DANUBIUS-PP

Preparatory Phase for the pan-European Research Infrastructure DANUBIUS–RI "The International Centre for advanced studies on river-sea systems"

Report on quality assurance procedures in the future DANUBIUS-RI

Deliverable 6.8

European Commission

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Abstract

DANUBIUS-RI will provide the Research Infrastructure (RI) to enable multi- and interdisciplinary research along the River-Sea Continuum and within a range of River-Sea Systems (RSS) across Europe, to facilitate an integrated process and system understanding and to address key societal challenges for a sustainable management of RSS in the future. The DANUBIUS-RI Preparatory Phase (DANUBIUS-PP project) develops the necessary structures and processes to ensure that this overall objective will be achieved[1].

Deliverable 6.8 presents the quality assurance procedures for the future DANUBIUS-RI. The first section summarises the key relevant components across the WPs of DANUBIUS-PP that contribute to the development of a set of quality assurance procedures that will govern the operation of DANUBIUS-RI. These largely comprise the outputs from: WP3 – the structure of the ERIC; WP4 - Data Policy and Services; WP5 - the Structure and Architecture of the RI; WP6 – the development of the DANUBIUS Commons; WP7 – protocols for Data Handling; WP8 – Data Interfaces; WP9 – Human Resources; WP10 – Communications. This information provides the framework for the detail of the DANUBIUS Commons. The second section presents the structure of the quality assurance procedures system and implementation in DANUBIUS-RI.

This deliverable presents a proposed structure of the Commons that will be implemented for both the management and technical requirements of the distributed RI. The Commons will ensure consistency in the data and services that will be delivered and ensure that high standards are maintained to meet the needs of both the European and global research communities, as will be expected of a world leading infrastructure.

[1]DANUBIUS-PP Part B. Proposal number SEP-210362517, p. 3

1 Introduction

1.1 Overview of DANUBIUS-RI

DANUBIUS-RI's vision is to achieve healthy River-Sea systems and advance their sustainable use, in order to live well within the planet's ecological limits by 2050. In other words, "Making River-Sea systems work". Therefore, DANUBIUS-RI's mission is to facilitate and contribute excellent science on understanding the continuum from river source to sea to provide integrated knowledge and data for sustainable management, use and protection of River-Sea Systems. This will be implemented through all its components - Hub, Nodes, Supersites, Data Centre and Technological Transfer Office, and e-learning office - through a series of products and services.

The strategic priorities of DANUBIUS-RI are:

- To advance transnational and interdisciplinary research linking rivers and seas and addressing environmental and societal challenges by providing (for the first-time) a harmonized and fit-for-purpose toolbox for environmental research in this field (observation – analysis – modelling – societal impact)
- To provide and integrate existing and new data and knowledge for advancing the understanding of the river-sea continuum functioning
- To promote knowledge exchange and education, synergies with stakeholders, and the scientific evidence base for future environmental policymaking
- To provide immediate and quantifiable benefits to society by: increasing resilience to global and environmental change across the river – sea continuum (managing hazards; advancing and balancing the sustainable use of natural resources and environmental protection; providing opportunities for research innovation; supporting economic development and enhance business opportunities), thereby supporting the UN2030 SDG's and blue growth.

1.2 Need for the Commons

The interdisciplinary research and innovation required to meet the strategic priorities span freshwater and marine environments and require the development and application of a mutual well defined language, and agreed scientific standards and operating methodologies. To-date, lack of harmonised conventions and standards has been a significant impediment to research in these key environments. In addition, such a distributed and highly complex research infrastructure (RI) as DANUBIUS-RI will not function effectively without a harmonised framework for the common values or common standards (short: Commons), governed by core Principles that all partners adhere to.

The DANUBIUS Commons therefore define and comprise a set of harmonized regulations, methods, protocols and standards for the scientific and non-scientific (e.g. management) activities of the RI. They will guarantee the integrity, consistency and quality of service provision and enable the RI to achieve the vision as presented in the Science and Innovation Agenda (SIA) and work to address the key scientific priorities.

1.3 Aim of the deliverable

This deliverable collates the key relevant components across the WPs of DANUBIUS-PP that contribute to the development of a set of quality assurance procedures that will govern the operation of DANUBIUS-RI. These largely comprise the outputs from: WP3 – the structure of the ERIC; WP4 - Data Policy and Services; WP5 - the Structure and Architecture of the RI; WP6 – the development of the DANUBIUS Commons; WP7 – protocols for Data Handling; WP8 – Data Interfaces; WP9 – Human Resources; WP10 – Communications. This information provides the framework for the detail of the DANUBIUS Commons.

