



## EXCELERATE Deliverable 14.1

<b>Project Title:</b>	ELIXIR-EXCELERATE: Fast-track ELIXIR implementation and drive early user exploitation across the life sciences
<b>Project Acronym:</b>	ELIXIR-EXCELERATE
<b>Grant agreement no.:</b>	676559
	H2020-INFRADEV-2014-2015/H2020-INFRADEV-1-2015-1
<b>Deliverable title:</b>	Data Quality Assurance Governance
<b>Ethics requirements</b>	POPD - Requirement No. 5
<b>Lead Beneficiary:</b>	1: EMBL (ELIXIR Hub)
<b>WP Title</b>	Belongs to WP12 Excellence in ELIXIR Management and Operations
<b>Contractual delivery date:</b>	31 August 2016
<b>Actual delivery date:</b>	31 August 2016
<b>Partner(s) contributing to this deliverable:</b>	ELIXIR partners

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## Table of contents

1. Executive Summary .....	3
2. Delivery and schedule.....	3
3. Adjustments made.....	3
<b>ELIXIR-EXCELERATE Quality Management Strategy .....</b>	<b>4</b>
1. Background.....	4
2. Scope .....	4
3. Definition of terms .....	4
4. Considerations.....	6
5. Quality Management Structure.....	7
6. Quality management processes and implementation plan .....	10
6.1. Plan Quality Management process.....	12
6.2. Creating a process improvement plan .....	14
6.3. Assigning roles and responsibilities.....	14
6.4. Perform Quality Assurance process .....	14
6.5. Control Quality process .....	15
7. Recommendations for the future ELIXIR-EXCELERATE Quality Policy .....	16

## 1. Executive Summary

This deliverable describes the ELIXIR-EXCELERATE Quality Management Strategy, addressing EXCELERATE Ethics requirement no. 5 on Data Quality Assurance Governance. The strategy describes the essential procedures and practices within ELIXIR-EXCELERATE concerning planning of quality management, performing quality assurance and controlling quality. It also depicts the overall organisation of ELIXIR with emphasis on authority and specific responsibilities related to quality assurance.

The definition of common processes and standards for the three main processes regarding the quality management (Planning, Assurance and Control) will facilitate the cooperation between the ELIXIR Nodes and will drive procedures to guarantee data quality and integrity.

The ELIXIR-EXCELERATE quality management strategy is compatible with the Project Management Body of Knowledge (PMBOK) practices and the International Organization for Standardization (ISO) standards, specifically ISO 9001:2015. The processes established will be iterated following the Plan-Do-Check-Act cycle, defined as the basis for quality improvement.

The Quality Management Strategy will be the foundation to drive the creation of an ELIXIR Quality Policy to be applied to the ELIXIR Services as the infrastructure grows and ELIXIR Services are established within the ELIXIR governance framework.

## 2. Delivery and schedule

The delivery is delayed:  Yes  No

## 3. Adjustments made

No adjustments were made.

# ELIXIR-EXCELERATE Quality Management Strategy

## 1. Background

ELIXIR's purpose is to help Europe's leading laboratories and data centres coordinate the collection, quality control and storage of biological information, and to ensure that these data are integrated and made accessible to all facets of the scientific community. ELIXIR's member states are committed to the provision of open-access data in the interests of advancing research in the life sciences.

The ELIXIR-EXCELERATE project proposal submitted to the call INFRADEV-3-2015 states that a final aim of the project is to safeguard the overall quality and integrity of the data generated and stored within Europe.

During the ethics review, the reviewers of the proposal asked

*“the independent expert Ethics Board to provide the Commission with a report on what quality control assurance processes and standards are being applied in ELIXIR-EXCELERATE to guarantee data quality and integrity (as this is at the center of whether the ELIXIR infrastructure adds value to the ERA)”.*

Based on this comment, a specific deliverable to describe the ELIXIR Quality Management Strategy was added to the project plan.

