to <PROVIDING PROJECT> scientists	
Curation and load of previously collected retrospective data	
Curation and load of additional retrospective data	
Load of first tranche of prospective data: interim look	
Load of prospective data: final dataset	

Regarding the retrospective studies, timelines tightly depend on the data collection dates (i.e. when all data of a cohort have been collected from a center). Therefore, the Task Committee will review and adjust the timelines according to the data collection dates, and/or consortium resource every 3 months.

It should also be noted that timelines/delivery dates for the prospective studies are hard to define precisely. This is due to several factors such as patient recruitment time, regulatory issues, etc. It is therefore the responsibility of the Task Committee to ensure that the progress is continuously monitored and that resources are available for data load when the studies are finalized.

Project wind-down

eTRIKS mission is to sustain collaborators' data beyond the end of their project, and eTRIKS will release <PROVIDING PROJECT> datasets and Images under the conditions agreed by the consortia. Therefore, the final data access restrictions could be set 3 months before the end date of the <PROVIDING PROJECT> project, and <PROVIDING PROJECT> datasets and Images may remain accessible to <PROVIDING PROJECT> participants beyond the end of the <PROVIDING PROJECT> project. In case <PROVIDING PROJECT> decides that the access to <PROVIDING PROJECT> data will be public <PROVIDING PROJECT> will send a written notice to eTRIKS and will perform the data anonymisation according to the [highest anonymisation standards described in](#) the most recent European directives on personal data protection at least six (6) months before the end of the <PROVIDING PROJECT> project.

1. Annexes

Detailed <PROVIDING PROJECT> data table

eTRIKS Data curation guidelines and process



Data hosting needs

<i>For each data type needed to be hosted, indicate the files types and the corresponding categories.</i>					
Data Class	File type	Criticality	Confidentiality	Access requirements	Space
Raw data	Unformatted, formatted, binary	Essential	Special access	Reference	Landing
Reference data	Formatted, database files	Required	Special access	Reference	Reference
Processed data	Formatted, binary, database files	Highly required	Special access	Frequently used	Landing, Testing.
Curated data	Formatted, binary, database files	Highly required	Special access	Frequently used	Landing, Testing, Working.
Codes	Formatted	Essential	Special access	Frequently used	Landing, Testing, Working.
Documentation and Metadata	Unformatted, formatted	Essential	Special access	Frequently used	Landing, Testing.
User data	Output tranSMART files	Essential	Highly confidential	Frequently used	Testing, Working.

Category Description

Data class	<ul style="list-style-type: none"> a) Raw data from measuring instruments and bioassays results b) Reference data from private or public databases (to be used in calibration solutions and raw data indexing or annotation) c) Processed data from raw data d) Curated data originated from <i>a)</i> to <i>d)</i> to allow information reading and transfer in a standardized format e) Codes that is to say: scripts, software libraries, and code sources vital to data analysis f) Documentation and Metadata to be linked to the above categories describing origins, formats, operating instructions, etc.. g) User data from the user personal directory
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File type	<ul style="list-style-type: none"> a) Unformatted documents such as text files b) Formatted documents such as <i>.doc</i>, <i>.xls</i>, <i>.ppt</i> (or any of the corresponding <i>OpenDocument</i> formats), <i>.rtf</i>, <i>.html</i>, <i>.pdf</i>, <i>.ps</i>,... c) Database files where data are organized in a structured format record storage d) Binary files, generally raw data, where data is encoded in binary form for computer storage and processing purposes
Criticality	<ul style="list-style-type: none"> a) Essential data refers to any unique information that cannot be reproduced, such as <i>medical</i> or <i>raw</i> data b) Highly required data refers to information that can be recreated, but at great cost in <u>computing time</u> such as some <i>analysis results</i> or <i>curated data</i> c) Required data refers to information that can easily be recreated, but at great cost in <u>download time</u> such as <i>reference data</i> d) Deferrable data refers to information <u>under the user responsibility</u> such as personal analysis software or scripts and the corresponding metadata. e) Replaceable data refers to information easily recreated and replaced, such as <i>public codes</i> and their corresponding metadata
Confidentiality	<ul style="list-style-type: none"> a) Public: everyone, even people outside the Project may access the data b) Restricted: all Project members may access the data c) Special access: only some Project members and at least a CC-IN2P3 member (for managing purposes) may access the data d) Highly confidential: data access allowed only to some Project members
Access requirements	<ul style="list-style-type: none"> a) Frequently used data refers to I/O information that needs to be accessible synchronously on the lowest latency support b) Available data refers to I/O information accessible synchronously on a low latency support, and to the storage of large (> 1 Gb) files c) Reference data refers to information that may be accessed asynchronously on a high latency support. Ideal for massive file storage

Appendix 5

A general template for eTRIKS DPA involving a subset of eTRIKS partners

Data Processing Agreement

by and between

<Insert name and
Address of <Data Controller>>

- hereinafter „**<Data Controller>**“ -
- <change <Data Controller> to name of provider throughout the document>

and

those participants of the Innovative Medicines Initiative (“IMI”) eTRIKS consortium
listed in **Appendix 1**

- hereinafter collectively „**Contractors**“ -

Preamble

WHEREAS, <Data Controller> is a participant of the IMI (or other funding body as appropriate) <insert Project name> consortium and owns or otherwise controls certain collections of data and visual representations other than text, hereafter referred to as Datasets and Images (as defined below).

WHEREAS, Contractors are some or all of the participants of the IMI eTRIKS consortium, which is led by a coordinator and a managing entity as indicated in **Appendix 1a**, and are each independent contractors; Contractors have developed certain software or know-how for the eTRIKS platform in the IMI eTRIKS consortium and have expert knowledge in the use of this newly developed platform.

WHEREAS, <Data Controller> wishes to have Contractors undertake activities in connection with the eTRIKS platform using the Datasets and Images.

THEREFORE, the parties agree as follows:

Section 1

Definitions

4. “Datasets” means collections of data owned or controlled by <Data Controller> that are transferred to one or more Contractors by <Data Controller> and their derivations, improvements and results, excluding any Task Data, generated in the course of or as a result of this agreement.
5. “Images” means visual representations other than text that are transferred to one or more Contractors by <Data Controller> and their derivations, improvements and results generated in the course of or as a result of this agreement.
6. “Task Data” means any information, data, know-how, inventions, and other developments made or discovered for the data process during the course of the Services as set forth in Appendix 2, which includes, without limitation, programmatic scripts, algorithms, and software of data transformation and analysis, but which are neither Datasets nor Images.