This deliverable presents a proposed structure of the Commons that will be implemented for both the management and technical requirements of the distributed RI. The Commons will ensure consistency in the data and services that will be delivered and ensure that high standards are maintained to meet the needs of both the European and global research communities, as will be expected of a world leading infrastructure.

2 Summary of the inputs into the DANUBIUS Commons

2.1 International Quality Management Standards (Deliverable 6.1)

DANUBIUS-RI is an infrastructure that is more complex than most existing environment orientated RIs in terms of the multiple interactions and data flows and services between the Hub, Nodes and Supersites across Europe, necessitating a robust quality management system to ensure effective and efficient operation. The International Organization for Standardisation (ISO) provides a number of quality management systems that may serve as an appropriate framework. Seeking accreditation under one or more ISO standards may be considered a longer-term option for DANUBIUS-RI. However, in developing the Management System for the RI, the frameworks proposed by these standards can be adopted in developing the Quality Management System for DANUBIUS-RI. In the setting up of the management and leadership roles, ISO 9001 and ISO/IEC 17025 provide clear guidance as to the structures required whilst ISO 14001 and ISO 27001 also contain relevant requirements for DANUBIUS-RI's approach to the environment and data security respectively.

ISO 9001:2015 has been adopted by over a million organisations and is the most widely accepted standard in the world. Although developed largely for business and with a specific focus on the customer, the standard is suitable for all types of organizations. The latest standard 2015 has been revised to reflect the many changes in the way we now do business – new technology, greater access to information, higher customer expectations, globalization and increasing importance of service industries. The new standard cuts bureaucracy by being less prescriptive and focusing more on the context of each organization. It guides organizations to build a management system suited to individual needs without imposing irrelevant paperwork or requirements which add no value. The standard adopts a risk based approach and has become a tool for preventive action.

The ISO 9001 QMS comprises the following requirements in its scope:

- Customer focus: improving customer satisfaction and retention
- Leadership: defining key roles and responsibilities
- Engagement of people: improving internal communication
- Process approach: increasing efficiency and reducing waste
- Improvement: ensuring business growth through continual improvement
- Evidence-based decision making: identifying and addressing customer and employee requirements
- Relationship management: making the organization better

The ISO 14001 QMS standard focusses on the environment and sustainability, and provides important environmental credentials to the organisation. The requirements of this standard include:

- Setting out the principles for an eco-friendly management system and includes:
    - waste disposal
    - energy consumption
    - use of natural resources

- Providing guidance for implementing an environmental policy
- Bringing down costs through improving efficiency, productivity and reducing waste
- Assisting in legislative compliance and reduces risk

The ISO 27001 focusses on the management of information security. The standard provides the framework to ensure the integrity and security of your corporate information and will provide a robust platform for information security management. This standard is particularly important when dealing with data that contains details of individuals. This may become critical if social science and health data are collected, for example. The requirements of the standard include:

- Confidentiality: ensuring that access to information is appropriately authorized
- Integrity: safeguarding the accuracy and completeness of information and processing methods
- Availability: ensuring authorized users have access to information when required

ISO/IEC 17025 focuses on all the requirements testing and calibration laboratories crosses over the two standard organizations ISO that focusses on management and technical requirements for testing (analysis), and the IEC (International Electrotechnical Commission) that focusses on the calibration of instrumentation.

Testing organisations (analytical laboratories) often require ISO/IEC 17025 to enable commercial analyses to be performed for clients (government, industry and for the support of legal actions). The organisations that require this standard have to prove that they operate a quality system, are technically competent and can generate technically valid results. The standard sets out:

- Requirements for labs to perform tests (analyses) and calibrations
- Includes standard, non-standard and lab-developed methods
- Applicable to all labs irrespective of size
- Management system for quality, administrative and technical operations, including sampling

The review of standards are highlighted in the Common European Research Information Format (CERIF), which is an international standard for the exchange of research information, which provides a model for the development of research information systems [7]. CERIF is the EU recommended standard to member states that:

- Provides tools for management information – research performance and data generation
- Provides details on projects: individuals involved, funding, patents, publications etc.
- Provides data at national level to assess performance
- Provides access to data storage
- Automatically links to other research information systems (Research Gate etc)

