

**RESULTS OF THE COLLABORATION AGREEMENT WORKING GROUP MEETING
AT LONDON HEATHROW AIRPORT ON 27 SEPTEMBER 2013**

Purpose of the paper

To inform the ELIXIR Interim Board about the results of the Collaboration Agreement Working Group meeting at London Heathrow Airport on 27 September 2013 and about the terms of the Collaboration Agreement template.

Action required

To take note of the results of the Collaboration Agreement Working Group meeting at Hilton London Heathrow Airport on 27 September 2013 and discuss the draft Collaboration Agreement template.

Voting requirements

No voting is required.

1. Background

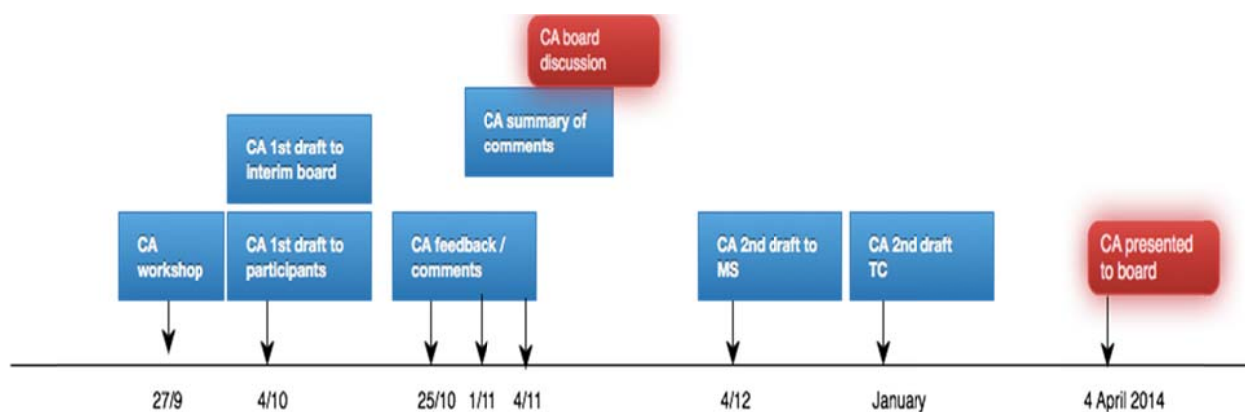
At the last ELIXIR Interim Board meeting it was decided to establish a Working Group for the drafting of the ELIXIR Collaboration Agreement template. The meeting of the Working Group took place at London Heathrow London Airport on 27 September 2013. The purpose of the meeting was to discuss the framework for the Collaboration Agreements between the ELIXIR Hub and ELIXIR Nodes. All participants were invited to bring in their ideas and raise their concerns. The results of the whole meeting are summarised in the annexed minutes. [Annex 1: Collaboration Agreement Working Group Meeting Minutes]

The meeting was chaired by Alf Game (BBSRC). The participants included representatives of seven future ELIXIR Member States and of EMBL. The attendees comprised government delegates, legal advisors and scientists. Breakout sessions served to consider four key legal issues concerning the Collaboration Agreement, namely the preamble, the provision of services and funding, governance and liability. The results of the breakout session were summarised on a set of PowerPoint slides. [Annex 3: Slides - Collaboration Agreement Working Group meeting]

Following the meeting, the legal advisor to ELIXIR, Vera Herkommer was tasked to produce a first draft of a Collaboration Agreement template. The content of the draft Collaboration Agreement template is open for discussion of the Interim ELIXIR Board Delegates. [Annex 4: First draft of ELIXIR Collaboration Agreement template]

2. Timeline (or next steps)

Suggestions by the Interim ELIXIR Board will enter into another revised draft template, which will be discussed by the Collaboration Agreement Working Group. The template will be approved by the ELIXIR Board once it is in place.



3. Action required

To take note of the results of the Collaboration Agreement Working Group meeting at London Heathrow Airport on 27 September 2013 and discuss the draft Collaboration Agreement template.

Annex 1: Minutes of the Collaboration Agreement Working Group meeting

Annex 2: Breakout session documents

- 1. Preamble and Purpose of the Collaboration Agreement
- 2. Provision of Services; Funding
- 3. Governance
- 4. Liability

Annex 3: Slides of the Breakout session results

Annex 4: Draft Collaboration Agreement template

ELIXIR Collaboration Agreement – legal issues
held on 27 September 2013 at Hilton London Heathrow Airport

Participants

| | |
|---|-------------|
| Rafael de Andrés-Medina , Institute of Health Carlos III | Spain |
| Rolf Apweiler , Joint Associate Director, EMBL-EBI | EMBL |
| Niklas Blomberg , ELIXIR Director | ELIXIR |
| Dmitry Denisov , Legal Counsel for Office of Research & Development, Uni. of Tartu | Estonia |
| Jasper Diderich , Manager Genomics Centres, Netherlands Genomics Initiative | Netherlands |
| Paul Hallam , BBSRC Finance and Governance | UK |
| Christian Hambro , Gram, Hambro & Garman | Norway |
| Jonas Jeppson , Legal Counsel, Swedish Research Council | Sweden |
| Kjell Petersen , University of Bergen | Norway |
| Bengt Persson , Uppsala University, BILS | Sweden |
| Lucie Pocha , Trainee Lawyer, EMBL International Relations | EMBL |
| Chris Ponting , Oxford University | UK |
| Andrew Smith , ELIXIR Senior External Relations Officer | ELIXIR |
| Alfonso Valencia , Spanish National Cancer Research Centre (CNIO) | Spain |
| Anna Wetterbom , Swedish Research Council | Sweden |

| | |
|----------------------------------|---|
| Joy Friesner , | Acting ELIXIR Scientific Administrator (Minutes) |
| Alf Game, BBSRC (Chair) , | Vice- Chair of the Interim ELIXIR Board |
| Vera Herkommer, EMBL , | Head of Legal Services to International Relations (Legal Advisor) |

Welcome

The Chair advised that the purpose of the meeting was to discuss the framework for the Collaboration Agreements between the ELIXIR Hub and ELIXIR Nodes. It should provide a forum for all parties involved to bring in ideas and raise concerns. Following the meeting a draft collaboration agreement template would be established and sent to all participants.

Information regarding the ratification process of the ECA and the Assessment report by the High Level Expert Group

Niklas Blomberg presented information about the ECA ratification process and the draft Assessment Report by the High Level Expert Group. He advised that following agreement of the ECA by ELIXIR Member States, the ECA had been signed by the UK and Sweden. It is expected that more countries will sign the ECA in the coming months. All efforts are focussed on having the ECA and ELIXIR enter into force prior to its launch on 18 December 2013 in Brussels.

The ESFRI Prioritisation process of Research Infrastructures is proceeding and will serve to rank research infrastructures based on scientific excellence and governance. The deadline for feedback is 1 November. Everyone will be asked for input into the report and it will be discussed at the Heads of Nodes meeting, 21-22 October 2013.

The draft Assessment Report from the High Level Expert Group has recently been circulated. He advised that ELIXIR had been rated as a top tier RI. The positive outcome is noted but in addition

Date: 27 September 2013

the report provides a number of good recommendations to ELIXIR concerning the coordination of investments, governance structures and asset benefit realization.

He advised that the Collaboration Agreements would form a key part of ELIXIR's governance framework. The agreement would be the key instrument for service delivery across the European infrastructure, as well as being the key instrument to contain risk and protect Member States from one another in the case of an incident such as a breach of personal data. As Marja-Liisa Niemi, the representative from Finland, was unable to attend the meeting in person, her comments submitted in advance of the meeting were presented to the group.

The following general comments were raised:

The Chair commented that with regard to comments from the ESFRI Assessment Group, what ELIXIR aims to achieve is completely new, and there is not an existing model that can be copied. ELIXIR is incomparable in its scale. To achieve the Assessment Group's grand ambition, it is important not to be daunted by issues such as governance, in which ELIXIR would need to function as a whole. In the same way, as the framework enables trust and cooperation to develop within the ELIXIR framework, the individual components involved may need to concede some aspects of control and autonomy. He added that there is a great deal to be proud of as reflected in the Assessment Group's report.

Christian Hambro commented that there is an established ESFRI in the social sciences called CESSDA (<http://www.cessda.org/>) with a similar structure to ELIXIR's Hub and Nodes model. He suggested that it would be useful to compare templates with them due to the similar structure. Vera Herkommer has contacted CESSDA and is awaiting feedback.

Key issues to be considered when drafting the agreement

Vera Herkommer advised that the template should focus on what is core to the Collaboration Agreement, with specific details to be negotiated with the individual Nodes. A detailed description of the services provided would be annexed to each Agreement. The Collaboration Agreement template would be for approval by the Board once the ECA is in force, such as negotiations can begin with each Node.

In terms of parameters for the Collaboration Agreement, there are framework issues to keep in mind:

- There are three stakeholders due to the special legal structure of ELIXIR: EMBL/ELIXIR Board/ELIXIR Node.
- The ECA provides the framework between the Hub and Node to provide some fixed points for the Node approval process.
- The ECA has established the SAB and the Heads of Nodes Committee, which the Collaboration Agreement will refer to.
- Some ELIXIR Board decisions that are necessary to finalise the template remain pending, including the SAB evaluation term and ethical guidelines.
- The suggestions of the Expert Assessment Group should also be considered.

Date: 27 September 2013

The Working Group was divided into four groups, with each to consider a difference topic pertinent to the Collaboration Agreement:

1. Preamble and Purpose of the Collaboration Agreement (Annex 2.1)
2. Provision of Services; Funding (Annex 2.2)
3. Governance (Annex 2.3)
4. Liability (Annex 2.4).

The breakout sessions consisted of the following Working Group members:

| Breakout session 1 Preamble | Breakout session 2 Provision of Services & Funding | Breakout session 3 Governance | Breakout session 4 Liability |
|---|---|---|--|
| Andrew Smith Bengt Persson Alfonso Valencia | Christian Hambro Chris Ponting Rolf Apweiler Jasper Diderich Alf Game | Rafael de Andrès-Medina Vera Herkommer Lucie Pocha Paul Hallam Anna Wetterbom | Jonas Jeppson Dmitry Denisov Niklas Blomberg Kjell Petersen |

Vera Herkommer advised that additional topics would be included in the Collaboration Agreement. Based on feedback from each of the breakout groups, Vera Herkommer will then produce a first draft template of the Collaboration Agreement.