Section 2

Subject of the Agreement

1. Contractors shall undertake reasonable efforts to perform the activities as set forth in **Appendix 2** (hereinafter “eTRIKS Activities”).

For the avoidance of doubt, when in this agreement (including but not limited to its annexes) an obligation is assigned to “Contractors” to perform the eTRIKS Activities or abide by certain standards in that regard, such obligations shall vest only in those Contractors which are assigned to perform the eTRIKS Activities.

2. The eTRIKS Activities include in particular:
 - a) provision of web-based access to computer and software systems to enable and sustain secure storage, access, and use/re-use of Datasets and Images by <Data Controller>.
 - b) deliverables as defined Appendix 2, including but not limited to:
 - Curation and loading of Datasets and/or Images
 - <Insert other specific requirements here, e.g. other activities>
4. The Contractors responsible for the relevant activities shall undertake reasonable efforts to perform the eTRIKS Activities within the timelines set forth in **Appendix 2**. In the event Contractors expect a delayed performance, Contractors through their coordinator and managing entity shall inform <Data Controller> in writing of such delay and the underlying reasons and shall suggest possible remedy.
4. *Contractors shall report on a regular basis to <Data Controller> in writing setting out the progress of the eTRIKS Activities.*

Section 3

Third parties

1. Contact persons for <Data Controller> and her/his substitute at Contractors for any questions and instructions regarding the conduct of the eTRIKS Activities are the coordinator and the managing entity of IMI eTRIKS as set forth in Appendix 1a.
2. Any subcontracting or any assignment of any of Contractors’ obligations under this Agreement to a third party requires prior written approval by <Data Controller> at <Data Controller>’s sole discretion. Contractors shall provide name and address of the subcontractor and the scope of Services to be performed by the third party.
3. In case Contractors subcontract all or part of the eTRIKS Activities, they shall ensure that such subcontracted activities shall be performed in accordance with the terms of this agreement.

Section 4

Cooperation by <Data Controller>; Material Transfer

6. <Data Controller> or a third party working on behalf of <Data Controller> shall provide to Contractors the Datasets and Images, which are needed to perform the eTRIKS Activities as described in **Appendix 2**.
7. Contractors shall undertake reasonable efforts to review the Datasets and Images received from <Data Controller> as to possible deficiencies in consideration of the intended purpose and inform <Data Controller> of any deficiencies found.
8. Contractors shall use the Datasets and Images solely for the purpose of the eTRIKS Activities. Contractors shall not make the Datasets and Images available to any third party (except in case of subcontracting under Section 3). Contractors shall limit access to the Datasets and Images to those employees who are involved in the performance of the eTRIKS Activities, imposing on them restrictions on disclosure and use equivalent to those set out herein.
9. At any time upon request of <Data Controller>, Contractors shall return to <Data Controller> such Datasets and Images.
10. Contractors agree that the Datasets and Images are and shall remain the sole property of <Data Controller>. Nothing in this Agreement shall be construed as a grant to Contractors of any rights in the Datasets and Images other than expressly herein provided.

Section 5

Changes in capacity, surplus and deficient performance

Changes and additions regarding the scope of eTRIKS Activities are only binding if the parties have agreed upon them in writing.

Section 6

Consideration

Contractors provide the eTRIKS Activities under this agreement without any compensation by <Data Controller>.

Section 7

Results / Warranty / Defects

4. <Data Controller> and Contractors agree that all Datasets and Images shall be the exclusive property of <Data Controller>.

5. <Data Controller> and Contractors agree that any Task Data developed or created by Contractors shall be owned by Contractors in accordance with the agreement(s) among them.
6. Contractors and <Data Controller> agree to comply with all applicable laws, governmental regulations and guidelines applicable to the eTRIKS Activities. <Data Controller> and Contractors agree to the terms set forth in **Appendix 3** relating to the anti-trust principles, **Appendix 4** relating to the prevention of corruption – third party guidelines and **Appendix 5** relating to data protection processing. It is hereby expressly agreed that the terms and conditions in the data protection processing agreement as set forth in Appendix 5 shall take priority over this Agreement.
<Appendix 5 is only needed if the data are not fully anonymised, otherwise it and any references to it can be removed>

Section 8

Confidentiality

7. Each party possesses information of a secret and confidential nature which information is regarded by such party as an asset of considerable value. With respect to <Data Controller> this includes, without limitation, the Datasets and Images (hereinafter "<Data Controller> Information"). With respect to Contractors this includes all proprietary information relating to the eTRIKS platform and Task Data owned or controlled by Contractors (hereinafter "Contractors Information"; <Data Controller> Information and Contractors Information hereinafter collectively the "Information").
8. The receiving party agrees to treat all Information of the disclosing party strictly confidential both during the cooperation and after the expiration of this Agreement. The receiving party (i) shall not use the Information for its own purposes or those of any third party, (ii) shall not disclose the Information to any other third party without obtaining the prior written consent of the disclosing party, (iii) shall provide access to the Information only to such minimum number of its or its Affiliates' employees, or permitted subcontractors with a need to know the Information for the purpose of this Agreement imposing on them restrictions on disclosure and use equivalent to those set out herein and (iv) except if otherwise provided herein, shall not transfer the Information to any third party without the prior written consent of disclosing party. For the purposes of this Agreement, "Affiliates" shall mean with respect to a party, any person, corporation, firm, joint venture or other entity which, directly or indirectly, through one or more intermediates, controls, is controlled by or is under common control with such party. As used in this definition, "control" means possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of the outstanding voting securities or by contract or otherwise. Such Affiliates will only use the Information in accordance with this Section 7.
9. The obligation of confidentiality and non-use does not apply to Information which:

- f) is available to the public at the time of receipt by the receiving party from the disclosing party; or
 - g) becomes public knowledge other than through a breach of this Agreement by the receiving party of the Information; or
 - h) the receiving party (this includes any Affiliate) can prove was known to the receiving party before the date of its disclosure by the disclosing party; or
 - i) the receiving party (this includes any Affiliate) has legally obtained from a third party that does not owe a duty of confidentiality, whether expressly or indirectly, to the disclosing party; or
 - j) was independently developed by the receiving party (this includes any Affiliate) without reference to or use of the Information.
10. Furthermore, the parties may disclose Information to the extent that such disclosure is required to comply with law or an enforceable judicial order, provided, however, that the receiving party shall give reasonable advance notice, as legally permissible, to the disclosing party and, at the so informed disclosing party's request, shall cooperate to seek a protective order or other appropriate remedy. The receiving party shall use its reasonable efforts to secure confidential treatment of any Information that will be disclosed.
 11. Information shall not be deemed to be public knowledge merely because any part of such Information is contained in general disclosures or because individual features of the Information are known or become known to the public.
 12. On completion of the Agreement, completion of the eTRIKS Activities or at any time at the disclosing party's request, the receiving party shall return to the disclosing party any Information or, at the disclosing party's option and cost, destroy such Information and promptly confirm destruction in writing. Return or destruction of the Information shall not affect the receiving party's obligation to keep the Information confidential pursuant to this Section 8.
 13. For the avoidance of doubt Task Data is foreground of the eTRIKS project and shall be shared within the eTRIKS consortium as provided for in the eTRIKS Project Agreement.