A framework for the DANUBIUS-RI commons may be based on the components of the ISO/IEC17025 and ISO 9001 International Standards. Both these International Standards provide clear requirements that fit well with the management of a research infrastructure, including: leadership, customer focus, communication (external and internal), continual

improvement, evidence-based decision making, assessing conflicts of interest and contracting and procurement arrangements. In addition, ISO/IEC 17015 provides clear requirements in relation to personnel and human resources (skills and training requirements), laboratory conditions, the validation of new methods and instrumentation, measurement traceability, sampling and sample processing, and assurance in results, data and reporting. The development of policies and procedures to meet the aims of these standards will provide a strong overarching Commons structure to ensure quality data and services whilst maintaining flexibility for research, development and innovation, and any associated validation, before these data and services are distributed more widely. These standards also provide the framework for effective communication and dissemination. Such an overarching Commons structure has direct relevance to all aspects of DANUBIUS-RI and should be central in the design and operation of the Hub, Nodes, Supersites, Data Centre and Technology Transfer Office.

2.2 Principles for the Commons and Framework for selection and approval of Standards and Procedures (Deliverable 6.4)

Harmonisation of approaches to research and innovation on RS systems is essential for mutual understanding and will be enabled by DANUBIUS Principles and Commons (cp. 1.2).

DANUBIUS Principles are generally accepted values, ideas or rules that explain or control how DANUBIUS operates. They serve as the foundation for the RI system and are defined as DANUBIUS understanding of scientific values:

- high-quality cross-disciplinary research
- environmental and societal challenges
- inter-comparability
- education
- holistic and cross-disciplinary understanding of RSS
- sustainable management
- interoperability and robustness
- training and mobility of scientific staff
- knowledge provision
- harmonization
- transparency and open access
- support of early career scientists
- best practices
- knowledge exchange
- stakeholder- and public engagement

These Principles are implemented through the Commons for both the management and technical aspects of DANUBIUS-RI operation. Each Commons will be harmonized regulations, methods, procedures and standards for various technical and management based activities. The DANUBIUS-RI Commons need to: 1) fulfil transdisciplinary scientific requirements; 2) maintain the general organisation of DANUBIUS-RI including its internal

and external interaction and integration; and 3) promote the combined vision, values and mission of DANUBIUS-RI and its stakeholders.

All Commons have to guarantee a defined minimum quality that consequently sets a quality label ("DANUBIUS approved"). Commons are based on internationally accepted standards and/or high level of professional expertise. The implementation of the DANUBIUS Commons will be facilitated by the adoption of appropriate methodological and technological selection criteria for individual Commons, with respect to accuracy, range, sensitivity, specificity, robustness, capacity, longevity and cost efficiency. Established control mechanisms (e.g. ring tests) will ensure and inspect the comparability between the different facilities of DANUBIUS-RI. Representatives of DANUBIUS-RI components guide the approval process for the Commons and therefore preclude the establishment of untested or out-of-date (lab-) routines.

The constant update of Commons is guaranteed by regular and additional on-demand review processes that aim for steady integration of new procedures and scientific findings. Commons affecting the structure of the entire RI (e.g. early career scientist definition) are reviewed/revised every 5 years after implementation. Commons associated with Components (e.g. measurement methods) and the Scientific Agenda (e.g. research goals) are re-assessed every 3 years after implementation. Consequently, DANUBIUS-RI will be able to continuously offer data and expert support of international state of the art quality for RS systems and thus remaining the centre and reference for excellence in RS systems.

The wider argument for developing the DANUBIUS Commons can be illustrated by the challenges in long term data sets for methyl mercury species and the given analytical artefacts from certain time periods. Some of the methods used to detect different mercury species in sediments are biased by the creation of analytical artefacts although they may have represented the ‘state-of-the-art’ at the time (e.g., Hellmann et al. 2018). A lasting consistent approach is required to process data of this nature, where there are possible questions over the comparability of different methods for statistical and modelling purposes.

2.3 Data Protocols and Handling (Deliverable 7.7)

The stored data in the DANUBIUS repository will be accessible using DANUBIUS-RI Portal as unique point of access to all e-services providing the interface with all users. All the services will be provided in a secured environment, managed by the Data Centre, for the users of the DANUBIUS partners as well as for the public as a trusted source of information in the scientific domains of the research infrastructure. The portal should perform a number of functions to provide all the necessary services (Fig. 1).

Identified functions, related to the data flow, are:

a. Data access - the access to data stored in the repository is the main service offered by DANUBIUS-RI portal. Data can be provided in various forms: time series, records, scientific publications, results of simulation and numerical modelling, graphic images (including time series) and video recordings.