This deliverable describes the ELIXIR-EXCELERATE Quality Management Strategy. Such strategy includes not only details on the Quality Assurance Strategy, but also explains how the Quality Management will be planned and how the Quality Control will be carried out. The Quality Management Strategy will be the foundation to drive the creation of an ELIXIR Quality Policy to be applied to the ELIXIR Services. Consequently, future policy will affect all data generated and used in the five different ELIXIR service platforms (i.e. Data, Tools, Interoperability, Compute and Training).

## 2. Scope

The main aim of this deliverable is to describe the essential procedures and practices within ELIXIR-EXCELERATE concerning planning of quality management, performing quality assurance and controlling quality. It also depicts the overall organisation of ELIXIR with emphasis on authority and specific responsibilities related to quality assurance.

As stated in the Node Collaboration Agreement, the ELIXIR Nodes are responsible to implement internal quality assurance mechanisms and systems in order to ensure that Node-funded and Commissioned Services provided within ELIXIR meet the high quality standards requirements.

## 3. Definition of terms

The definitions below, some of them included in the ELIXIR Consortium Agreement<sup>1</sup>, shall be considered for the purpose of this deliverable.

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<sup>1</sup> ELIXIR Consortium Agreement, [https://www.elixir-europe.org/documents/elixir\\_consortium\\_agreement](https://www.elixir-europe.org/documents/elixir_consortium_agreement)

Agreement	The ELIXIR Collaboration Agreement including its annexes.
Commissioned Services	Technical and administrative services that generally fall under the responsibility of the ELIXIR Hub which are carried out by the ELIXIR Nodes and are funded through the ELIXIR Budget as outlined in ECA, Art. 8.6.
Commissioned Services Contract	The Commissioned Services Contract outlines the Commissioned Services for the duration of the Agreement as defined in ECA, Art. 8.6.
ECA	The ELIXIR Consortium Agreement.
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 Programme	The 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 referred to as "Programme".
EMBL	The European Molecular Biology Laboratory.
EMBL-EBI	The European Bioinformatics Institute, an outstation of the EMBL.
Industry Advisory Board	A body established to promote open innovation and cross-company research partnerships.
Node-funded 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 the Agreement; the term Node-funded Services has the same meaning as Additional Services as defined in ECA, Art. 8.5.2.
Scientific Advisory Board	A body established according to ECA, Art. 6.4, 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 labelled ELIXIR Services or ELIXIR Resources, Node-funded 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 Node-funded Services for the duration of the Agreement.
Terms of Use	Terms of service, which the ELIXIR Node is responsible to establish, and which all Users have to abide by when using ELIXIR Services.
User	Any individual or group of individuals, in academia and industry, that has access to and uses ELIXIR Services.

The following definitions make reference to terms used in the framework of Quality Management:

Control Quality	Quality Control is a procedure to ensure a certain level of quality in the project, product or result. The major function of Quality Control is measuring services to determine if they meet the quality standards. It also involves documenting the achievement of agreed-to requirements.
Indicator	A quantitative or qualitative variable that provides reliable means to measure a particular phenomenon or attribute.
Measure	A measure is a value that is quantified against a standard.
Metric	Aspects that have to be measured and compared against the baselines, being that quality standards or a business's own track record, to assess the quality of a plan, process or product. A metric can be a calculated or be a composite measure or quantitative indicator based upon two or more indicators or measures. Metrics help to put a variable in relation to one or more other dimensions.
Quality	Degree in which the characteristics of a product, project or result fulfil a set of requirements settled beforehand. If those characteristics meet all requirements, high or excellent quality is achieved but if those characteristics do not meet all requirements, a low or poor level of quality is achieved.
Quality Assurance	Quality assurance is a process that is performed while the work is being done. This process uses data gathered by the Control Quality process and verifies: If the quality requirements, organizational policies, and processes defined in Plan Quality Management are producing the results we intended; If based in our current knowledge, the work we planned is the right quality work to meet the requirements; If the procedures defined to fulfil the requirements are being followed; and if we can improve the way we are doing the work.
Quality Management	Quality Management ensures that a product or service is consistent. Quality Management includes three processes: Quality Planning, Quality Assurance, and Quality Control. Overarching these three processes is the concept of continuous improvement by planning, doing, checking and acting to improve the quality of a product or service.
Quality Planning	Quality Planning involves identifying which quality standards and requirements are relevant to the project, determining how to satisfy them, and documenting how will be demonstrated that the project complies with those.
Quality Standard	A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

## 4. Considerations

The Quality Policy to be developed will include a lightweight compliance check procedure, which will tie into related procedures already under development<sup>2</sup>.