Concerning the Provision of Services, the question was raised which services the Nodes would not only provide but also receive from the Hub. It was suggested that the services provided by the Hub could be included in a separate document, such as the ELIXIR Programme¹, that could be referred to in the Collaboration Agreement. It was added that another likely scenario could be that two Nodes could provide services to the Hub in a joint mission. It would therefore be important to ensure that the dependencies are clearly stated. This would become particularly relevant in the event that one Node cannot deliver their services because another Node does not comply with their obligation.

Niklas Blomberg advised that there are parallel processes where the Nodes define services in discussion with national funding bodies as well as ELIXIR discussions on what constitutes a core service.

Presentation of results of breakout sessions and plenary discussion

Breakout 1: Preamble and Purpose of the Collaboration Agreement (annexes 2.1 and 3)

Andrew Smith advised that the group had identified those issues requiring further discussion and suggested areas needing additions.

- He suggested that in the case where Nodes are providers of joint services that it is listed in the annex of the Collaboration Agreement those joint services for which the Node leads.

¹ The term "Programme" is used in the sense of Art. 6.2.4. m. ECA, see also the definition in the ECA.

- With regards who can sign the Agreement on behalf of a Node, it was suggested that there could be a mandate to sign, it could be countersigned or signed by a legal representative.
- The term 'national institutes', as used in the example text (annex 2.1), was queried as the most appropriate term to use. It was advised that previously the term 'centres of excellence' had been used and perhaps this was an area for discussion.
- It was noted that the example text (annex 2.1) mentions roles and responsibilities of - in case of a distributed Node - the lead organisation. It was queried whether in case of a distributed Node something needed to be included in the Preamble with regards roles and responsibilities of the organisations which are part of the Node but not signing the Collaboration Agreement. It should also be clarified who or what gains the status of an ELIXIR Node in the case of distributed Nodes.

Regarding the contents of the Preamble it was suggested:

- as preferable to have fewer, comprehensive Collaboration Agreements to limit the number of agreements requiring signing.
- that a statement about mature and new services be included in the Preamble, as well as in the Service Delivery Plan (SDP).
- that there should be a statement on the mechanism for updating SDPs, to allow for scientific advances and that the inclusion of new activities should be a simple process.
- that a statement be included that Nodes would strive for sustainability of funding.
- that a statement be included for the case where the delivery of a Node's services is dependent on services from the Hub/another Node. It was suggested that this could be listed in the SDP also.
- that a statement could be included that Nodes are responsible for coordinating the activities of their national partners.

The following general comments were made:

Bengt Persson queried that the Collaboration Agreement would not come into effect ahead of a full Board meeting. Vera Herkommer confirmed that the Collaboration Agreement template would have to be approved by the Board once in place. However, she advised that a draft template could be used to start the negotiation process with potential Nodes at an earlier point of time. Niklas Blomberg added that once five countries have signed the ECA, ELIXIR would then have a full Board, and it would then be possible to move ahead by written procedure in well-founded cases.

It was generally agreed that the Collaboration Agreement should be a short, standardised template for all countries, with Node-specific details (in particular a description of services) to be included in the annex. It was suggested that the Collaboration Agreement should be general enough such as should two Nodes collaborate, only a new SDP would be required.

Christian Hambro suggested that the Collaboration Agreement template provide information on the services provided and that the annex might contain the following:

- What is to be delivered
- Timelines

- Procedures for quality assurance.

Christian Hambro advised that the Collaboration Agreement should contain clauses on the recognition and review of the Service Delivery Plan and have the ability to say “enough is enough” should the required standards not be met. A process and time limits should be established on how things will work. He added that evaluation is useful but not an alternative to internal quality assurance systems. The Chair agreed that a key point is the time and quality definitions and advised that guidance could be provided on what to include in the annex to the Collaboration Agreement.

Anna Wetterbom added that the Board would mandate to what extent the ELIXIR Director would be able to negotiate with the Nodes, otherwise it would be unworkable for the ELIXIR Director. Vera Herkommer confirmed that approval would be required by the Board. Anna Wetterbom suggested that the Collaboration Agreement template should be as precise and inclusive as possible to keep negotiations to a minimum. The template should be designed to apply as broadly as possible and only be amended where absolutely necessary. Otherwise it would be necessary to go back to the Board constantly.

Alfonso Valencia queried a country having to sign many Collaboration Agreements based on the number of ‘projects’. Vera Herkommer advised that the Collaboration Agreement is entered into with the Nodes, not the countries. The term ‘project’ should be avoided as this terminology was not used in the ECA. She advised that ‘Nodes’ could consist of only a single or several research institutes. The Chair advised that from the outset it was envisaged that there would be more than one Node per country, however, this is not currently the case. He suggested that a foreseeable exception would be a federal country, where it would make sense to have more than one Node. The assumption of ‘one country, one Node’ is currently used however it is not being prescribed.

Alfonso Valencia advised that reasons for having several Collaboration Agreements depends on the governance and the partners involved. He advised that a framework is needed which allows for various solutions. Niklas Blomberg advised that it would be in no one’s interests to govern multiple Collaboration Agreements and that currently it was foreseen to have one Collaboration Agreement per Node.

Chris Ponting advised that training tends not to be included in terms of services. Vera Herkommer advised that training is included as suggested wording in the Preamble (annex 2.1). Chris Ponting advised of the importance of explicitly mentioning training as a service.

Breakout 2: Provision of Services; Funding (annexes 2.2 and 3)

Rolf Apweiler advised that the following issues should be considered:

- The distinction between service and research and development (R&D) should be considered. This distinction is straight forward for resources and databases, but more complicated for R&D, in terms of the standard of services provided for services such as ENSEMBL and other genome databases.

Date: 27 September 2013

- The distinction between Commissioned and Additional Services was also raised. It was advised that commissioned services are defined in the list of definitions provided in the ECA.
- It was suggested that Additional Services be defined as all services at a Node.
- However, not all services would be classed as ELIXIR affiliated services. Pilot and emerging services would not be classed as affiliated services. Mature services with a “kitemark” from the ELIXIR Board or SAB would be considered ELIXIR affiliated services. It was suggested that not the entirety of a Nodes services should be affiliated with ELIXIR.
- Other additional services may be mentioned, in principle, but not as part of the Service Delivery Plan.
- Commissioned services should only rely on affiliated and commissioned services, and not on pilots, emerging or legacy services. The issue of legacy would need to be considered, in terms of whether a service would have a death plan.

The following general comments were raised:

Rolf Apweiler clarified that the ECA would differentiate between commissioned services and additional services, (referring to Art. 8.5.2 ECA) and that both could have the nature of technical services. Vera Herkommer agreed and advised that the two terms were applied to indicate the different funding sources: according to the ECA commissioned services are funded by the Hub.

A query was raised regarding the situation whereby Nodes are obliged to provide a service but cannot do so without receiving complementary support from the Hub or another Node. It was suggested that this would need to be reflected in the Collaboration Agreement, potentially in a multi-way agreement. Niklas Blomberg advised that this is not an unlikely situation that activities are dependent on a number of Nodes, citing the example of UniProt.

It was suggested that where several Nodes are jointly involved in delivering a service, the service would be a candidate to become a commissioned service. Niklas Blomberg advised that there would need to be a mechanism for promotion of services to commissioned services avoiding the necessity to renegotiate the whole Collaboration Agreement or implement several.

Chris Ponting raised a query with regards provisions for third parties and whether there would be any constraints should the Hub or a Node work with the USA, for example. Vera Herkommer advised that a start would be made with the obvious agreements. Andrew Smith advised that membership of third countries is covered by Art. 4.1 and liability with third parties (Art. 9.2).

The following issues were also for consideration:

- It was advised that there must be a mechanism and timelines for the review of collaboration agreements and Service Delivery Plans, for both commissioned and affiliated services, as science advances.

Date: 27 September 2013

- Necessity of sustainability/defaulting plan
It was queried what would happen to mature services in a worst case scenario, e.g. an earthquake, when there are thousands of users dependent on a service, and what would happen should funding run out.
- Spell out dependencies to services of other Nodes and the Hub
It was suggested that there be neither dependencies on pilot services nor legacy services.

The following general comments were raised:

Vera Herkommer also explained that the term “additional services” as used in Art. 8.5.2 ECA was meant to comprise only those services provided and funded by a Node that - following previous evaluation through the SAB and approval by the Board - were implemented into the Collaboration Agreement. The ECA does not refer to services that are delivered by a Node without request by the ELIXIR Hub.

Kjell Petersen queried what an “affiliated” service is. He added that should a service not be listed in the Service Delivery Plan, it could not be called an affiliated service. All affiliated services would need to be stable and reliable enough to cope with lots of dependencies. With the need to have a curation process for emerging core services.

The Chair advised that it might not always be clear what is brought into ELIXIR and what comes as part of the surrounding environment thus contributing to growth and development. Rafael de Andrès Medina suggested that only those services that became part of the Collaboration Agreement would be legally binding and that any other services would be outside the argument. Potential services carried out by a Node should be listed elsewhere and not in a legal document.

Niklas Blomberg advised of the importance in distinguishing between core ELIXIR services, with sustainable funding and mature service delivery organisations and other services. Niklas Blomberg added that services e.g. Uniprot, can be built on top of as there is confidence in their sustainability.

The Chair advised that there must be clear usage of the ELIXIR brand. The ELIXIR badge would apply only to those commissioned and additional services, part of ELIXIR, to ensure quality of the services provided. Only those services should be included that are actually intended to be binding on the parties.

Niklas Blomberg advised that he viewed the ELIXIR kitemark as acting as an enablement pathway for services on their way to becoming more sustainable. The ELIXIR kitemark will be discussed at the October Heads of Nodes meeting.

Rolf Apweiler advised that instead of completely dismissing a Node, a Node could outline the services it would offer and a decision could then be made on which Node activities would receive an ELIXIR kitemark. Only reputable services would be afforded an ELIXIR kitemark.

It was generally agreed the importance of using keywords correctly. Should they not be used correctly this could cause communication difficulties and become more of a problem later on. The

Date: 27 September 2013

Chair advised of the importance of conforming with the language used in the ECA. It was advised that the Hub could provide clarification with regards any terminology.