Section 9

Term and Termination

1. The term of this Agreement shall commence effective upon last signature hereof and shall last until completion of the eTRIKS Activities or expiration or early termination of the OncoTrack Project Agreement, whichever is earlier.
2. *<Data Controller> may terminate this Agreement without cause in parts or in its entirety at the end of every month upon giving three (3) months notice. In the event of termination, Contractors shall inform <Data Controller> in writing about the*

remainder of any and all eTRIKS Activities already commenced. Contractors shall perform these in accordance with the conditions set forth in this Agreement.

3. The terms set forth in Sections 6, 7, 8, 9 and 10 shall survive any termination or expiration of this Agreement.

Section 10

Miscellaneous

5. This Agreement may not be assigned or otherwise transferred - in parts or in its entirety - by either party without the prior written consent of the other parties.
6. This Agreement sets forth the entire understanding and agreement of the parties relating to the subject matter hereof. No modification or amendment to this Agreement will be effective unless in writing and signed by both parties. Any notice to be given by either party under this Agreement shall only be effective if in writing.
7. The invalidity of a particular provision of this Agreement shall not affect the validity of the remaining provisions. The parties shall replace the invalid provisions with a valid provision that comes closest to effectuating the intent of the parties at the time of the Agreement's execution. This shall also apply if the provisions of this Agreement should be found to be incomplete.
8. The following appendices shall form an integral part of this Agreement:
 - f) Appendix 1: List of participants of the IMI eTRIKS consortium party to this contract (The Contractors)
 - g) Appendix 2: eTRIKS Activities
 - h) Appendix 3: Anti-trust Principles
 - i) Appendix 4: Prevention of Corruption – Third Party Guidelines
 - j) Appendix 5: Data Protection Processing Agreement <Appendix 5 is only needed if the data is not fully anonymised otherwise it and any refers to it can be removed>

Section 11

Governing law / Place of proceedings

This Agreement shall be governed by, subject to and construed in accordance with the laws of Belgium without reference to its conflict of laws provisions. Any legal action arising under this Agreement shall be instituted in Brussels, Belgium.

<Depending on local laws, it may be necessary to change the Governing Law>

(The remainder of this page is intentionally left blank.)

Signed for and on behalf of:

<Data Controller> –

Date:.....

i. V.

Signed for and on behalf of:

Participants of the IMI eTRIKS
consortium

Date:.....

1st Contractor signatory

2nd Contractor signatory

Appendix 1: List of participants of IMI eTRIKS consortium who are party to this contract

<Insert names and addresses of all eTRIKS partners who are signatories to the agreement here – there is a list at the bottom to cut and paste from to get the correct wording>

Appendix 1a: IMI eTRIKS consortium Coordinator and Managing Entity

Coordinator of the IMI eTRIKS Consortium

AstraZeneca AB, a company incorporated in Sweden under no. 556011-7482 with offices at S-151 85 Södertälje, Sweden (“**AZ**”); acting as coordinator under the agreement entitled “European Translational Information & Knowledge Management Services” (IMI grant agreement No. 115446)

Managing Entity of the IMI eTRIKS Consortium

Imperial College of Science, Technology & Medicine, whose administrative offices are at Exhibition Road, South Kensington Campus, London, SW7 2AZ, UNITED KINGDOM (“**ICL**”) acting as Managing Entity under the agreement entitled “European Translational Information & Knowledge Management Services” (IMI grant agreement No. 115446)

Appendix 2: eTRIKS Activities

Insert full list of agreed services and activities here

Appendix 3: Anti-trust principles

Meetings of parties in connection with this Agreement or the eTRIKS Activities shall not be occasions where such party’s representatives or other invited participants:

- exchange or discuss proprietary business information that is not necessary to the activities of the Consortia, such as pricing policies, terms and conditions of sale, marketing or product plans, costs of production and distribution issues;
- confer about division or allocation of sales territories or customers;
- establish blacklists or boycotts of suppliers, purchasers or competitors;
- coerce members to implement particular programs or policies; or
- resolve problems unique to a single member or a small, select group of members.

Because the parties represent a substantial segment of the pharmaceutical industry, each party should avoid any activity that forecloses business opportunities of non-

members or stifles innovation by the parties. The parties should not exercise control over the other parties' independent business activities.

Appendix 4: Prevention of Corruption – Third Party Guidelines

Each party agrees that the conduct of the eTRIKS Activities requires compliance with the highest ethical standards and all anti-corruption laws applicable in the countries in which the party conducts business under this Agreement (including as appropriate, the provisions of the U.K. Bribery Act and the U.S. Foreign Corrupt Practices Act). In particular all party employees and any third party acting for or on behalf of a party must ensure that all dealings with third parties, both in the private and government sectors, are carried out in compliance with all relevant laws and regulations and industry and professional codes of practice and with the standards of integrity required for an IMI project. Each party values integrity and transparency and has zero tolerance for corrupt activities of any kind, whether committed by employees, officers, or third-parties acting for or on behalf of the party.

Corrupt Payments – the party's employees and any third party acting for or on behalf of the party, shall not, directly or indirectly, promise, authorise, ratify or offer to make or make any "payments" of "anything of value" (as defined in the glossary section) to any individual (or at the request of any individual) including a "government official" (as defined in the glossary section) for the improper purpose of influencing or inducing or as a reward for any act, omission or decision to secure an improper advantage or to improperly assist the company in obtaining or retaining business.

Government Officials – Although this policy prohibits payments by a party or third parties acting for or on its behalf to any individual, private or public, as a "quid pro quo" for business, due to the existence of specific anticorruption laws in the countries where we operate, this policy is particularly applicable to "payments" of "anything of value" (as defined in the glossary section), or at the request of, "government officials" (as defined in the glossary section).

Facilitating Payments – For the avoidance of doubt, facilitating payments (otherwise known as "greasing payments" and defined as payments to an individual to secure or expedite the performance of a routine government action by government officials) are no exception to the general rule and therefore prohibited.