The ELIXIR Collaboration Agreement highlights that every Node will deliver services considering the achievement of the best quality of services.

ELIXIR offers two types of services: Node-funded Services and Commissioned Services.

<sup>2</sup> E.g. Service Delivery Plans, Node Application reviews and Commissioned Service Contracts

The Service Delivery Plans defines the quality of the Node-funded Services and the internal quality assurance system established by the Node, and how the Node-funded Services are evaluated.

The Commissioned Services Contract will define the quality of the Commissioned Services, the internal quality assurance system established by the Node, and how the Commissioned Services will be evaluated.

The Head of Node is responsible of overseeing the internal quality assurance mechanism in place at the Node as far as it relates to the ELIXIR Service.

ELIXIR is committed to enabling open science by providing freely available online services, databases and software relating to data contributed from life-science experiments to the largest possible community, although controlled access shall be implemented where necessary.

ELIXIR recognises that, while data and knowledge provided by ELIXIR will be freely accessible, this does not mean that the use of data is unencumbered; restrictions on the use of data may arise due to legal, ethical, copyright or license considerations.

ELIXIR recognises that the purpose of many ELIXIR Services is to facilitate the open sharing of research data; they do not assume the ownership of the data but provide a platform where data owners can share their data with the community.

Every ELIXIR Service (i.e. Node-funded Services included in the Node Service Delivery Plan and Commissioned Services - either Implementation Studies or Infrastructure Services) involving personally identifiable or Sensitive Data must have a regulatory framework ensuring that these data are made available for research in a way that is compliant with all relevant (e.g. EU-level, national and local or internal) legal and ethical requirements.

ELIXIR Services participate in a multitude of research projects in both national and international settings that are governed by project-specific policies and codes. Such policies may impose additional requirements on ELIXIR Services that go beyond the scope of this strategy.

## 5. Quality Management Structure

The arrangements for quality management will complement, and be fully integrated with, the governance arrangements for other aspects of ELIXIR Services.

The ELIXIR-EXCELERATE quality management structure is the following:

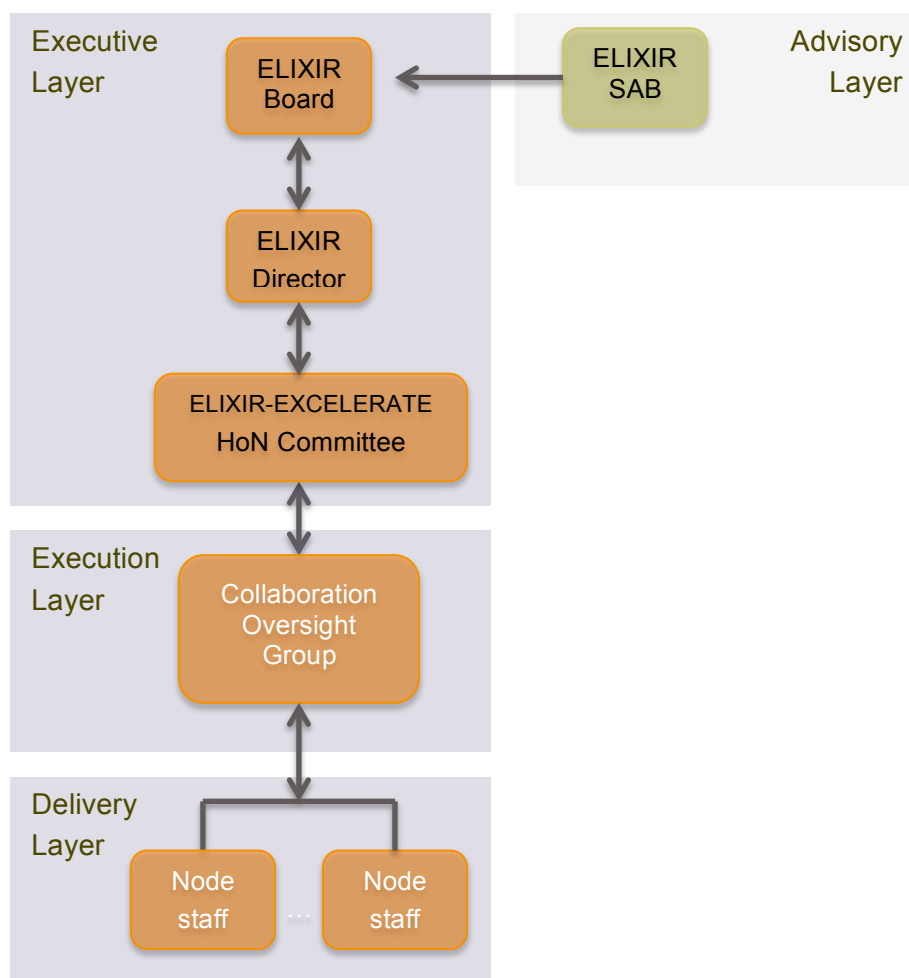


Figure 1. ELIXIR-EXCELERATE Quality Management Structure

The Quality Management Structure includes three main layers and a complementary layer (the Advisory layer). The model implies that each layer has roles and responsibilities that will enhance and streamline the overall effort to achieve a wide-trust quality system.

The **Executive layer** includes the leadership team. The leadership team involves the ELIXIR Board, the ELIXIR Director and the ELIXIR-EXCELERATE HoN Committee. The ELIXIR Director consults the ELIXIR-EXCELERATE HoN Committee to define the overall strategic objectives regarding quality. Afterwards, the ELIXIR Director submits the proposal to the ELIXIR Board seeking its approval and prioritization.

The leadership team is not involved in the day-to-day execution of the projects and activities, but is updated through specific reports on the overall performance.

Hence, the strategic plan is established at the Executive layer, and it takes into consideration the feedback that the Advisory layer (ELIXIR SAB and ELIXIR IAC) provides on specific matters.

The **Execution layer** receives the strategic plan developed by the Executive layer and



interprets it. It sets the foundation groundwork for solid requirements definition in support of the strategic plan. This layer can make adjustments to the day-to-day delivery performance and can define reporting requirements to the Delivery level resources.

The Collaboration Oversight Group forms the Execution layer. This group is established by the Parties and comprises the ELIXIR Director, the Head of Node and other individuals appointed by them.

In the **Delivery layer**, the day-to-day performance of the Services and activities are controlled and delivered to meet the strategic objectives. This layer is responsible for achieving the goals and results that have been defined by the upper layers. This is the layer where the work is being planned, constructed, tested, deployed and delivered. The Delivery layer is composed of the staff from the different Nodes.

In order to foster a clear understanding, below is the definition of the ELIXIR-EXCELERATE governance bodies, the collaboration oversight group, and advisory bodies present in the different layers of the quality management structure:

**ELIXIR Board:** The ELIXIR Board is ELIXIR's ultimate decision-making body representing the ELIXIR Member States and ELIXIR Member organisations. The ELIXIR Board consists of administrative and scientific delegates and oversees the financial and scientific execution and impact of ELIXIR considering, as appropriate, advice from the two advisory groups SAB and IAC.

**ELIXIR Director:** The ELIXIR-EXCELERATE Project Coordinator (Niklas Blomberg, ELIXIR Director), is the legal entity acting as the intermediary between the Parties and the Funding Authority. The Project Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and the Consortium Agreement such as overall reporting and financial management of the project.