The Chair advised that the group had been asked to consider funding. He added that the example text (annex 2.2) stated that non-commissioned, technical and administrative services provided by the Node would be the responsibility of the Node to fulfil, thus, there is a clear distinction of responsibility and a process should services not be delivered.

Breakout 3: Governance (annexes 2.3 and 3)

Vera Herkommer advised that the group had considered three issues:

- Internal governance (as outlined in the Collaboration Agreement)
- External governance (governance bodies mainly established by the ECA with a link to Node activities)
- Distributed Nodes

Vera Herkommer advised in general terms that the ideal governance structure was designed to prevent conflict by using explicit wording, and to ensure clear distribution of responsibilities. Against this background the suggested wording in the supporting document (annex 2.3?) was changed and made stronger to clarify the responsibilities of the Head of Node and the Steering Committee.

Internal governance

Vera Herkommer explained that the Collaboration Agreement should introduce two governance bodies, i.e. the “Head of Node” and the “Steering Committee”.

The **Head of Node** would represent the Node at the Heads of Nodes Committee with full representative and authoritative power to act on behalf of the Node (and in the case of a distributed Node, on behalf of all research institutes involved in the Node). The Head of Node would be obliged to ensure that correct ethical procedures are followed and to inform the ELIXIR Director in the case of any ELIXIR service changes or other developments, thus ensuring transparency. The Heads of Nodes Committee assembles all Heads of Nodes. This committee is chaired by the ELIXIR Director and is a key body for development of the ELIXIR Programme (as set out in the ECA). Additionally the Heads of Nodes Committee will maintain an active overview of the ELIXIR service portfolio and actively develop external funding strategies.

Anna Wetterbom suggested the Head of Node be responsible for the Node’s deliverables to ensure that the Node delivers the services it deemed it would. It would therefore be important to have an enforceable legal structure at Node-level in place.

Chris Ponting queried the situation should a Head of Node retire or move institute and how this would affect the institute that holds the Node. He advised that an arrangement should be in place for agreeing a new Head of Node. The Chair advised that it is the responsibility of the Node to ensure the continuation of services. A Node may not want to continue its services should the Head of Node leave, in which case another institute may want to run the services and there should be scope within the agreement to deal with this scenario. There would be different responses based

Date: 27 September 2013

on the situation but the Collaboration Agreement would be specific on who is liable and responsible for resolving the issue.

Vera Herkommer advised that the **Steering Committee** would monitor the delivery of a set of established targets. Key Performance Indicators (KPIs) would need to be developed by the Steering Committee for measuring the quality of the provided services, as highlighted in the Expert Assessment Group report. The Steering Committee would monitor the success of the Node and international best practice.

The Chair advised that the Head of Node would be accountable but in the case of a distributed Node, they could potentially be undermined if a representative from the distributed Node was on the Steering Committee. Vera Herkommer advised that the example text is deliberately vague. It is thought that the Steering Committee would be made up of, as a minimum, the ELIXIR Director, the Head of Node and other representatives as deemed necessary by the ELIXIR Director and Head of Node.

External governance

Two “external” governance bodies would need to be considered, i.e. the SAB (Art. 6.4 ECA) and the Heads of Nodes Committee (Art. 6.5 ECA). The role of the SAB takes place before the Collaboration Agreement comes into force and the Node application process is such that the SAB would evaluate future Nodes. Furthermore, SAB evaluation of Node Services will have to take place regularly as well as towards the end of the term. The Frequency and process for these reviews is currently unknown, pending a decision from the ELIXIR Board once in place.

Structure of distributed Nodes

Vera Herkommer advised that distributed Nodes would need to be organised in a legally sound manner to ensure delivery of their services. This could be achieved by creating a company, an association or forming a consortium so that the Node has a stable structure. The Head of Node would need to ensure that he/she has the right to speak on behalf of his/her own institute as well as the other institutes involved. As the Head of Node signs off on services being delivered by another institute, this could give rise to questions of liability. A legally enforceable structure could protect a Head of Node against associated risks.

Kjell Petersen advised that the Norwegian Research Council had required a consortium agreement to be set-up, between five universities, before the Norwegian Node could be funded. Kjell Petersen is to provide a copy of this consortium agreement to Vera Herkommer.

Alfonso Valencia advised that for scientific reasons, where there are distributed Nodes, that there be a leading institute.

Rafael de Andrés Medina advised that new constituencies cost money and that the annex should describe the structure and composition of the facilities as an integral part of the Collaboration Agreement.

Alfonso Valencia queried whether countries would have the ability to organise themselves into a legal structure, citing the example of the EGA database and whether this would require an agreement between EBI and CRG, Barcelona. Niklas Blomberg again pointed to the example of

Date: 27 September 2013

UniProt, which is likely to be an ELIXIR service. EBI and SIB are involved with UniProt together with third party, PIR, so UniProt would be distributed over at least two universities.

Niklas Blomberg warned against creating extensive overhead through requirement of additional, ELIXIR specific, governance structures for Nodes. Instead of having a prescriptive governance structure, it should simply be insisted that there is a governance structure in place such that ELIXIR can connect governance structures already in place for many Nodes.

The Chair summarised that once principles have been established, a decision can then be made on where information should be, i.e. distributed in several sets of governance documents. It would need to be known that things are in place somewhere. Vera Herkommer advised that there are different options on where information can be included. She added that the Collaboration Agreement should contain those elements which are mandatory, further information could be included in the Service Delivery Plan. Guidelines can be established by the Board on the minimum information the Service Delivery Plan should contain.

Breakout 4: Liability (annexes 2.4 and 3)

Kjell Petersen advised that the discussion had focussed more on risk than liabilities.

- He suggested that the template Collaboration Agreement cover all modes of collaboration, i.e. Node-Hub, Node-Node, with specific details to be included in the annex and Service Delivery Plan.
- He added that the Hub should be treated equally as a Node when providing services.
- He advised that the core principle of every party being responsible for its own actions, and those of its employees, is stricter than the example text (annex 2.4) provided. Responsibility for any liability would be with the organisation providing the Node Service. Niklas Blomberg stated that there is a clear distinction between liability as dealt with in the ECA and in the Collaboration Agreement. Whereas ELIXIR Member States jointly will be liable for all operations that fall into the Hub's responsibility, each Node is responsible for activities that fall into the Node's responsibility. This should be reflected by the Collaboration Agreement.
- It was suggested that there be a declarative clause that a Node's operations would follow national legislation which would be important in the case of a breach of sensitive data, anti-corruption etc.
- He advised that if successful, ELIXIR would be seen as a whole. Thus, should there be an issue with a single Node, this would affect the reputation of ELIXIR as a whole, thus preventative measures must be taken to avoid reputational damage.
- He suggested that the template Agreement cover joint delivery of services and how risk/liability would be apportioned. In the case of two Nodes making a joint venture to provide a service, they would share the risk equally, or a more detailed description would be included in the Service Delivery Plan. It must be ensured that the SDP addresses certain areas and assurances that quality is tested and monitored.
- He suggested that disclaimers be standard and included in the SDP such that a Node would not have to write a SDP from scratch. Similarly for "take down" notices, it was suggested that there be a standardised procedure on the handling of any claims and challenges.

The following general comments were raised:

In terms of liability, Christian Hambro queried whether the Collaboration Agreement would mention preventative measures and document quality assurance systems. Vera Herkommer advised that results from the breakout sessions would provide guidance on this by identifying risks that might occur or are to be negotiated on a case by case basis. She added that regular evaluation could occur through the SAB, providing feedback to the Node and feedback to the Board, a mechanism to ensure that service levels are being met.

Kjell Petersen advised that should a service not meet the required minimum standard, that this would pose a reputational risk to ELIXIR as a whole. He added that the example text (annex 2.4) be expanded to state that in the case of minimum standards not being met, that party would be liable. Niklas Blomberg advised that should there be a failure to maintain services, the right to revoke the ELIXIR kitemark must exist.

The Chair queried the level of quality standard required and quality assurance in relation to risk and noted that ELIXIR is not a commercial undertaking. Expectations need to be managed through transparency of terms-of-service to minimize reputational risks.

Christian Hambro suggested that one option is that the Collaboration Agreement would not contain clauses on the issue of liability, hence in case of a claim this is regulated through applicable law and the agreements set forth in the ECA. Vera Herkommer advised that a general clause could be included in the Collaboration Agreement regarding liability.

The Chair queried who ensures that a **user** does not do anything wrong. Kjell Petersen advised that rules can be established on this. Jonas Jeppson suggested that the user uses the data at their own risk. Niklas Blomberg advised that as a guiding principle, the individual's employer would ultimately be responsible. The Chair suggested that it be made clear what is an individual's responsibility. Kjell Petersen advised that for a service based on data coming from elsewhere in the network, the data provider would need to warrant that they have the rights to that data. Should there be an IP infringement, the Hub would be liable having provided the data.

Rafael Andrès de Medina queried jurisdiction in case of any conflicts. Niklas Blomberg advised that existing national legislation could be referred to such as laws would not need to be restated but that the group would need to agree on the governing law for the Collaboration Agreement.

Kjell Petersen advised that the 'core principle' text (third bullet point, slide 9, annex 3) a suggestion by his breakout group, was more explicit than the example text for liability (annex 2.4). Vera Herkommer queried the terminology of the 'core principle', clarifying that 'party' indicated the Hub-Node relationship and 'actions' indicated services delivered by Node but not services delivered by the Hub. Kjell Petersen suggested that this would remain valid for the Hub also, whilst perhaps the Hub's services might be stated elsewhere.

In terms of a risk register, the following areas were considered:

- Intellectual property infringements

- Personal data protection
- Minimising risk
- Commissioned services.

Niklas Blomberg advised that discussions had taken place with the technology transfer arm of EMBL regarding IP risks and ownership of IP. A Node would own the IP of the services it provides, thus providing a preventative measure.