GLOSSARY

The terms defined herein should be construed broadly to give effect to the letter and spirit of the ABAC Policy. Each party is committed to the highest ethical standards of business dealings and any acts that create the appearance of promising, offering, giving or authorising payments prohibited by this policy will not be tolerated.

Anything of Value: this term includes cash or cash equivalents, gifts, services, employment offers, loans, travel expenses, entertainment, political contributions, charitable donations, subsidies, per diem payments, sponsorships, honoraria or provision of any other asset, even if nominal in value.

Payments: this term refers to and includes any direct or indirect offers to pay, promises to pay, authorisations of or payments of anything of value.

Government Official shall mean: Any officer or employee of a government or any department, agency or instrument of a government; Any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; Any officer or employee of a company or business owned in whole or part by a government; Any officer or employee of a public international organisation such as the World Bank or United Nations; Any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or Any candidate for political office.

Appendix 5: Data Protection Processing Agreement

<This section is needed if any of the data are personal data as defined by current EU directive>

between <Data Controller> –

<Address>

- hereinafter referred to as “<Data Controller>” -

and the participants of the Innovative Medicines Initiative (“IMI”) eTRIKS consortium listed in **Appendix 1** and any future eTRIKS participants, whose accession will be communicated to <Data Controller> promptly upon such accession

- hereinafter collectively “Contractors”

<Data Controller> and Contractors are individually referred to as “Party” and collectively as the “Parties”.

Contractors and <Data Controller> have entered into a Data Processing Agreement dated [.....] under which Contractors perform certain activities (“eTRIKS Activities”) for <Data Controller> as described in that agreement (“Data Processing Agreement”).

In connection with the eTRIKS Activities, <Data Controller> will transfer to certain Contractors Datasets and Images which may include personal data within the meaning of the EU Directive 95/46/EC on the protection of individuals with regard to the processing of

personal data and on the free movement of such data (to the extent such Datasets and Images include personal data, including information regarding the health of patients, “Personal Data”).

This Agreement specifies the obligations of the Parties with respect to the storage, use and processing by Contractors of the Personal Data provided by <Data Controller> under the Data Processing Agreement (“Processing”).

This Agreement governs the actions aimed to ensure that <Data Controller>’s and Contractors’ Processing of the Personal Data meet the requirements for the protection of personal data stipulated in the EU Directive 95/46/EC as implemented for <insert specific national law of <Data Controller>’s country, if applicable> “The Act”, and other applicable laws implanting such Directive.

19. Contractors will perform Processing of the Personal Data as part of the eTRIKS Activities under the Data Processing Agreement as data processor on behalf of <Data Controller>. The Processing of Personal Data shall only take place on servers located in the European Economic Area and Data may not be transferred to any location outside the European Economic Area (EEA) without the approval of <Data Controller> and provided that an agreement with the company in a third country in accordance with the rules on standard contractual clauses for the transfer of personal data as set forth in the decision of the European Commission dated 5 February 2010 (2010/87/EU) is concluded..
20. <Data Controller> continues to be the Data Controller of the Data Sets and Images and will remain responsible for protecting the rights of the data subjects and thus for determining whether the Processing of their personal data is admissible. Both Parties will ensure compliance with the requirements for the protection of personal data stipulated in the EU Directive 95/46/EC and the applicable laws implanting such Directive. To this, <Data Controller> shall provide Contractors with identity and the location of the organizations that <Data Controller> will allow to process the Data hosted in the eTRIKS platform (hereafter called “the Organizations”). However, only <Data Controller> will ensure compliance with <the Act and any other> <may need to reword depending on if there is a specific Act mentioned above> applicable data protection regulations, especially the EU Directive 95/46/EC when <Data

Controller> or the Organizations export(s) the Data from the eTRIKS platform and process(es) them outside the eTRIKS platform.

21. <Data Controller> shall provide the Personal Data to Contractors complete, accurate and up to date and in such form as is necessary for Contractors to process the Personal Data in accordance with the Data Processing Agreement.
22. <Data Controller> warrants that it is entitled to provide the Personal Data under this Agreement under applicable laws regulations and that all relevant consents and approvals in connection herewith, if required, have been obtained.
23. Contractors will perform Processing of the Personal Data only in accordance with the instructions of <Data Controller> for those purposes which are specified in the Data Processing Agreement.
24. The Contractors who will perform the eTRIKS Activities confirm that they have implemented the technical and organizational measures designed to meet the specific requirements of data protection in accordance with EU Directive 95/46/EC. For that purpose such Contractors have created their internal organization in a way that it complies with the requirements of data protection and privacy. Contractors ensure that technical and organizational measures for adequate security against misuse and loss of the Personal Data within the eTRIKS platform are maintained, in particular:
 - i) to prevent unauthorized persons from gaining access to data processing systems for processing or using data (access control),
 - j) to prevent data processing systems from being used without authorization (access control),
 - k) to ensure that persons authorized to use a data processing system have access only to the data they are authorized to access, and those data cannot be read, copied, altered or removed without authorization during processing (access control),
 - l) to ensure that data cannot be read, copied, altered or removed without authorization during electronic transfer or transport or while being recorded onto data storage media, and that it is possible to ascertain and

check to which bodies data is intended to be transferred using data transmission facilities (disclosure control),

- m) to ensure that it is possible after the fact to check and ascertain whether personal data have been entered into, altered or removed from data processing systems and if so, by whom (input control),
- n) to ensure that data processed on behalf of others are processed strictly in compliance with <Data Controller>'s instructions (job control),
- o) to ensure that data are protected against accidental corruption, destruction or loss (availability control),
- p) to ensure that data collected for different purposes can be processed separately.

One measure in accordance with the sub-paras. a) to d) is in particular the use of the latest encryption procedures.

- 25. With respect to the Processing of Personal Data, Contractors agree to engage only those individuals who are obliged to maintain the confidentiality of the Data pursuant to EU Directive 95/46/EC. Contractors shall designate an appropriate number of employees to supervise and monitor the use of the Personal Data left in their care.
- 26. Contractors shall notify <Data Controller> in the event of an interruption in processing, a suspected breach of the data protection provisions or any other irregularity involving the processing of <Data Controller>'s data. <Data Controller> shall notify Contractors without delay if <Data Controller> becomes aware of any errors or irregularities, including, without limitation, those ascertained while reviewing results.
- 27. Contractors agree to inform <Data Controller> upon request about the Personal Data. Contractors will maintain the Personal Data on their data processing systems and have to check periodically whether the obligations under No. 6 are fulfilled.
- 28. In case <Data Controller> is required under applicable data protection law to provide information regarding the Data Processing towards a data subject,

Contractors will provide the necessary information (if required) to <Data Controller> within a reasonable period of time. In case a data subject approaches <Data Controller> regarding a correction or deletion of Data, <Data Controller> will immediately inform Contractors, and the Parties will discuss in good faith, taking into account applicable data protection law, how to deal with any such request.