**ELIXIR-EXCELERATE Heads-of-Nodes Committee:** The Heads-of-Nodes (HoN) Committee is comprised of one senior representative per Node and is the legal decision-making body for the project. The HoN Committee will be responsible for decisions on overall financial management and resourcing, changes to project structure and approval of additional partners. The Project Coordinator chairs the Committee. The Committee shall be quorate if two-thirds or more of its members are present or represented. Where necessary, decisions can be passed by written procedure. The HoN committee will meet quarterly with two face-to-face meetings annually organised alongside other meetings. Thus the Head-of-Nodes group, chaired by the ELIXIR Director, will act as the project Executive Board, the supervisory body for the execution of the Project. In the context of ELIXIR-EXCELERATE it will report to the General Assembly and is accountable for overall delivery to the ELIXIR Board through reports and annual SAB review.

**Collaboration Oversight Group:** it is established to ensure a regular exchange of information, joint coordination and monitoring of tasks and responsibilities of the Parties. It may propose and initiate subsequent steps to further the collaboration of the ELIXIR Hub and ELIXIR Node. The rights and obligations of the ELIXIR Director and the Head of

Nodes remain unaffected by the decisions of the Collaboration Oversight Group.

The Collaboration Oversight Group shall:

- Identify key performance indicators and establish target values which may be used for the assessment of the service delivery of the Nodes in accordance with the Service Delivery Plan and the Commissioned Services Contract;
- 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;
- Review the ELIXIR Node's allocation of funds for the purposes of providing Commissioned Services in accordance with the Commissioned Services Contract; and
- Monitor the compliance of the ELIXIR Nodes with the ELIXIR Ethics Policy.

**ELIXIR Scientific Advisory Board (SAB):** The fully independent SAB combines the expertise of world-renowned experts to provide scientific strategic feedback to the ELIXIR Board. The SAB has played an integral role in reviewing the Node applications of each participating Node and will provide recommendations for the scientific strategy of the ELIXIR-EXCELERATE project. The ELIXIR SAB includes experts in the biological and biomedical life science area whose backgrounds cover science and industry and are elected by the ELIXIR Board. The SAB meet in person once a year in winter and hold one teleconference in summer. They provide direct feedback to the ELIXIR Board.

ELIXIR also counts with an ELIXIR Industry Advisory Committee (IAC) that will also be considered as stakeholder to define the quality requirements even if it is not part of the ELIXIR-EXCELERATE Quality Management Structure.

## 6. Quality management processes and implementation plan

The ELIXIR-EXCELERATE quality management strategy is compatible with the PMBOK<sup>3</sup> practices and the International Organization for Standardization (ISO) standards, specifically ISO 9001:2015<sup>4</sup>.

Quality management includes all the processes that organizations use to direct, control, and coordinate quality. These processes include quality planning, quality control and quality assurance. The activities developed by these processes and a proposed implementation plan is described below:

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<sup>3</sup> A Guide to the Project Management Body Of Knowledge (PMBOK® GUIDE) Fifth Edition, An American National Standard ANSI/PMI 99-001-2013, ISBN: 978-1935589679.

<sup>4</sup> Implementing ISO 9001:2015, Jan Gillet (Author), Paul Simon (Contributor), Susannah Clarke (Contributor), ISBN: 978-1908984500.

Processes	Actions	Implementation Plan
Plan Quality Management	<ul style="list-style-type: none"> <li>▪ Determine quality requirements and standards.</li> <li>▪ Define processes and metrics.</li> <li>▪ Create process improvement plans.</li> <li>▪ Determine all roles and responsibilities.</li> </ul>	2016-2017
Perform Quality Assurance	<ul style="list-style-type: none"> <li>▪ Follow processes.</li> <li>▪ Determine if processes are correct.</li> <li>▪ Perform quality audits (internal or external inspections).</li> </ul>	2017-2019
Control Quality	<ul style="list-style-type: none"> <li>▪ Measure performance against defined metrics.</li> <li>▪ Analyse and evaluate performance.</li> <li>▪ Influence the factors that cause variations versus the desired metric values.</li> <li>▪ Determine if variances warrant a corrective action or a change request.</li> <li>▪ Request changes.</li> <li>▪ Perform quality control.</li> </ul>	2017-2019

Figure 2. ELIXIR-EXCELERATE Quality Management Processes, action and implementation plan.