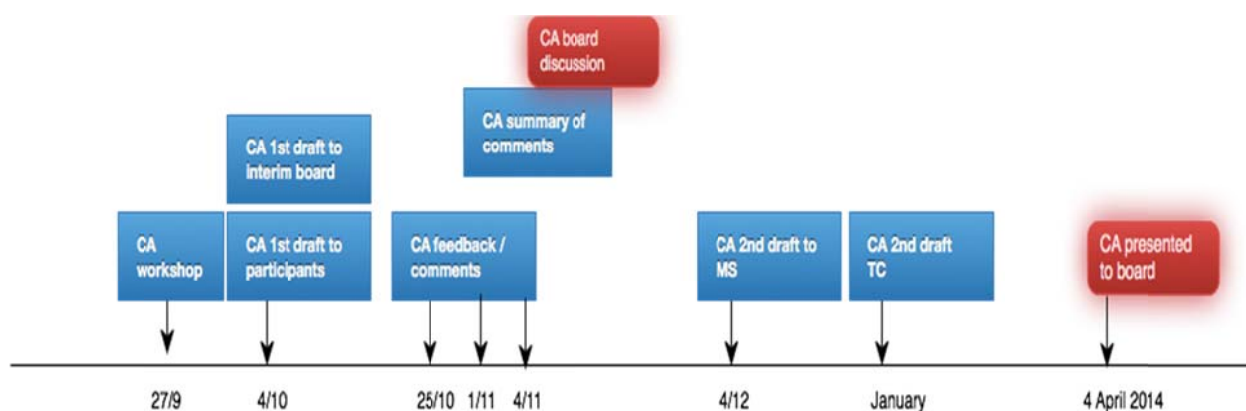
Christian Hambro advised that dispute settlement is covered in article 20 of the ECA and should nothing further be written about it, article 20 would be followed.

Kjell Petersen advised that he would provide his notes on this subject to Niklas Blomberg.

Collaboration Agreement structure, drafting process and timelines

Vera Herkommer advised that she would draft a template Collaboration Agreement in 1.5-2 weeks, based on feedback received at this Working Group meeting. The template Collaboration Agreement would then be circulated to the Collaboration Agreement Working Group to give feedback by 25 October. A summary of the main results from the Working Group would be presented to the Working Group, then the ELIXIR Interim Board. She reminded that the term of the Collaboration Agreement and conditions under which Nodes are evaluated is currently undecided, pending a decision by the ELIXIR Board.

Vera Herkommer advised that it had been useful to gauge feeling on the provided example texts (annexes 2.1, 2.2, 2.3, 2.4). Regarding the issue of IP, some good wording had been suggested and Vera Herkommer may ask the Working Group for clarification on IP issues. She advised that ethical issues, as mentioned in the Expert Assessment Group report, would need to be considered in more detail. Vera Herkommer advised that she would propose a suggestion for governance law. There is an example of dispute resolution at the end of the ECA and the Collaboration Agreement could include a similar dispute settlement clause referring to arbitration. Otherwise the usual provisions would be added to the template (e.g. regarding amendment of the text).



The Chair suggested that the template Collaboration Agreement be posted on a password-protected, closed website such that any comments made would be visible to the whole Working Group. The Hub will explore setting up a closed website for this purpose.

ELIXIR Collaboration Agreement – legal issues 27 September 2013

Breakout session 1: Preamble and Purpose of the Collaboration Agreement:

Expected outcome

The breakout session group is invited to present the results of the session on one or two slides. In particular, please concentrate on the key issues as regards the relation between the Hub and the Node. It would be very helpful if additionally short notes could be established.

Introduction

The **Preamble** should set the frame/context for the collaboration and inform the reader of the rationale of the agreement. It usually mentions the different stakeholders involved, i.e. EMBL (acting for the ELIXIR Hub), the ELIXIR Consortium and the national institute that will get the status of an ELIXIR Node. The Preamble is usually not considered to be binding but rather constitutes an informative part of the agreement.

ELIXIR is based on the ECA, which gives **EMBL a special role**. According to Art. 4.1.1 d. EMBL is first of all a full member in ELIXIR and is therefore represented in the decision-making body, the ELIXIR Board. Secondly, and as outlined under Art. 2.3 and 5.4.1. EMBL has agreed to take on a couple of specific services, such as acting as the legal entity to the outside on the basis of a mandate by the ELIXIR Board. Therefore whenever we speak of the "ELIXIR Hub", it is in fact the EMBL acting to the outside in accordance with the decisions of the ELIXIR Board.

The **ECA** sets the frame also for the relationship between the ELIXIR Hub and the Nodes. For example, before the Node is able to enter into a Collaboration Agreement it must have passed successfully an internal application process, during which the application must be supported by the host country. The successful candidate is then allowed to enter into negotiations of the Collaboration Agreement with the ELIXIR Hub. Therefore, the text of the Collaboration Agreement does not need to deal with this application process. However, the Preamble is a good means to point at the necessary steps that need to have taken place beforehand.

The **Purpose** of the Collaboration Agreement is to define the relationship between the Hub and the Nodes. The Collaboration Agreement will therefore deal for example with the delivery of services, financial provisions, quality control, IP and liability. Most importantly the Collaboration Agreement will establish the national institute's status of an ELIXIR Node.

Example text for Preamble

The Parties hereby agree to conclude a Collaboration Agreement (hereinafter referred to as “the Agreement”) within the framework of the “*European Life-Science Infrastructure for Biological Information*” (**ELIXIR**), a research infrastructure organized in the form of a central hub and distributed nodes, which shall operate and manage, in the widest sense of these terms, an interlinked collection of biological data resources, tools and literature. ELIXIR is a research infrastructure of global significance and open to scientists of all disciplines.

The Parties,

- acknowledging that ELIXIR is a distributed research infrastructure whose Hub was established by the ELIXIR Consortium Agreement and is located at EMBL’s outstation, the European Bioinformatics Institute on the Wellcome Trust Genome Campus in Hinxton, Cambridge, UK;
- acknowledging that EMBL as host of ELIXIR acts as a Party to this agreement as mandated by the ELIXIR Consortium;
- acknowledging that the collaboration between the ELIXIR Hub and an ELIXIR Node takes place within the frame as set by the ELIXIR Consortium Agreement, involving in particular a previous and successful application process accepted by the ELIXIR Board;
- acknowledging that ELIXIR Nodes receive all possible support through the ELIXIR Hub to the extent that it falls within the limits of its mission;
- recognising that ELIXIR’s challenges can best be addressed by combining European and national operations;
- recognising that data and knowledge provided by ELIXIR will be freely accessible, although controlled access shall be implemented where necessary;
- recognising the need for extensive training in general areas of data resources and bioinformatics infrastructures.

Example text for purpose of the Agreement

The Agreement provides the [name of the institute] with the **status of an ELIXIR Node** and defines its relationship, rights and responsibilities towards the ELIXIR Hub within the framework of the ECA.

This Agreement is not intended, and nothing contained herein shall be deemed, to create any partnership, agency or joint venture amongst the Participants or any of the Participants, nor to establish any other legal entity constituted amongst any or all of the Participants.

Following successful application to become an ELIXIR Node as described in the ECA¹ and by concluding this agreement the [national institute] is granted the **status of an ELIXIR Node** for the duration of this agreement.

¹ Art. 8.1 to 8.4 in connection with Art. 6.2.4 n. and Art. 8.5.



**ELIXIR Collaboration Agreement – legal issues
27 September 2013**

Breakout session 2: Provision of Services; Funding

Expected outcome

The breakout session group is invited to present the results of the session on one or two slides. In particular, please concentrate on

- the two different categories of services (i.e. “technical and administrative services” and “Commissioned Services”)
- Terminology for the annexed overview of services to be provided by the Node (e.g. “Service Delivery Plan”) and
- a possible mechanism on how to adapt the Service Delivery Plan before the end of the term of the Collaboration Agreement.

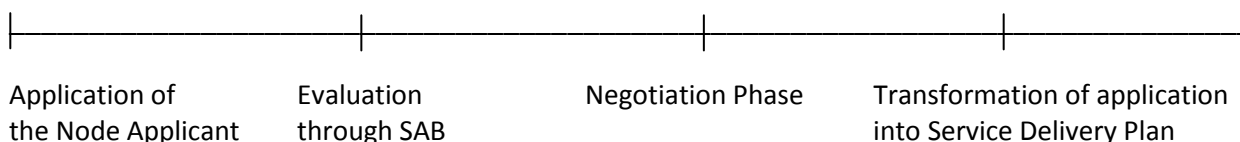
It would be very helpful if additionally short notes could be established.

Introduction “Provision of services”

Nodes will provide technical and administrative services to support the ELIXIR infrastructure.

The details of those services to be provided by the Node will become part of an overview document that could possibly be called “**Service Delivery Plan**” and be annexed to the Collaboration Agreement. The Service Delivery Plan outlines the services for the duration of this Agreement. It will be the result of an application process as described in Art. 8.1 to 8.4 ECA during which the SAB reviews an application including a detailed description of sustainable services, which is approved by the ELIXIR Board. The scientific proposal as approved by the ELIXIR Board finally becomes the Service Delivery Plan.

Process according to Art. 8.1 ECA:



The “High Level Expert Group”¹ in its draft assessment pointed out that ELIXIR should ensure monitoring of impact of ELIXIR. Key performance indicators should be developed out of the collaboration agreements and assuming that these would include a detailed description of services.

¹ A Highlevel Expert Group on the Assessment of the projects on the ESFRI Roadmap (draft), 2013, p. 49.

The Service Delivery Plan should also highlight how financial sustainability is secured for the duration of this Agreement. If the sustainability is not demonstrably guaranteed then already the application to the ELIXIR Board should fail and the ELIXIR Hub would never enter into negotiations of the Collaboration Agreement. The same is true for renewal of the Collaboration Agreement: EMBL would only agree to renew the collaboration agreement once it was mandated by the ELIXIR Board according to Art. 8.8.3. The ELIXIR Board will only agree in case of demonstrated financial sustainability.

Consequently, the Articles regarding “Services” should be rather short and referring to the annexed Service Delivery Plan. The Collaboration Agreement should also demonstrate a mechanism on how to update/adapt the Service Delivery Plan before the end of the Collaboration Agreement and under which conditions. The provision would have to find a balance between the wish for long term planning and unforeseeable changes that would make an adaptation wishful.