29. <Data Controller> will periodically check that Contractors maintain the technical and organizational measures pursuant to No 6. Contractors acknowledge and agree that the authority responsible for monitoring <Data Controller>'s protection of personal data may also monitor Contractors' operations to the extent permitted by law.
30. The Parties will provide to each other the name of the Privacy Officer taking care of the technical and organizational measures pursuant to No 6.
31. Contractors may only engage a subcontractor for the performance of Processing Data with the prior written consent of <Data Controller> (a "Subcontractor").
32. In case Subcontractors are engaged, Contractors shall procure in their agreement with such subcontractors that the requirements for confidentiality, data protection and data security correspond to the regulations in this Agreement. Contractors shall procure that <Data Controller> has the same control rights at the subcontractors as provided in No. 11.
33. This Agreement has the same term as the Data Processing Agreement and the respective termination provisions apply accordingly. Following expiration of this Agreement Contractors shall (1) immediately stop any Processing of Data, (2) delete any Personal Data on its IT systems and (3) procure that Subcontractors shall immediately stop any Processing of Personal Data and delete any Personal Data on their IT systems.
34. Capitalised terms not defined in this Agreement shall have the meaning as set forth in the Data Processing Agreement.

35. This Agreement is governed by laws of Belgium. As regards any disputes arising under or out of this Agreement the Parties herewith submit exclusively to the jurisdiction of the courts of Brussels, Belgium.

<It may be necessary to change the country of governance>

36. Unless otherwise regulated in this Agreement, the terms of the Data Processing Agreement shall apply. In case of any discrepancy between this Agreement and the Data Processing Agreement, this Agreement shall prevail.

THIS SECTION DOES NOT FORM PART OF THE AGREEMENT AND IS PROVIDED AS AN AID TO THE COMPLETION OF APPENDIX 1 - IT SHOULD BE REMOVED BEFORE FINALISING THE AGREEMENT

List of participants of IMI eTRIKS consortium <to be copied into Appendix 1 as needed and the deleted>

AstraZeneca AB, a company incorporated in Sweden under no. 556011-7482 with offices at S-151 85 Södertälje, Sweden (“**AZ**”); acting as coordinator under the agreement entitled “European Translational Information & Knowledge Management Services” (IMI grant agreement No. 115446)

Imperial College of Science, Technology & Medicine, whose administrative offices are at Exhibition Road, South Kensington Campus, London, SW7 2AZ, UNITED KINGDOM (“**ICL**”) acting as Managing Entity under the agreement entitled “European Translational Information & Knowledge Management Services” (IMI grant agreement No. 115446)

University of Luxembourg, Luxembourg Centre for Systems Biomedicine (UL), whose administrative offices are at 7 avenue des Hauts-Fourneaux, L-4362 Esch-sur-Alzette, LUXEMBOURG;

ID Business Solutions Limited (IDBS), whose administrative offices are at 2 Occam Court, Surrey Research Park, Guildford, Surrey, GU2 7QB, UNITED KINGDOM;

BioSci Consulting (BSC), whose administrative offices are at Weg naar Geneuth 95, 3631 Maasmechelen, BELGIUM;

Centre National de la Recherche Scientifique (CNRS), whose administrative offices are at Campus Gérard-Mégie, 3 rue Michel-Ange - F-75794, Paris cedex 16, FRANCE;

CDISC Europe Foundation (CDISC), whose administrative offices are at 141 rue Saint-Lambert 1200 Woluwe-St Brussels, Belgium;

Janssen Pharmaceutia NV (JANSSEN), whose administrative offices are at Turnhoutseweg 30, B-2340 Beerse, BELGIUM;

F. Hoffman-La Roche Limited (Roche), whose administrative offices are at Grenzacherstrasse 124, CH-4070 Basel, SWITZERLAND;

GlaxoSmithKline Research & Development Limited (GSK), whose administrative offices are at 980 Great West Road, Brentford, Middlesex, TW8 9GS, UNITED KINGDOM;

Sanofi-Aventis Recherche & Développement (SARD), whose administrative offices are at Avenue Pierre Brossolette 1, Chilly-Mazarin 91385, FRANCE;

Bayer Pharma AG (Bayer), whose administrative offices are at Mullerstrasse 178, D-13353, Berlin, GERMANY;

Merck KGaA (ME), whose administrative offices are at Frankfurter Strasse 250, 64293 Darmstadt, GERMANY;

Pfizer Limited (Pfizer), whose administrative offices are at Ramsgate Road, Sandwich, Kent, CT13 9NJ, UNITED KINGDOM:

Eli Lilly and Company Limited (LLY), whose administrative offices are at Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, UNITED KINGDOM;

H. Lundbeck A/S (LUB), whose administrative offices are at Ottiliavej 9, Valby DK-2500, DENMARK

THE CHANCELLOR MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD (UOXF), whose administrative offices are at University Offices, Wellington Square, Oxford, Oxon OX1 2JD, United Kingdom

Appendix 6

Sample text for a specific agreement between one partner from each consortium

Data Processing Agreement

by and between

<Insert name and
Address of <Data Controller>>

- hereinafter „**<Data Controller>**“ –
- <change <Data Controller> to name of provider throughout the document>

and

<insert name and address of data processing organisation here>

- hereinafter „**Contractor**“ -

Preamble

WHEREAS, <Data Controller> is a participant of the IMI ApprOach consortium and owns or otherwise controls certain collections of data and visual representations other than text, hereafter referred to as Datasets and Images (as defined below).

WHEREAS, Contractor is a participant of the IMI eTRIKS consortium; Contractor has developed certain software or know-how for the eTRIKS platform in the IMI eTRIKS consortium and has expert knowledge in the use of this newly developed platform.

WHEREAS, <Data Controller> wishes to have Contractor undertake activities in connection with the eTRIKS platform using the Datasets and Images.

THEREFORE, the parties agree as follows:

Section 1

Definitions

7. “Datasets” means collections of data owned or controlled by <Data Controller> that are transferred to Contractor by <Data Controller> and their derivations, improvements and results, excluding any Task Data, generated in the course of or as a result of this agreement.
8. “Images” means visual representations other than text that are transferred to Contractor by <Data Controller> and their derivations, improvements and results generated in the course of or as a result of this agreement.
9. “Task Data” means any information, data, know-how, inventions, and other developments made or discovered for the data process during the course of the Services as set forth in Appendix 1, which includes, without limitation, programmatic scripts, algorithms, and software of data transformation and analysis, but which are neither Datasets nor Images.