Following the framework, we will first plan the quality processes, policies, techniques, methods, and metrics. Then, using the tools in quality control, we will measure the results by using the identified tools, techniques, and methods to see whether they comply with the identified metrics. In quality assurance, we are going to identify whether the process is working and also if there are ways to improve it.

Hence, the difference between the three processes is clear. Plan Quality Management helps to determine which are the procedures, tasks and who is to be responsible of them. Control Quality involves that the team developing the services gathers measures that later will be compared with the defined metrics and its thresholds. Finally, Quality Assurance verifies if the processes planned are producing the expected result (i.e. the expected quality measures).

The different processes are iterated and have a clear relation with the quality model defined by the Plan-Do-Check-Act cycle, defined as the basis for quality improvement by the quality theorist Shewhart<sup>5</sup> and modified by Deming<sup>6</sup>.

<sup>5</sup> Shewhart, Walter Andrew (1939). *Statistical Method from the Viewpoint of Quality Control*. New York: Dover. ISBN 0-486-65232-7

<sup>6</sup> Deming, W. Edwards (1964) [1943]. *Statistical Adjustment of Data*. Dover. ISBN 0-486-64685-8

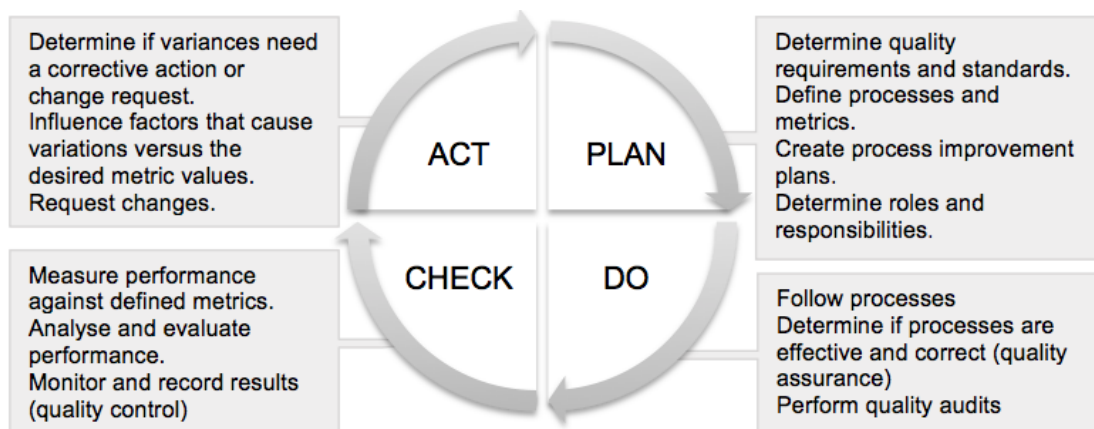


Figure 3. Continuous improvement cycle mapping actions of the quality management processes

## 2.1 Plan Quality Management process

The objectives of planning the quality management are to determine the requirements and the standards that may be applicable, define the metrics that are going to be measured and checked to assess the quality of the services, determine the processes that are going to be followed, create a plan that will allow to improve the processes and determine roles and responsibilities between the team.

### Determining the requirements and standards

Since ELIXIR provides services that are grouped in five different platforms (Data, Interoperability, Compute, Tools and Training), the requirements and the applicable standards will be selected taking into account the feedback and input provided by the Platform leadership teams and all the relevant stakeholders. Moreover the particularities of each type of service will be considered.