The “Services” chapter should highlight the two different categories of Services, i.e. “technical and administrative services” and “Commissioned Services”. The term “Commissioned Services” is introduced by the ECA and also described in the “Role of the Hub, Nodes and EMBL” document. The ECA states under “Definitions”:

“Technical and administrative services that fall under the responsibility of the ELIXIR Hub and are funded through the ELIXIR Budget; they may be carried out by one of the ELIXIR Nodes pursuant to a Collaboration Agreement or by the EMBL pursuant to a Work Programme”.

Introduction Funding

The funding chapter should pick up the two different categories of services and describe the funding situation for both of them:

- Funding for technical and administrative services by the Node must be provided by the Node;
- Funding for Commissioned Services (following decision by the Board) is provided by the ELIXIR Hub.

Example text for Services

Services provided by the ELIXIR Node

Description of services

The ELIXIR Nodes shall provide technical and administrative services as outlined in the Service Delivery Plan, which was accepted by the ELIXIR Board following review by the SAB (Annex: Service Delivery Plan).

Commissioning of technical services by the ELIXIR Node

The ELIXIR Node shall provide Commissioned Services as outlined in the proposal (Annex: Service Delivery Plan), with the effect as described under [Reference to Article dealing with Funding provided by the ELIXIR Hub]

Example text for Funding

Funding

Funding for services provided by ELIXIR Nodes

Funding of technical and administrative services as described in the annexed Service Delivery Plan, which are not Commissioned Services, falls into the responsibility of the ELIXIR Node.

Funding for Commissioned Services provided by the ELIXIR Node

Services provided by the ELIXIR Node and which are marked as Commissioned Services in the Proposal (Annex) shall be funded through the ELIXIR Budget.

ELIXIR Collaboration Agreement – legal issues 27 September 2013

Breakout session 3: Governance

Expected outcome

The breakout session group is invited to present the results of the session on one or two slides. In particular, please concentrate on the suggested two governance bodies and on the structure of the Node.

It would be very helpful if additionally short notes could be established.

Introduction

In this group, the governance bodies established through the Collaboration Agreement and the structure of future Nodes should be discussed.

The “Governance” chapter should mainly deal with two bodies, i.e. the “Head of Node” (not the Committee!) and the “Steering Committee”, which should at least consist of the ELIXIR Director and the Head of the Node. The Collaboration Agreement will refer to other bodies as well such as the SAB or the ELIXIR Board. However, these are “external” bodies that are already in place and established through the ECA. External bodies should also be defined under Definitions:

ELIXIR Board A body established according to Art. 6.2 ECA and which is composed of representatives of ELIXIR’s members. It is ELIXIR’s principal decision-making body as defined in Art. 6.2 ECA.

Scientific Advisory Board A body established according to Art. 6.4 ECA and which is composed of independent scientists that oversee the quality of the ELIXIR activities as supervised by the ELIXIR Board and ELIXIR Director, and carried out by the ELIXIR Nodes and the ELIXIR Hub.

Based on the number of legal entities involved, there might be two types of Nodes:

1. Single legal entity providing the complete service package,
2. Several legal entities providing an integrated service package.

Both cases should be covered in the governance chapter of the Collaboration Agreement template. Several institutions can collaborate to put together the complete package needed for the Node. However, the involvement of several legal entities would require that one identifiable accountable entity must be established (through the formation of a new legal entity or the

appointment of an existing legal entity). Quality assurance mechanisms would need to ensure that all entities involved deliver excellent services.

Example text for Governance:

Governance

1. Head of Node

Appointment of the Head of Node

The ELIXIR Node appoints a Head of Node.

Task of the Head of Node

The Head of Node shall be the strategic contact point for all matters related to this Agreement. The Head of Node shall in particular

- Monitor all services provided by the Node as part of the annexed Scientific Plan.
- Become a member in the Heads of Nodes Committee as established based on the ECA and participate in related meetings.
- Ensure smooth information exchange related to ELIXIR both internally and towards the ELIXIR Hub.

2. Steering Committee

Composition

The Steering Committee is established by the Parties and comprises the ELIXIR Director, the Head of Node and other individuals appointed by them.

Tasks of the Steering Committee

The Steering Committee shall ensure regular exchange of information, joint coordination and monitoring of tasks and responsibilities of the Parties within an agreed schedule. Specifically, it supervises and agrees on:

[list of possible tasks of the Steering Committee]

Meetings of the Steering Committee

The Steering Committee shall meet at least once a year as well as at any reasonable request of any of the Parties, to follow-up and decide on all substantial issues that ensure the best project implementation.

Structure of a Node

Under definitions:

ELIXIR Node

A national or international research institute or a group of distributed national or international research institutes in one Member State acting as one single legal entity entering into a Collaboration Agreement with the EMBL to provide services with a European dimension and that have an added value for ELIXIR.

Status as ELIXIR Node

Following successful application to become an ELIXIR Node as described in the ECA¹ and by concluding this agreement the [national institute] is granted the status of an ELIXIR Node for the duration of this agreement.

OR (in the case of multiple distributed research institutes in one Member State):

Following the successful application to become an ELIXIR Node as described in the ECA² and by concluding this agreement the [distributed national research institutes] represented by and acting through [relevant legal entity] are granted the status of one single ELIXIR Node for the duration of this agreement.

¹ Art. 8.1 to 8.4 in connection with Art. 6.2.4 n. and Art. 8.5.

² Art. 8.1 to 8.4 in connection with Art. 6.2.4 n. and Art. 8.5.

**ELIXIR Collaboration Agreement – legal issues
27 September 2013**

Breakout session 4: Liability

Expected outcome

The breakout session group is invited to present the results of the session on one or two slides.

It would be very helpful if additionally short notes could be established.

Introduction

This session primarily deals with the assessment of potential risks rather than regulating them. The group is asked to list risk scenarios, which requires outlining typical services/activities by the Nodes such as for example

- Provide data resources;
- Provide services, training and assistance to establish a fully integrated and sustainable network of resources and tools that will facilitate data dissemination and international collaboration;
- Promote standards;
- Provide appropriate computer infrastructure for processing, archiving and analysing the data;
- Provide infrastructure for tools;
- ELIXIR Consortium Agreement Revision1 - final 13;
- Support applications for funding of ELIXIR related activities; and
- Provide other services as decided by the ELIXIR Board.

This may include matters concerning e.g.

- violation of data protection rules;
- violation of IPRS of researchers or database rights of those compiling the databases;
- inaccuracy of the data;
- failure of the system supporting the database/bugs/viruses, etc.;
- anti-corruption and
- country specific requirements regarding employment law addressing reputational, ethical and financial risks.

More broadly, the Collaboration Agreement may also have to cover risks resulting from the non-compliance with standards required by the Hub or with contractual arrangements.

In particular those participants with a scientific background are invited to think about how risks could be minimised (e.g. internal verification processes, consent forms, ...). This would allow

thinking about which legal safeguards are necessary towards third parties (disclaimers, agreement on use of the data).

Finally, if the risk materialises (i.e. lawsuit by a third party) how should the liability be allocated between the Hub and the Node (in this liability clause), taking into account the extent to which the Hub or Node are de facto able to pre-empt the risk.

The risk register from this breakout will be used to refine the example text below and ensure that all major cases are covered.

Example text for liability:

Liability [this clause needs to be expanded and is a very preliminary proposal]

The Parties will hold each other liable only for wilful injury or gross negligence. The same rule applies with respect to damage suffered by delegated personnel during the time of their delegation. Damage suffered by third parties will be borne by the Party whose personnel is responsible for it.

Breakout Session 1: Preamble

Issues for further discussion

- Nodes as providers of joint services
- Who can sign on behalf of Node?

...Most importantly the Collaboration Agreement will establish the **national institute's** status of an ELIXIR Node

- Is 'national institutes' best term? Centres for excellence, or universities or institutes, national organisation...

...The Agreement provides the [name of institute] with the status of an ELIXIR Node...

- What about other Node partners who won't sign CA?

Breakout Session 1: Preamble

Suggestions for areas needing additions

- Would prefer fewer more comprehensive CAs
- Statement that both mature services and also new services (eg, pilots) should be included
- Needs to be mechanism to update SLAs over time
- Statement on striving for sustainability of funding
- Statement of the principle that in delivering services Nodes also rely on services from Hub and other Nodes (could be listed in SLA if needed?)
- Needs to reflect that ELIXIR Nodes are responsible for coordinating the work with their national partners

Breakout Session 2: Provision of Services

- *Distinction between service and R&D*
- Distinction between Commissioned and Additional Services
- Define Additional Services:
 - All services at a node
- Not all should be affiliated with Elixir
- Other additional services to be mentioned in principle, but not part of service delivery plan
- Commissioned Services can only rely on and Affiliated and commissioned Services, not on pilots, emerging or legacy services

Breakout Session 2: Provision of Services Affiliated Services

- Mature services with Elixir kitemark
- Not Pilot or emerging ones
- Legacy?