Section 2

Subject of the Agreement

1. Contractor shall undertake reasonable efforts to perform the activities as set forth in **Appendix 1** (hereinafter “Service Activities”).

For the avoidance of doubt, when in this agreement (including but not limited to its annexes) an obligation is assigned to Contractor to perform the Service

Activities or abide by certain standards in that regard, such obligations shall vest only in Contractor and not other participants in the eTRIKS consortium.

2. The Service Activities include in particular:
 - a) provision of web-based access to computer and software systems to enable and sustain secure storage, access, and use/re-use of Datasets and Images by <Data Controller>.
 - b) deliverables as defined in Appendix 1, including but not limited to:
 - Curation and loading of Datasets and/or Images
 - <Insert other general requirements here, e.g. other activities>
5. The Contractor shall undertake reasonable efforts to perform the Service Activities within the timelines set forth in **Appendix 1**. In the event Contractor expects a delayed performance, Contractor shall inform <Data Controller> in writing of such delay and the underlying reasons and shall suggest possible remedy.
4. *Contractor shall report on a regular basis to <Data Controller> in writing setting out the progress of the Service Activities.*

Section 3

Third parties

1. Contact persons for <Data Controller> and her/his substitute at Contractor for any questions and instructions regarding the conduct of the Service Activities are <insert contact name (s) here>.
2. Any subcontracting or any assignment of any of Contractor's obligations under this Agreement to a third party requires prior written approval by <Data Controller> at <Data Controller>'s sole discretion. Contractor shall provide the name and address of the subcontractor and the scope of Services to be performed by the third party.
3. In case Contractor subcontracts all or part of the Service Activities, they shall ensure that such subcontracted activities shall be performed in accordance with the terms of this agreement.

Section 4

Cooperation by <Data Controller>; Material Transfer

11. <Data Controller> or a third party working on behalf of <Data Controller> shall provide to Contractor the Datasets and Images, which are needed to perform the Service Activities as described in **Appendix 1**.

12. Contractor shall undertake reasonable efforts to review the Datasets and Images received from <Data Controller> as to possible deficiencies in consideration of the intended purpose and inform <Data Controller> of any deficiencies found.
13. Contractor shall use the Datasets and Images solely for the purpose of the Service Activities. Contractor shall not make the Datasets and Images available to any third party (except in case of subcontracting under Section 3). Contractor shall limit access to the Datasets and Images to those employees who are involved in the performance of the Service Activities, imposing on them restrictions on disclosure and use equivalent to those set out herein.
14. At any time upon request of <Data Controller>, Contractor shall return to <Data Controller> such Datasets and Images.
15. Contractor agrees that the Datasets and Images are and shall remain the sole property of <Data Controller>. Nothing in this Agreement shall be construed as a grant to Contractor of any rights in the Datasets and Images other than expressly herein provided.

Section 5

Changes in capacity, surplus and deficient performance

Changes and additions regarding the scope of Service Activities are only binding if the parties have agreed upon them in writing.

Section 6

Consideration

Contractor provides the Service Activities under this agreement without any compensation by <Data Controller>.

Section 7

Results / Warranty / Defects

7. <Data Controller> and Contractor agree that all Datasets and Images shall be the exclusive property of <Data Controller>.
8. <Data Controller> and Contractor agree that any Task Data developed or created by Contractor shall be owned by Contractor

9. Contractor and <Data Controller> agree to comply with all applicable laws, governmental regulations and guidelines applicable to the Service Activities. <Data Controller> and Contractor agree to the terms set forth in **Appendix 2** relating to the anti-trust principles, **Appendix 3** relating to the prevention of corruption – third party guidelines.

Section 8

Confidentiality

14. Each party possesses information of a secret and confidential nature which information is regarded by such party as an asset of considerable value. With respect to <Data Controller> this includes, without limitation, the Datasets and Images (hereinafter "<Data Controller> Information"). With respect to Contractor this includes all proprietary information relating to the eTRIKS platform and Task Data owned or controlled by Contractor (hereinafter "Contractor Information"; <Data Controller> Information and Contractor Information hereinafter collectively the "Information").
15. The receiving party agrees to treat all Information of the disclosing party strictly confidential both during the cooperation and after the expiration of this Agreement. The receiving party (i) shall not use the Information for its own purposes or those of any third party, (ii) shall not disclose the Information to any other third party without obtaining the prior written consent of the disclosing party, (iii) shall provide access to the Information only to such minimum number of its or its Affiliates' employees, or permitted subcontractors with a need to know the Information for the purpose of this Agreement imposing on them restrictions on disclosure and use equivalent to those set out herein and (iv) except if otherwise provided herein, shall not transfer the Information to any third party without the prior written consent of disclosing party. For the purposes of this Agreement, "Affiliates" shall mean with respect to a party, any person, corporation, firm, joint venture or other entity which, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such party. As used in this definition, "control" means possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of the outstanding voting securities or by contract or otherwise. Such Affiliates will only use the Information in accordance with this Section 8.
16. The obligation of confidentiality and non-use does not apply to Information which:
- k) is available to the public at the time of receipt by the receiving party from the disclosing party; or
 - l) becomes public knowledge other than through a breach of this Agreement by the receiving party of the Information; or
 - m) the receiving party (this includes any Affiliate) can prove was known to the receiving party before the date of its disclosure by the disclosing party; or
 - n) the receiving party (this includes any Affiliate) has legally obtained from a third party that does not owe a duty of confidentiality, whether expressly or indirectly, to the disclosing party; or
 - o) was independently developed by the receiving party (this includes any Affiliate) without reference to or use of the Information.

17. Furthermore, the parties may disclose Information to the extent that such disclosure is required to comply with law or an enforceable judicial order, provided, however, that the receiving party shall give reasonable advance notice, as legally permissible, to the disclosing party and, at the so informed disclosing party's request, shall cooperate to seek a protective order or other appropriate remedy. The receiving party shall use its reasonable efforts to secure confidential treatment of any Information that will be disclosed.
18. Information shall not be deemed to be public knowledge merely because any part of such Information is contained in general disclosures or because individual features of the Information are known or become known to the public.
19. On completion of the Agreement, completion of the Service Activities or at any time at the disclosing party's request, the receiving party shall return to the disclosing party any Information or, at the disclosing party's option and cost, destroy such Information and promptly confirm destruction in writing. Return or destruction of the Information shall not affect the receiving party's obligation to keep the Information confidential pursuant to this Section 8.
20. For the avoidance of doubt Task Data is Foreground of the eTRIKS project and shall be shared within the eTRIKS consortium as provided for in the eTRIKS Project Agreement.