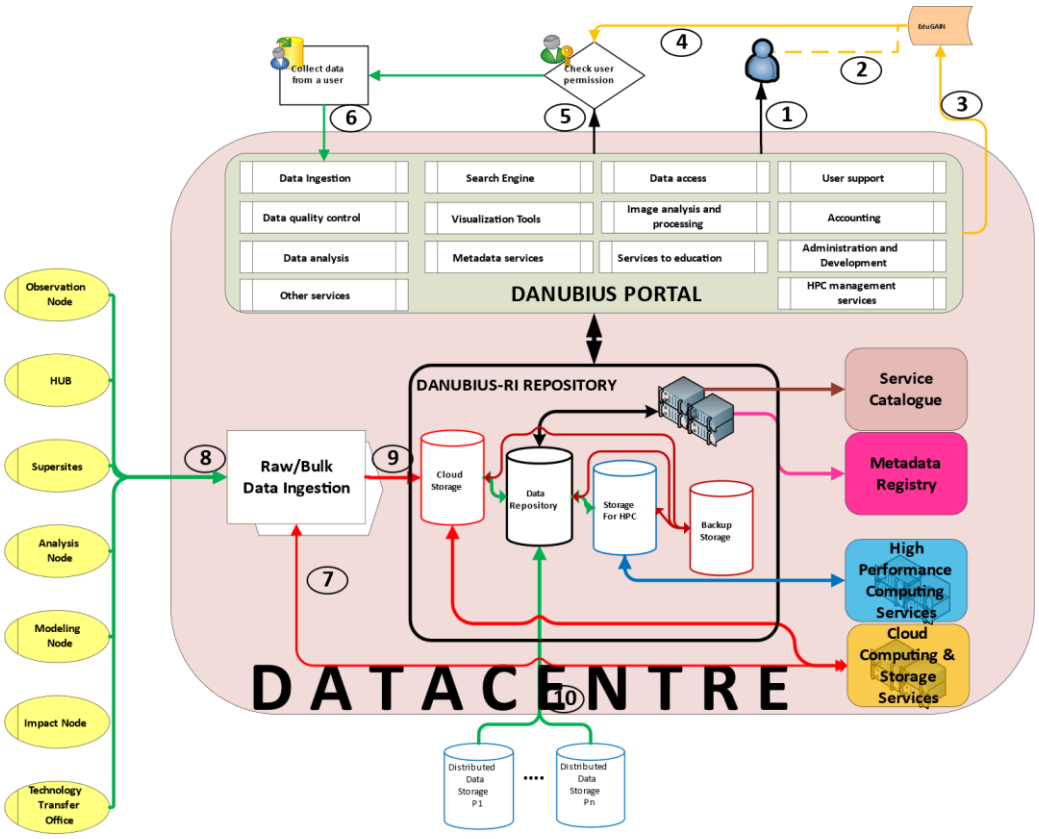

Fig. 1 Data Centre services and data flow

b. Data Ingestion – for users willing to contribute with data to the DANUBIUS-RI repository, a special procedure will be used to assure the uniformity of the submitted data as well as consistency with the metadata registry.
c. Data quality control – this function will be used to ensure a quality control of the data. The rules will be defined for each type of data and it is recommended to implement artificial intelligence algorithms, to minimize the human intervention of data quality thematic teams.
d. Search engine - will serve all users providing information from all sections of the portal, depending on the user's profile.
e. Accounting - all portal operations will be monitored, all transaction recorded for both anonymous users and those who have a portal account with certain access rights, including data (or any other information) submission to be stored in the repository.
f. Raw/Bulk Data Ingestion system consist of a series of software programs, computing and storage resources intended to provide automatic procedures to get all the data and information from all data providers into the data repository, with minimal user intervention, in the best possible form according to the enforced data policies and data formats (Fig. 2).

2.4 Data Access Policy (Deliverable 4.4)

E-services offered at DANUBIUS-RI are on access through the wide access mode, specific to e-services, and offered through a 4-tier subscription plan. In compliance to European

regulations (e.g. ASPIRE regulation), DANUBIUS-RI first e-service tier will offer raw environmental data and limited e-services for free without subscription. Additional data and limited e-services will be made available against subscription (at no cost for the user). The next 3 e-service tiers gradually offer all other e-services plus support against payment. The current DANUBIUS-RI funding scheme plans that the 2nd tier shall be charged around €400/year/institution for access to e-services included in the 1st tier plus refined data, filters, exploitation and visualisation tools. A 3rd tier, charged around €4,000/year/institution, includes more advanced data treatment tools, models, and methods. Eventually, a 4th tier, charged around €8,000/year/institution, includes all e-services plus support from DANUBIUS-RI experts and technicians. Institutions located in ERIC Member countries will obtain a 75% discount on those prices.