Breakout Session 2: Provision of Services

To consider:

- Necessity of review plan/timelines to revise collaborative agreement and service delivery plan with regard to both commissioned and affiliated services
- Necessity of sustainability/defaulting plan
- Spell out dependencies to services of other nodes and the hub

Breakout Session 3: Governance

- **Head of Node** representing Node in Head of Nodes Committee
 - full representative and authoritative power for Head of Node for Node/all research institutes that are part of a distributed Node
 - wording to be changed to create accountability/responsibility on the side of the Head of Nodes: The Head of Node is responsible for the delivery of services.
 - ensure compliance with national rules and international best practice (especially concerning ethics)
 - inform ELIXIR Director of collaborations with other Nodes (transparency to ensure that in the best interest of ELIXIR)
 - other responsibilities of Head of Nodes (funding etc)
 - ECA describes the tasks of the Head of Node Committee

Breakout Session 3: Governance

- **Steering Committee:** distributed Nodes could have more than one representative for their research institutes
 - wording to be changed: The task of the Steering Committee is to monitor the delivery/ensure that success is measured.
 - Steering Committee could be acting as Ethics Committee to ensure compliance with national rules and international best practice

Breakout Session 3: Governance

- **Structure of distributed Nodes**
 - Responsibility to deliver in the hands of the Head of Node: Nodes should be able to choose a suitable legal framework within the applicable domestic rules
 - Head of Node has to inform the ELIXIR Hub about structure
 - Hub should not be responsible for inter-Node problems
 - best practice/obligation: legally enforceable agreement at Node level so that Head of Node can provide quality assurance
 - agreement at Node level: lay out responsibilities, rights and obligations of distributed Nodes and Head of Nodes

Breakout Session 4: Liability and risk

- Valuable to have template agreement that covers all modes of collaboration within ELIXIR (Node-Hub, Node-Node, ...)
- Note that when Hub provide services it also covered by following requirements
- Core principle is that each party is responsible for own actions, actions of it's employees and keep other parties to ELIXIR protected
 - E.g. up to node to take out insurance if they so wish
- Declarative clause on operation in line with national legislation etc
- Note that Reputational risks (eg data protection) is shared by all parties
- Template need to cover joint deliveries and how risk / liability is apportioned
- It will be important, and useful, to have standardized disclaimer and take-down notices

Breakout Session 4: Liability and Risk

- Intellectual Property infringements
 - Need to warrant ownership and freedom to operate
- Personal data protection
 - Reputational, legal and financial risks
- Minimizing risk
 - How much do we require / prescribe quality assurance systems
 - Erroneous and data-loss scenarios?
 - Recognize that this is regulated by other bodies and national legislation / minimal technical standards
 - Disclaimers
- Commissioned service?
 - Mechanism to catch scenario where number of nodes require / jointly deliver service

ELIXIR COLLABORATION AGREEMENT
BETWEEN THE EUROPEAN MOLECULAR BIOLOGY LABORATORY
AS PART OF AND MANDATED BY THE ELIXIR CONSORTIUM
AND THE (...)
IN ORDER TO ESTABLISH AN ELIXIR NODE

Table of Contents

| | |
|--|----|
| 1. Preamble | 5 |
| 2. Definitions | 6 |
| 3. Purpose of the Agreement | 9 |
| 4. Status as ELIXIR Node | 9 |
| 5. Provision of Services by the Node | 10 |
| 5.1 Types of Services | 10 |
| 5.2 The Service Delivery Plan | 10 |
| 5.3 The Commissioned Service Contract..... | 11 |
| 6. Internal Quality Assurance System | 12 |
| 7. Access by Users..... | 12 |
| 7.1 Training..... | 12 |
| 7.2 Terms of Use..... | 12 |
| 7.3 Breach of User Agreement..... | 12 |
| 7.4 Refusal of access..... | 13 |
| 7.5 Publication policy | 13 |
| 7.6 Usage of the ELIXIR label/logo | 13 |
| 8. Confidentiality | 13 |
| 8.1 Confidentiality against third parties..... | 13 |
| 8.2 Exceptions..... | 13 |
| 8.3 Term of confidentiality clause | 14 |
| 9. Provision of Services by the ELIXIR Hub | 14 |
| 10. Governance..... | 14 |
| 10.1 Head of Node | 14 |
| 10.1.1 Appointment of the Head of Node..... | 14 |
| 10.1.2 Role and tasks of the Head of Node..... | 14 |
| 11.2 Steering Committee..... | 15 |
| 11.2.1 Composition..... | 15 |
| 11.2.2 Role and tasks of the Steering Committee..... | 15 |

ELIXIR Collaboration Agreement _ Version sent out to WG

| | | |
|--------|--|----|
| 11.2.3 | Meetings of the Steering Committee | 16 |
| 12. | Evaluation of the ELIXIR Node | 16 |
| 12.1 | Evaluation by the Scientific Advisory Board..... | 16 |
| 12.2 | Evaluation by the Ethics Advisory Board | 16 |
| 13. | Liability | 16 |
| 14.1 | Background Warranties..... | 17 |
| 14.2 | Liability | 17 |
| 14.3 | Indemnities | 17 |
| 14.4 | Publications | 17 |
| 14.5 | Inventions | 18 |
| 15. | Ethics | 18 |
| 16. | Term and Termination of the Agreement | 18 |
| 16.1 | Term of the Agreement | 18 |
| 16.2 | Termination by the ELIXIR Node | 18 |
| 16.3 | Termination by ELIXIR Hub | 19 |
| 16.4 | Requirements for renewal of the Agreement | 19 |
| 17. | General Provisions..... | 20 |
| 17.1 | Inconsistencies and severability | 20 |
| 17.2 | Notices..... | 20 |
| 17.3 | Amendments..... | 20 |
| 17.4 | Assignment..... | 20 |
| 18. | Governing Law | 20 |
| 19. | Settlement of Disputes..... | 20 |
| | Annex 1 – Service Delivery Plan | 22 |
| | Annex 2 – Commissioned Services Contract | 23 |
| | Annex 3 – ELIXIR Programme..... | 24 |
| | Annex 4 – Key Performance Indicators | 25 |
| | Annex 5 – ELIXIR Ethics Policy | 26 |

This ELIXIR Collaboration Agreement is made by and between:

The EUROPEAN MOLECULAR BIOLOGY LABORATORY (EMBL) as part of and mandated by the ELIXIR Consortium, hosting the ELIXIR Hub located at EMBL's Outstation the European Bioinformatics Institute (hereinafter referred to as "EMBL-EBI"), located on the Wellcome Trust Genome Campus in Hinxton, UK, Cambridgeshire CB10 1SD, represented by Dr. Niklas Blomberg, ELIXIR Director,

Hereinafter called "**the ELIXIR Hub**"

and

in case of a single Node:

[Name of Institute], based in [location], represented by [...]

in case of a distributed Node:

1. Alternative: [Name of the lead institute, "acting on behalf of" or "as mandated by"], based in [location], represented by [...];
2. Alternative: [Name of the legal entity that assembles all institutes involved], based in [location], represented by [...];
3. Alternative: [Names of institutes involved], based in [locations of all institutes], represented by [representative of each institute].

Hereinafter called "**the [name of the country, e.g. UK] ELIXIR Node**"

Also called the "Party" or the "Parties"

1. Preamble

The Parties hereby agree to conclude a Collaboration Agreement (hereinafter referred to as “the Agreement”) within the framework of the “*European Life-Science Infrastructure for Biological Information*” (**ELIXIR**), a research infrastructure organized in the form of a central hub and distributed nodes, which shall operate, manage and sustain, in the widest sense of these terms, an interlinked collection of biological data resources, tools and literature. ELIXIR is a research infrastructure of global significance and open to scientists of all disciplines.

The Parties,

- acknowledging that ELIXIR is a distributed research infrastructure whose Hub was established by the ELIXIR Consortium Agreement and is located at EMBL’s outstation, the European Bioinformatics Institute on the Wellcome Trust Genome Campus in Hinxton, Cambridge, UK;
- acknowledging that EMBL as host of the ELIXIR Hub acts as a Party to this agreement as mandated by the ELIXIR Consortium;
- acknowledging that the collaboration between the ELIXIR Hub and an ELIXIR Node takes place within the framework set by the ELIXIR Consortium Agreement, involving in particular a previous and successful application and approval to be considered an ELIXIR Node by the ELIXIR Board;
- acknowledging that the ELIXIR infrastructure combines data, compute, training, tools and standards, all of which comprise services provided by ELIXIR;
- acknowledging that ELIXIR Nodes receive all possible support, which is necessary for the successful delivery of their services, through the ELIXIR Hub to the extent that it falls within the limits of its mission;
- acknowledging that the ELIXIR Nodes will collaborate in their delivery of services in order to achieve the best quality of services;
- recognising the role of the ELIXIR Member States in providing the necessary means for the establishment and operation of ELIXIR Nodes;
- recognising that the ELIXIR Hub and the ELIXIR Nodes are striving for a sustainability of funding for the provision of their services based on the service strategy as established in the ELIXIR Programme;
- recognising that ELIXIR’s challenges can best be addressed by combining European and national operations;
- recognising that data and knowledge provided by ELIXIR will be freely accessible, although controlled access shall be implemented where necessary; recognising the need for extensive training in general areas of data resources and bioinformatics infrastructures.

Agree as follows

ELIXIR Collaboration Agreement _ Version sent out to WG

2. Definitions

Any word(s) or expression(s) appearing in this Collaboration Agreement shall have the meaning ascribed to them in this Agreement.

Additional Services Technical and administrative Services that fall under the administrative and financial responsibility of the Node and that become part of the Service Delivery Plan, which is part of Annex 1 of this Agreement; the terminology is used in accordance with Art. 8.5.2 ECA.

Agreement The ELIXIR Collaboration Agreement.

Application Process Application process as outlined in Art. 8.1 ff. ECA.

Background [to be added by EMBLEM]

Commissioned Services Technical and administrative services that fall under the responsibility of the ELIXIR Hub and are funded through the ELIXIR Budget as outlined in Art. 8.6 ECA.

ECA The ELIXIR Consortium Agreement.

Effective Date The Agreement shall be deemed effective when executed by both Parties whose signature is provided for on the signature pages hereof.

ELIXIR Board A body established according to Art. 6.2 ECA and which is composed of representatives of ELIXIR's members. It is ELIXIR's principal decision-making body as defined in Art. 6.2 ECA.

ELIXIR Budget This comprises all planned revenues and expenditures for the ELIXIR Hub which shall be prepared annually by the ELIXIR Director, taking into account the Financial Plan and its activities as defined in the ECA.

| | |
|----------------------------------|--|
| ELIXIR Hub | The central organisation coordinating ELIXIR, acting through and under the supervision of the ELIXIR Board and the leadership of the ELIXIR Director. It shall provide administrative and technical services for ELIXIR as established under the ECA. It shall use EMBL's legal personality as mandated by the ELIXIR Consortium. |
| ELIXIR Member State | Any State that is a signatory to the ELIXIR Consortium Agreement. |
| ELIXIR Node | A national or international research institute or a group of distributed national or international research institutes in one Member State [list alternatives] acting as or through one single legal entity entering into a Collaboration Agreement with the EMBL to provide services with a European dimension and that have an added value for ELIXIR. |
| ELIXIR Programme | Five year scientific programme adopted by the ELIXIR Board defining the scientific goals of ELIXIR and establishing the steps to achieve them (in accordance with the ECA hereinafter "Programme"). |
| EMBL | The European Molecular Biology Laboratory. |
| EMBL-EBI | The European Bioinformatics Institute, an outstation of the EMBL. |
| Scientific Advisory Board | A body established according to Art. 6.4 ECA and which is composed of independent scientists that oversee the quality of the ELIXIR activities as supervised by the ELIXIR Board and ELIXIR Director, and carried out by the ELIXIR Nodes and the ELIXIR Hub. |
| Services | All services, additional and commissioned, provided by the ELIXIR Nodes and the ELIXIR Hub including associated activities and investment necessary to properly deliver the services, such as |

the provision of equipment, personnel and/or training.