Section 9

Term and Termination

1. The term of this Agreement shall commence effective upon last signature hereof and shall last until completion of the Service Activities or expiration or early termination of the ApprOAch Project Agreement, whichever is earlier.
2. *<Data Controller> may terminate this Agreement without cause in parts or in its entirety at the end of every month upon giving three (3) months notice. In the event of termination, Contractor shall inform <Data Controller> in writing about the remainder of any and all Service Activities already commenced. Contractor shall perform these in accordance with the conditions set forth in this Agreement.*
3. The terms set forth in Sections 6, 7, 8, 9 and 10 shall survive any termination or expiration of this Agreement.

Section 10

Miscellaneous

9. This Agreement may not be assigned or otherwise transferred - in parts or in its entirety - by either party without the prior written consent of the other parties.
10. This Agreement sets forth the entire understanding and agreement of the parties relating to the subject matter hereof. No modification or amendment to this Agreement will be effective unless in writing and signed by both parties. Any notice to be given by either party under this Agreement shall only be effective if in writing.
11. The invalidity of a particular provision of this Agreement shall not affect the validity of the remaining provisions. The parties shall replace the invalid provisions with a valid provision that comes closest to effectuating the intent of the parties at the time of the Agreement's execution. This shall also apply if the provisions of this Agreement should be found to be incomplete.
12. The following appendices shall form an integral part of this Agreement:
 - k) Appendix 1: Service Activities
 - l) Appendix 2: Anti-trust Principles
 - m) Appendix 3: Prevention of Corruption – Third Party Guidelines
 - d) Appendix 4: Data Protection Processing Agreement

Section 11

Governing law / Place of proceedings

This Agreement shall be governed by, subject to and construed in accordance with the laws of Belgium without reference to its conflict of laws provisions. Any legal action arising under this Agreement shall be instituted in Brussels, Belgium.

<Depending on local laws, it may be necessary to change the Governing Law>

(The remainder of this page is intentionally left blank.)

Signed for and on behalf of:

<Data Controller> –

Date:.....

i. V.

Signed for and on behalf of:

<Data Processing organisation>

Date:.....

1st signatory

2nd signatory

Appendix 1: Service Activities

Appendix 2: Anti-trust principles

Meetings of parties in connection with this Agreement or the Service Activities shall not be occasions where such party's representatives or other invited participants:

- exchange or discuss proprietary business information that is not necessary to the activities of the Consortia, such as pricing policies, terms and conditions of sale, marketing or product plans, costs of production and distribution issues;
- confer about division or allocation of sales territories or customers;
- establish blacklists or boycotts of suppliers, purchasers or competitors;
- coerce members to implement particular programs or policies; or
- resolve problems unique to a single member or a small, select group of members.

Because the parties represent a substantial segment of the pharmaceutical industry, each party should avoid any activity that forecloses business opportunities of non-members or stifles innovation by the parties. The parties should not exercise control over the other parties' independent business activities.

Appendix 3: Prevention of Corruption – Third Party Guidelines

Each party agrees that the conduct of the Service Activities requires compliance with the highest ethical standards and all anti-corruption laws applicable in the countries in which the party conducts business under this Agreement (including as appropriate, the provisions of the U.K. Bribery Act and the U.S. Foreign Corrupt Practices Act). In particular all party employees and any third party acting for or on behalf of a party must ensure that all dealings with third parties, both in the private and government sectors, are carried out in compliance with all relevant laws and regulations and industry and professional codes of practice and with the standards of integrity required for an IMI project. Each party values integrity and transparency and has zero tolerance for corrupt activities of any kind, whether committed by employees, officers, or third-parties acting for or on behalf of the party.

Corrupt Payments – the party's employees and any third party acting for or on behalf of the party, shall not, directly or indirectly, promise, authorise, ratify or offer to make or make any "payments" of "anything of value" (as defined in the glossary section) to any individual (or at the request of any individual) including a "government official" (as defined in the glossary section) for the improper purpose of influencing or inducing or as a reward for any act, omission or decision to secure an improper advantage or to improperly assist the company in obtaining or retaining business.

Government Officials – Although this policy prohibits payments by a party or third parties acting for or on its behalf to any individual, private or public, as a "quid pro quo" for business, due to the existence of specific anticorruption laws in the countries where we operate, this policy is particularly applicable to "payments" of "anything of value" (as

defined in the glossary section), or at the request of, “government officials” (as defined in the glossary section).

Facilitating Payments – For the avoidance of doubt, facilitating payments (otherwise known as “greasing payments” and defined as payments to an individual to secure or expedite the performance of a routine government action by government officials) are no exception to the general rule and therefore prohibited.

GLOSSARY

The terms defined herein should be construed broadly to give effect to the letter and spirit of the ABAC Policy. Each party is committed to the highest ethical standards of business dealings and any acts that create the appearance of promising, offering, giving or authorising payments prohibited by this policy will not be tolerated.

Anything of Value: this term includes cash or cash equivalents, gifts, services, employment offers, loans, travel expenses, entertainment, political contributions, charitable donations, subsidies, per diem payments, sponsorships, honoraria or provision of any other asset, even if nominal in value.

Payments: this term refers to and includes any direct or indirect offers to pay, promises to pay, authorisations of or payments of anything of value.

Government Official shall mean: Any officer or employee of a government or any department, agency or instrument of a government; Any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; Any officer or employee of a company or business owned in whole or part by a government; Any officer or employee of a public international organisation such as the World Bank or United Nations; Any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or Any candidate for political office.

Appendix 4: Data Protection Processing Agreement

between

<Insert name and

Address of <Data Controller>>

- hereinafter referred to as “<Data Controller>” -

and

<insert name and address of Data processing organisation>

- hereinafter “Contractor”

<Data Controller> and Contractor are individually referred to as “Party” and collectively as the “Parties”.

Contractor and <Data Controller> have entered into a Data Processing Agreement dated [Date to be inserted] under which Contractor performs certain activities (“Service Activities”) for <Data Controller> as described in that agreement (“Data Processing Agreement”).

In connection with the Service Activities, <Data Controller> will transfer to Contractor Datasets and Images which may include personal data within the meaning of the EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (to the extent such Datasets and Images include personal data, including information regarding the health of patients, “Personal Data”).