To identify all the requirements that have to be considered, we will need to have a register with all the stakeholders that will be affected or will affect the quality of the services. Also we will consider the risk register, a list of all the identified risks (being that opportunities and threats) that may affect the services and its estimated probability to occur in addition to its possible impact. Moreover, we will take into account the required standards (e.g. the acceptable waiting time for users accessing a database) and practices as well as organizational policies (such as the ELIXIR Ethics Policy) and procedures.

### Defining quality metrics

The quality metrics describe service aspects that have to be measured and how they have to be measured during Control Quality. The service aspects that will be measured will include those identified by the relevant stakeholders, e.g. those linked to provide value to the users, the scientific excellence and the service performance among others.

The measures of the different metrics will be compared with the standards and requirements settled, and they depend on the nature of the diverse ELIXIR services.

The Platforms identified indicators that include some of the basic quality metrics. As example, the ELIXIR Core Data resources (Task 3.1 of ELIXIR-EXCELERATE WP3), identified the next indicators:

- The resource has an international independent Scientific Advisory Board
- The resource has a legal framework (e.g. license, or public statement of open terms of use)
- The resource has a public privacy policy
- The data resource provides persistent and unique identifiers
- Data throughput of the resource
- Resource uptime (availability) per year
- Response times of key webpages of the resource
- The data resource uses recognised standards for metadata and data (such as MIMEA, JATS, INSDC features, or ontologies)
- The data resource provides access to scientific literature for origin of facts or context (data provenance)
- The data resource is available via a website/APIs/FTP/TripleStore
- The data resource is available in text/FASTA/XML/Dublin Core/tsv/JSON
- The resource offers a helpdesk
- The resource seeks users' community input into service design decisions and
- The resource takes into account user input into service design decisions
- The resource takes into account data governance
- The resource takes into account data models
- The resource undertakes training activities with the users' community

It must be noted that the metrics that will be considered as indicators for the quality of ELIXIR Core Resources are only providing an example. Not all the metrics will be equally applicable across all resources. Every resource will have a specific set of metrics to be measured and the value they offer to the end users will be considered.

### **Shaping the processes**

The processes to be created or adapted will compile all the work necessary to meet the defined standards, since the standards help us to define the thresholds of acceptable quality.

For example, we will develop quality checklists that will include a list of items to inspect and that the service may offer, or a list of steps to be performed while providing the service. It will be used during the Control Quality process when checking the quality of the services delivered.

We can also define checksheets that will be used during the Control Quality process and that will help us to record data regarding quality problems and how often a particular defect occurs (e.g. the number of times that the server does not respond to user

requests).

## 2.2 Creating a process improvement plan

The metrics and control limits will be used to guide the process improvement efforts of the service delivery. For example, we can include targets for improved performance based on the feedback of users, or the needs of dependent services.

Moreover, the processes defined to achieve the defined quality standards have to be reviewed to improve service performance. The process improvement plan will define how they will be checked.

## 2.3 Assigning roles and responsibilities

Finally, it has to be determined who will be involved in managing quality of ELIXIR Services, when, and what their specific tasks will be.

## 2.4 Perform Quality Assurance process

The process to perform quality assurance is developed while the work to provide the services is being done. The quality assurance involves checking if the processes being followed to deliver the services are the ones that have been defined during Plan Quality.

### **Follow processes**

While the work to deliver the services is being done, the processes defined during Plan Quality management have to be followed.

### **Perform quality audits (inspections)**

Audits are a tool for the Quality Assurance. These are structured internal or external reviews, which determine whether project activities comply with policies, processes and procedures defined. They also can confirm the implementation of approved change requests. Audits are the compliance check procedure that will need to be facilitated by the ELIXIR Hub.

The audits are different from the checks developed during Control Quality. For example, when the service it is being audited by Quality Assurance, the auditor will inform if the service is acceptable in terms of the processes followed to deliver it, but the auditor will not be able to determine if the service includes the contents or performance that it is expected to offer.

### **Determine if processes are correct**

Using the measurements gathered during Control Quality, we must evaluate the processes by answering the following questions:

- Are the quality requirements and processes settled in Plan Quality management providing the results we intended?