Service Delivery Plan

The Service Delivery Plan outlines the services for the duration of this Agreement. It is the result of an application process according to Art. 8.1 to 8.4 ECA during which the SAB reviews an application including a detailed description of sustainable services, which is approved by the ELIXIR Board. The scientific proposal as part of the application becomes the Service Delivery Plan which shall become part of this Agreement.

User

Any individual or group of individuals, in academia and industry, that has access to the ELIXIR Services and uses them for research purposes.

3. Purpose of the Agreement

The purpose of this agreement is to define the relationship between the ELIXIR Hub and the ELIXIR Node, in particular the ELIXIR Node's rights and responsibilities towards the ELIXIR Hub [and other ELIXIR Nodes] within the framework of the ECA.

This Agreement is not intended, and nothing contained herein shall be deemed, to create any partnership, agency or joint venture amongst the Parties or any of the Parties, nor to establish any other legal entity constituted amongst any or all of the Parties, unless all Parties have agreed and expressly stated their intention otherwise.

4. Status as ELIXIR Node

Following the successful selection process to become an ELIXIR Node as described in the ECA¹ and by concluding this agreement the [national institute/name of units of the institute/multiple research institutes or units thereof] is/are granted the status of an ELIXIR Node for the duration of this agreement (hereinafter called **the [name of the country, e.g. UK] ELIXIR Node**).

OR (in the case of a distributed Node in one Member State):

A distributed ELIXIR Node may choose to adopt any legal structure within the respective domestic laws and regulations which provides one legal entity, which is represented by the Head of Node, with a mechanism to enforce its obligations. Possible legal concepts include, but are not limited to, a company or association model and the formation of a consortium agreement.

Following the successful application to become an ELIXIR Node as described in the ECA² and by concluding this agreement the

Alternative 1: [Name of the lead Institute, "acting on behalf of" or "as mandated by" the Consortium xyz], based in [location], represented by [...]; or

Alternative 2: [Name of the newly established legal entity that assembles all institutes that form the ELIXIR Node], based in [location], represented by [...]; or

Alternative 3: [Name of each Institute involved], based in [location of each Institute], represented by [representative of each institute]

¹ Art. 8.1 to 8.4 in connection with Art. 6.2.4 n. and Art. 8.5.

² Art. 8.1 to 8.4 in connection with Art. 6.2.4 n. and Art. 8.5.

is/are granted the status of one single ELIXIR Node for the duration of this agreement, (hereinafter called **the [name of the country, e.g. UK] ELIXIR Node**).

5. Provision of Services by the Node

5.1 Types of Services

The Nodes provide technical and administrative services to the bioinformatics community. Depending on the source of funding the services either qualify as Additional Services (as described in the Service Delivery Plan in **Annex 1**) or Commissioned Services (as described in the Commissioned Service Contract in **Annex 2**).

5.2 The Service Delivery Plan

5.2.1 The Service Delivery Plan includes Additional Services that fall under the administrative and financial responsibility of the Node.

5.2.2 The Service Delivery Plan defines

- a. the nature of the Additional Services to be delivered, , [optional in case of Node-Node collaboration: and depending on what has been agreed, also services to other Nodes],
- b. the dependencies and complementarities of services in the case of a collaboration involving several ELIXIR Nodes,
- c. the timeliness of Additional Services,
- d. the quality of Additional Services,
- e. the quality assurance system established by [the Node] and how the Additional Services will be evaluated,
- f. the long term plans for service life-cycle management, and
- g. the safeguards that ensure that [the Node] continues to be able to fund and fulfil its obligation to deliver Additional Services.

5.2.3 The Service Delivery Plan may be revised and amended, if

- a. either of the Parties to this Agreement make an application for a change of the Service Delivery Plan explaining the need for the proposed changes [which are required to address changes that could not have been foreseen when the Service Delivery Plan was adopted] with a notice period of [●] months, and
- b. the Scientific Advisory Board approves of the proposed changes, and
- c. the ELIXIR Board accepts to adopt the changes into the Service Delivery Plan.

5.2.4 The Service Delivery Plan is valid until

- a. this Agreement is terminated in accordance with article 8.8 of the ECA, or
- b. the Parties, in the process of revising this Service Delivery Plan, have failed to reach an agreement and have served notice within a period of no less than [●] months.

5.3 The Commissioned Service Contract

5.3.1 The ELIXIR Board may commission technical or administrative services from the Node that would normally fall under the responsibility of the Hub.

These services will be funded through the ELIXIR Budget, subject to the provision and receipt of sufficient funding from the ELIXIR Budget (Commissioned Services).

5.3.2 The annexed Commissioned Service Contract describes those Commissioned Services that [the Node] shall deliver to the ELIXIR Hub, or to other Nodes or to third parties subject to previous evaluation by the Scientific Advisory Board and approval by the ELIXIR Board.

5.3.3 The Commissioned Services Contract defines

- a. the nature of the services to be delivered,
- b. the dependencies and complementarities of services in the case of a collaboration involving several ELIXIR Nodes,
- c. the timeliness of the services,
- d. the quality of services,
- e. the quality assurance system [the Node] has established,
- f. terms and conditions of evaluation of services, and
- g. the long term plans for service life-cycle management
- h. the safeguards that will ensure that [the Node] continues to be able to fund and fulfil its obligation to deliver Commissioned Services.

5.3.4 [The Node] is required to provide a report that makes the allocation of funds in its delivery of the Commissioned Services transparent for all ELIXIR Members.

5.3.5 The Commissioned Services Contract may be revised and amended, if

- a. either of the Parties to this Agreement make an application for a change of the Commissioned Services Contract explaining the need for the proposed changes [which are required to address changes that could not have been foreseen when the Service Delivery Plan was adopted] with a notice period of [●] months, and
- b. the Scientific Advisory Board approves of the proposed changes, and

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- c. the ELIXIR Board accepts to adopt the changes into the Commissioned Services Contract.

5.3.6 The Commissioned Services Contract will be valid until

- a. this Agreement is terminated in accordance with article 8.8 of the ECA, or
- b. the parties, in the process of revising Commissioned Services Contract, fail to reach an agreement, and have served notice within a period no less than [●] months.

6. Internal Quality Assurance System

Complementary to the quality assurance through the SAB, the ELIXIR Node is responsible to implement internal quality assurance mechanisms and systems in order to ensure that the Additional and Commissioned Services provided within ELIXIR meet the high quality standards required.

7. Access by Users

7.1 Training

The Node will provide for the basic training or support it deems necessary in the use of Services provided by the node as described in the Service Delivery Plan and the Commissioned Services Contract.

7.2 Terms of Use

The Node will provide clear terms of use for services. The Terms of Use should contain at least the following aspects such that they are clear on the part of the User:

- a. to be aware of the Node's IP and Data policies;
- b. to comply with ELIXIR guidelines and policies as approved by the ELIXIR Board;
- c. to ensure agreement by the User to obtain all necessary consents and to comply with all relevant ethical guidance, also providing sufficient information to the host Centre to allow a full and proper evaluation of safety and ethical risks; and
- d. to ensure the User's responsibility for any loss, damage or injury as a result of his/her failure to comply with the Node's Health & Safety policies and procedures and as a result of wilful behaviour.

7.3 Breach of User Agreement

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The Node will report to the ELIXIR Director any breaches by a User of its agreement, or any misuse of the ELIXIR-related Services.

7.4 Refusal of access

The ELIXIR Node shall not refuse access to individual users unless it has reasonable grounds to do so.

7.5 Publication policy

Publication and presentation of results arising from ELIXIR related Services that were carried out at the Node will acknowledge appropriately ELIXIR and the use of ELIXIR Services.

7.6 Usage of the ELIXIR label/logo

Services that are part of the Service Delivery Plan and the Commissioned Services Contract may be labelled as “ELIXIR Services” by the [name of the country] Node. Services that are part of the ELIXIR Programme may be labelled as “ELIXIR Services” by the ELIXIR Hub.

Neither Party shall use ELIXIR’s name [trademark?] or logo in any press release or product advertising, or for any other commercial purpose without the prior written consent of the ELIXIR Director, as mandated by the ELIXIR Board.

8. Confidentiality

8.1 Confidentiality against third parties

Each Party is committed to confidentiality against third parties for all information and objects that have not been published and are conveyed in confidence by the other Party. The receiving Party shall not use any such information and objects for any purpose other than in accordance with the terms of the Agreement. The disclosure of confidential information or objects requires written agreement by the other Party.

8.2 Exceptions

The confidentiality clause mentioned above under Paragraph 11.1 excludes:

- a. Objects or types of information which have been developed or are being developed by the receiving Party independent of the information;
- b. Objects or types of information which are part of the generally accessible state of technology or which reach this status without the fault of the receiving Party;

- c. Objects or types of information which were already in the possession of the receiving Party at the time of the announcement or
- d. Objects or types of information which were lawfully disclosed to a partner from a third party who is in lawful possession thereof without any commitment to confidentiality.
- e. Objects or types of information which is needed to be communicated to comply with applicable laws or with a court of administrative order.

8.3 Term of confidentiality clause

The above-mentioned confidentiality clause ends five years after the termination of this Agreement [or the respective Scientific Delivery Plan or Commissioned Services Contract], depending on which ends later. The Parties shall impose the same confidentiality on all of their affiliates and subcontractors, their employees and any other personnel working for them, who may have access to confidential information.

9. Provision of Services by the ELIXIR Hub

The ELIXIR Hub's general obligations with respect to all ELIXIR Nodes are described in general terms in Art. 3.3. ECA. The ELIXIR Hub's obligations to provide technical and administrative services to the whole bioinformatics community and to the [name of the country] Node in particular is part of the ELIXIR Programme, as evaluated by the Scientific Advisory Board and adopted by the ELIXIR Board and annexed to this Agreement [Annex 3].

10. Governance

10.1 Head of Node

10.1.1 Appointment of the Head of Node

The ELIXIR Node appoints a Head of Node.