This Agreement specifies the obligations of the Parties with respect to the storage, use and processing by Contractor of the Personal Data provided by <Data Controller> under the Data Processing Agreement (“Processing”).

This Agreement governs the actions aimed to ensure that <Data Controller>’s and Contractor’s Processing of the Personal Data meet the requirements for the protection of personal data stipulated in the EU Directive 95/46/EC as implemented for Germany in the German BDSG (the “Act”). and other applicable laws implanting such Directive.

37. Contractor will perform Processing of the Personal Data as part of the Service Activities under the Data Processing Agreement as data processor on behalf of <Data Controller>. The Processing of Personal Data shall only take place on servers located in the European Economic Area and Data may not be transferred to any location outside the European Economic Area (EEA) without the approval of <Data Controller> and provided that an agreement with the company in a third country in accordance with the rules on standard contractual clauses for the transfer of personal data as set forth in the decision of the European Commission dated 5 February 2010 (2010/87/EU) is concluded..
38. <Data Controller> continues to be the data controller of the Data Sets and Images and will remain responsible for protecting the rights of the data subjects and thus for determining whether the Processing of their personal data is admissible. Both Parties will ensure compliance with the requirements for the

protection of personal data stipulated in the EU Directive 95/46/EC and the applicable laws implanting such Directive. To this, <Data Controller> shall provide Contractor with identity and the location of the organizations that <Data Controller> will allow to process the Data Sets and Images hosted in the eTRIKS platform (hereafter called “the Organizations”). However, only <Data Controller> will ensure compliance with the Act and any other applicable data protection regulations, especially the EU Directive 95/46/EC when <Data Controller> or the Organizations use Data Sets and Images on the eTRIKS Platform and export(s) the Data from the eTRIKS platform and process(es) them outside the eTRIKS platform.

39. <Data Controller> shall provide the Personal Data to Contractor complete, accurate and up to date and in such form as is necessary for Contractor to process the Personal Data in accordance with the Data Processing Agreement.
40. <Data Controller> warrants that it is entitled to provide the Personal Data under this Agreement under applicable laws regulations and that all relevant consents and approvals in connection herewith, if required, have been obtained.
41. Contractor will perform Processing of the Personal Data only in accordance with the instructions of <Data Controller> for those purposes which are specified in the Data Processing Agreement.
42. Contractor confirms that they have implemented the technical and organizational measures designed to meet the specific requirements of data protection in accordance with EU Directive 95/46/EC. For that purpose Contractor has created their internal organization in such a way that it complies with the requirements of data protection and privacy. Contractor ensures that technical and organizational measures for adequate security against misuse and loss of the Personal Data within the eTRIKS platform are maintained, in particular:
 - q) to prevent unauthorized persons from gaining access to data processing systems for processing or using data (access control),
 - r) to prevent data processing systems from being used without authorization (access control),

- s) to ensure that persons authorized to use a data processing system have access only to the data they are authorized to access, and those data cannot be read, copied, altered or removed without authorization during processing (access control),
- t) to ensure that data cannot be read, copied, altered or removed without authorization during electronic transfer or transport or while being recorded onto data storage media, and that it is possible to ascertain and check to which bodies data is intended to be transferred using data transmission facilities (disclosure control),
- u) to ensure that it is possible after the fact to check and ascertain whether personal data have been entered into, altered or removed from data processing systems and if so, by whom (input control),
- v) to ensure that data processed on behalf of <Data Controller> are processed strictly in compliance with <Data Controller>'s instructions (job control),
- w) to ensure that data are protected against accidental destruction or loss (availability control),
- x) to ensure that data collected for different purposes can be processed separately.

One measure in accordance with the sub-paras. a) to d) is in particular the use of the latest encryption procedures.

- 43. With respect to the Processing of Personal Data, Contractor agrees to engage only those individuals who are obliged to maintain the confidentiality of the Data pursuant to EU Directive 95/46/EC. Contractor shall designate an appropriate number of employees to supervise and monitor the use of the Personal Data left in their care.
- 44. Contractor shall notify <Data Controller> in the event of an interruption in processing, a suspected breach of the data protection provisions or any other irregularity involving the processing of <Data Controller>'s data. <Data Controller> shall notify Contractor without delay if <Data Controller> becomes aware of any errors or irregularities, including, without limitation, those ascertained while reviewing results.

45. Contractor agrees to respond to any and all reasonable requests and enquiries made by <Data Controller> relating to the Processing of the Personal Data. Contractor will maintain the Personal Data on their data processing systems and will check periodically whether the obligations under No. 6 are fulfilled.
46. In case <Data Controller> is required under applicable data protection law to provide information regarding the Data Processing towards a data subject, Contractor will provide the necessary information (if required) to <Data Controller> within a reasonable period of time. In case a data subject approaches <Data Controller> regarding a correction or deletion of Data, <Data Controller> will immediately inform Contractor, and the Parties will discuss in good faith, taking into account applicable data protection law, how to deal with any such request.
47. <Data Controller> will periodically check that Contractor maintains the technical and organizational measures pursuant to No 6. Contractor acknowledges and agrees that the authority responsible for monitoring <Data Controller>'s protection of personal data may also monitor Contractor's operations to the extent permitted by law.
48. The Parties will provide to each other the name of the Privacy Officer taking care of the technical and organizational measures pursuant to No 6, as applicable.
49. Contractor may only engage a subcontractor for the performance of Processing Data with the prior written consent of <Data Controller> (a "Subcontractor").
50. In case Subcontractors are engaged, Contractor shall procure in their agreement with such subcontractors that the requirements for confidentiality, data protection and data security correspond to the regulations in this Agreement. Contractor shall procure that <Data Controller> has the same control rights over the subcontractors as provided for in this Agreement.
51. This Agreement has the same term as the Data Processing Agreement and the respective termination provisions apply accordingly. Following expiration of this Agreement Contractor shall (1) immediately stop any Processing of Data, (2) delete any Personal Data on its IT systems and (3) procure that Subcontractors

shall immediately stop any Processing of Personal Data and delete any Personal Data on their IT systems.

52. Capitalised terms not defined in this Agreement shall have the meaning as set forth in the Data Processing Agreement.
53. This Agreement is governed by laws of Germany. As regards any disputes arising under or out of this Agreement the Parties herewith submit exclusively to the jurisdiction of the courts of Berlin, Germany.
54. Unless otherwise regulated in this Agreement, the terms of the Data Processing Agreement shall apply. In case of any discrepancy between this Agreement and the Data Processing Agreement, this Agreement shall prevail.