- Based on current measures, is the work planned the right quality work for this service and to meet the user needs?
- Can we improve the way we are doing the work?

If the evaluation indicates that the processes are not providing the expected results and we decide to introduce changes to them or we have a change request from Control Quality, the modification shall be analysed. In the case it is accepted, it will have to be included in a new version of the quality processes.

## 2.5 Control Quality process

Control quality is a process aimed at measuring the level of quality of a service to later check if they meet the quality standards. It involves confirming and documenting the achievement of the agreed requirements.

It is important to highlight the difference between Control Quality and Quality Assurance. On one hand, Control Quality measures the product or result of the work (i.e. the quality of the ELIXIR Service), checks if it is acceptable and correctly delivered, so the team running the Service verifies it. On the other hand, Quality Assurance refers to the verification of the usage of the processes planned and that must be used to obtain the product or result.

### **Measure performance against defined metrics**

The quality metrics defined in the Plan Quality process will be measured during Control Quality using the identified tools and techniques.

### **Analyse and evaluate performance**

Once measurements have been gathered they will be compared with the defined metric thresholds and standards.

### **Determine if variances warrant a change request**

When the measures present variations versus the desired metric values, they have to be analysed. Since we have established thresholds beforehand (during the step “Plan quality process”), they will help us to assess if the variances require a change request

### **Request changes**

If we have determined that the variance between measures and the threshold of the metrics require a change, we will request it and it will have to be evaluated.

### **Monitor and record results**

The results on the quality of the delivered services and the results of the check of fitting the requirements have to be recorded.

## 7. Recommendations for the future ELIXIR-EXCELERATE Quality Policy

The strategy defined in the current document will be a foundation for building the ELIXIR-EXCELERATE Quality Policy. It must be considered that the outcomes of this policy development will be taken forward as ELIXIR's upon completion of the ELIXIR-EXCELERATE project.

Common quality criteria and an agreed set of metrics for ELIXIR Services, tailored to encompass the different characteristics of the different services, as well as transparency on how those services are used, will help to ensure excellence in European bioinformatics service provision.

Sharing information on how to collect and report quality criteria, and how to improve these over time, will build capacity across Nodes regarding effectiveness and excellence in resource management, strengthening the European position. As example, the ELIXIR-EXCELERATE WP10 "ELIXIR Node Capacity Building and Communities of Practice" has the main implementing a programme of organisational capacity building in newly formed ELIXIR Nodes, including sharing of best practice between partners in accessing EU Structural Funds (ESIF) for operating infrastructure.

Some important points to consider when defining and writing the ELIXIR Quality Policy are:

- **Need of a purpose statement.** We have to specify why we need the quality policy and why it is important to follow its directives.
- **Include background information.** It is useful to explain the quality procedures existing in the different Nodes. Also it is important to explain why having quality procedures and a policy is important now, how it aligns with other ELIXIR policies and how does it align with the strategic objectives.
- **Define scope.** Clarify the circumstances and the services in what the policy should be implemented or enabled. For example, the application of the policy may be linked to the maturity of the service or its development stage.
- **Assign roles and responsibilities.** It is highly important to define which groups or individual roles will be responsible for ensuring the policy is executed. Also the tasks expected for each individual have to be stated.
- **The Policy Statement.** This is the core of the quality policy and serves to guide the development of future rules and decision making about the quality strategy and execution across the ELIXIR. The considerations here must include aspects like: commitment to maintain standards of the ELIXIR services, identify the ownership and involvement within the organisation of all staff and particularly those with key roles, how to deal with conflicts, how the policy is going to be communicated, definition of procedures, state that the processes will be reviewed periodically to ensure that they remain effective in delivering the planned quality.
- **Clear definitions.** The policy needs to be communicated in a clear and concise manner to facilitate understanding.



- Include **applicable legislation**. State which acts and compliance directives bound the services. These acts and compliance directives have to be also considered in further depth in the individual procedures.
- **Add reference to relevant documents**. Refer the policies and standards linked to this policy.