10.1.2 Role and tasks of the Head of Node

The Head of Node is the strategic contact point for the ELIXIR Board and the ELIXIR Director in all matters related to this Agreement and has full representative authority to act on behalf of the Node and/or on behalf of all research institutes involved in the distributed Node. The tasks of the Head of Node include, but are not limited to the following:

- a. Ensure and coordinate the delivery of all services provided by the Node as established by the annexed Service Delivery Plan.
- b. Become a member of the Heads of Nodes Committee as established by the ECA and participate in related meetings.
- c. Become a member of the Steering Committee as established by this Agreement and participate in its meetings.
- d. Ensure smooth information exchange related to ELIXIR both internally within the Node and towards the ELIXIR Hub. In the case of a distributed Node, the Head of Node informs the ELIXIR Director of the legal structure of the Node. The Head of Node reports any collaboration agreements with other Nodes within ELIXIR to the ELIXIR Director.
- e. Ensure the compliance of the Node [and all involved national research institutes] with the ELIXIR Ethics Policy, national regulations and international best practice.
- f. Ensure compliance with the User Access Policy as adopted by the ELIXIR Node.
- g. Oversee the internal quality assurance mechanism the Node has adopted.
- h. Assist the Scientific Advisory Board in carrying out the scientific evaluation of the Node.
- i. Assist the Ethics Advisory Board in carrying out the ethical evaluation of the Node.

11.2 Steering Committee

11.2.1 Composition

The Steering Committee is established by the Parties and comprises the ELIXIR Director, the Head of Node and other individuals appointed by them.

11.2.2 Role and tasks of the Steering Committee

The Steering Committee ensures a regular exchange of information, joint coordination and monitoring of tasks and responsibilities of the Parties within an agreed schedule. The tasks of the Steering Committee include, but are not limited to the following:

- a. Identify key performance indicators and establish target values to be used for the assessment of the service delivery of the Nodes in accordance with the Service Delivery Plan and the Commissioned Services Contract;
- b. Monitor the implementation of the Service Delivery Plan and the Commissioned Services Contract and measure the progress of the ELIXIR Node by applying the established key performance indicators and target values;

- c. Review the ELIXIR Node's allocation of funds for the purposes of providing Commissioned Services in accordance with the Commissioned Services Contract;
- d. Monitor the compliance of the ELIXIR Nodes with the ELIXIR Ethics Policy.

11.2.3 Meetings of the Steering Committee

The Steering Committee shall meet at least once a year as well as at any reasonable request of any of the Parties, to follow-up and decide on all substantial issues that ensure the best implementation of the Service Delivery Plan and the Commissioned Services Contract. The Steering Committee shall establish rules of procedure.

12. Evaluation of the ELIXIR Node

12.1 Evaluation by the Scientific Advisory Board

The ELIXIR Node shall be evaluated by the Scientific Advisory Board [as determined by the ELIXIR Board]. Upon recommendation of the Scientific Advisory Board the ELIXIR Board shall decide whether it wishes to renew or terminate this Agreement (in whole or in part) with the ELIXIR Node.

12.2 Evaluation by the Ethics Advisory Board

The ELIXIR Node shall also be evaluated by the Ethics Advisory Board [as determined by the ELIXIR Board/in the same intervals as by the Scientific Advisory Board]. Upon recommendation of the Ethics Advisory Board, the ELIXIR Board shall decide whether it wishes to renew or terminate (in whole or in part) this Agreement with the ELIXIR Node.

13. Liability

The Parties confirm that they will operate in line with any applicable national rules and regulations. They will hold each other liable only for wilful injury or gross negligence. The same rule applies with respect to damage suffered by delegated personnel during the time of their delegation. Damage suffered by third parties will be borne by the Party whose personnel are responsible for it.

In the event that two or more Nodes undertake to jointly provide Services to the Hub, the Nodes are jointly and severally liable for any damage suffered by the ELIXIR Hub in relation to the Services provided unless stated otherwise in individual agreements between the respective Nodes.

14. Intellectual Property

14.1 Background Warranties

Each Party represents and warrants that it owns its Background and/or has the right to grant the licenses set out and contemplated herein. Each of the Parties will inform the Hub of any legal restrictions of which they are aware that may affect the use of their respective Background for the provision of services.

In respect of any Background, information or other materials supplied by one Party to another hereunder, the supplier Party shall be under no obligation or liability other than as expressly stated herein and no warranty condition or representation of any kind is made, given or to be implied as to the sufficiency, accuracy or fitness for purpose of such information or materials, or the absence of any infringement or any proprietary rights of third parties or the other Parties, by the use of such Background, information or other materials and the recipient Party shall in any case be entirely responsible for the use to which it puts such information and materials.

14.2 Liability

The respective other Parties cannot be held liable for acts or omissions committed by the Party performing work under the Collaboration Agreement. They shall not be liable for any defaults of any products or services created on the basis of knowledge resulting from the Collaboration, including, for instance, anomalies in the functioning and performance thereof, nor for claims of infringement of third party rights.

14.3 Indemnities

Each Party shall indemnify each other Party against all loss, damage or injury incurred by each such other Party resulting from any claim, complaint, proceeding or cause of action brought by a third party alleging or arising from (i) gross negligent or wilful misconduct or (ii) infringement of third party intellectual property rights by itself, its employees or its sub-contractors.

14.4 Publications

Any scientist shall give prior notice of any planned publication arising from ELIXIR-related activities including a set of the data to be published to the other Party at least 30 days before this information is made public. Any objection to the planned publication

shall be made within 25 days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted. Publications shall mention “ELIXIR”.

14.5 Inventions

The Parties agree that all intellectual property rights owned by a Party prior to entering the present Agreement shall remain the sole property of such Party. Inventions belong to the Party whose personnel have made them. Joint inventions belong to the Parties according to the intellectual contribution of the inventors. The inventors will lay down their contributions in an invention record and the Parties, as the case may be, will agree in writing in each case on the procedures for the management of the intellectual property, the commercial exploitation and the sharing of cost and revenue.

15. Ethics

Services delivered under this Agreement shall be in line with relevant laws and regulations and that consider best practices as well as with the Ethics Policy adopted by the ELIXIR Board. The ELIXIR Hub shall remind the ELIXIR Node of its obligation to ensure compliance of all relevant laws and regulations (and, where applicable, local ethical guidelines) when handling, storing, or processing personally identifiable data resulting from biomedical research.

The ELIXIR Node is responsible to implement its own Ethics Policy in order to ensure that the services provided within ELIXIR comply with the ELIXIR Ethics Policy and national rules and regulations as well as international standards of best practice.

16. Term and Termination of the Agreement

16.1 Term of the Agreement

The Agreement shall be effective as of the Effective Date and shall remain valid for a period of [●]. The Service Delivery Plan and the Commissioned Services Contract remain valid for the same period of time, unless they have been amended and/or terminated in accordance with clauses 5.2.3 – 5.2.4 and 5.3.5 – 5.3.6 of this Agreement.

16.2 Termination by the ELIXIR Node

The ELIXIR Node may terminate the Agreement at any time before the end of the term by giving at least twelve (12) months’ notice in writing to the ELIXIR Director.

16.3 Termination by ELIXIR Hub

The ELIXIR Hub, as mandated by the ELIXIR Board, may terminate the Agreement in case of a serious breach of the Agreement by the ELIXIR Node by giving at least three months notice in writing to the respective Head of Node.

The Agreement shall terminate immediately in the event that an ELIXIR Node ceases to comply with any one or more of the formal eligibility criteria as described in the ECA, which are the following:

- a. be or be part of a legal entity with legal personality under its domestic law, or in the case of multiple distributed research institutes with the status of one ELIXIR Node, to have created or appointed one accountable legal entity with legal personality under its domestic law;
- b. be located in an ELIXIR Member State and
- c. be able to demonstrate its financial sustainability in view of the activities it proposes to carry out for ELIXIR and as described in the Service Delivery Plan (Annex1) and the Commissioned Services Contract (Annex 2).

16.4 Requirements for renewal of the Agreement

The Agreement can be renewed by the Parties if the following cumulative conditions apply:

- a. Receipt of an evaluation of the Scientific Advisory Board that supports a continuation of the collaboration;
- b. Agreement by both Parties to renew the Agreement, which can be assumed once the Agreement would expire in less than six months before the regular end of the Agreement without any notice in writing from either Party to not renew the Agreement;
- c. The ELIXIR Node continues to fulfill formal eligibility criteria as described under 8.3.b. ECA.

17. General Provisions

17.1 Inconsistencies and severability

Should any provision of this Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Agreement. In such a case the parties to the Agreement will try amicably to agree on a new clause retrospectively which will substitute the invalid clause.

Any loopholes shall be closed by mutual agreement to fit the original intent of the Parties.

17.2 Notices

Any notice to be provided under this agreement shall be in writing to the registered addresses of the respective Head of Node or the ELIXIR Director.

17.3 Amendments

This Agreement may be amended in writing and by mutual consent of the parties.

17.4 Assignment

The rights and provisions detailed in this Agreement can be assigned only with prior approval of the other party

18. Governing Law

This Agreement shall be construed in accordance with and governed by the laws of England and Wales.

19. Settlement of Disputes

Any dispute, controversy or claim arising out of or in relation to this Agreement, or the existence, interpretation, application, breach, termination or invalidity thereof, which is not settled through the good offices of the Chair or Vice-Chair of the ELIXIR Board, shall be settled on the basis of the PCA Arbitration Rules 2012. The number of arbitrators shall be three. The language to be used in the arbitral proceedings shall be English.

The appointing authority shall be the Secretary-General of the Permanent Court of Arbitration. Each Party shall bear its own costs of arbitration. The arbitral tribunal may apportion its costs between the Parties if it determines that appointment is reasonable, taking into account the circumstances of the case.

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In witness whereof, the Parties have caused this Agreement to be executed by their duly authorised representatives as of the Effective Date.

[name of institute]

The EMBL as part of and mandated by the
ELIXIR Consortium, hosting the ELIXIR
Hub

Date [Name Name]

Date Niklas Blomberg

Annex 1 – Service Delivery Plan

Annex 2 – Commissioned Services Contract

Annex 3 – ELIXIR Programme

Annex 4 – Key Performance Indicators

Annex 5 – ELIXIR Ethics Policy