Access to other services (on-site and/or remote services) requires users to submit an application describing the purpose of the request, the work to be done, the resources to be mobilised (on the user side), the methodology, the expected outcome and impact, and the acceptance of the terms of access at DANUBIUS-RI (including the availability of data generated or used during the access, and the commitment to publish and credit DANUBIUS-RI – infrastructure and researchers – in the publications based on the results of the work). A panel of experts (Research Program Advisory Committee, RPAC) will be charged to review all applications, and rank applications by level of scientific interest. Applications with the highest scientific interest will be granted access to DANUBIUS-RI with the full support of experts and technicians, irrespective of the user affiliation or origin, and at no cost for the user. It is expected that 35% of access capacity at DANUBIUS-RI will be granted through this excellence access mode. In addition, 55% of access capacity will be granted following the same process, but with an application pool limited to those applications stemming from DANUBIUS-ERIC Member countries. This is the excellence

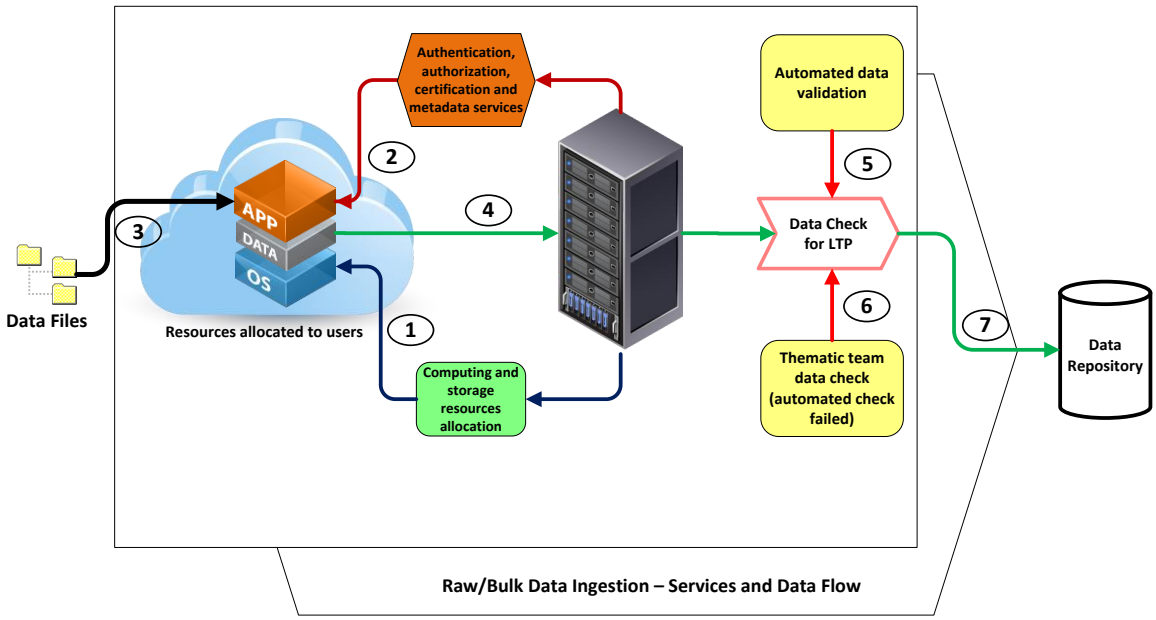

Fig. 2 Data flow for DANUBIUS components

and quota access mode. Eventually, other access modes exist at DANUBIUS-RI sharing the remainder of access capacity (10%). Those are:

- the market-driven access mode, dedicated to the private sector, and offered against payments representing the full cost of access plus a 30% margin (about 1.7% of access capacity on average, with an objective of 5%),
- the institutional access mode, dedicated to public authorities, to collaborate on subjects of public policy relevance and for which sound scientific data and expertise are required (about 1.7% on average, with an objective of 4% of access capacity)
- the training & education access mode, for training and education services, which do not require a panel to assess the scientific excellence of applicants (about 2% of access capacity on average)
- the fast track access mode, enabling a fast access to researchers engaged in a race to publish on a "hot" scientific subject (about 0.8% on average)
- the emergency access, dedicated to public authorities, to obtain *ad nutum* an access to DANUBIUS-RI facility, data, and expertise in situations of emergency (about 0.75% on average)

A small "slack" (access capacity reserve) is planned to cope with unexpected sudden surge of demand in any of the access modes or any unexpected high demand for support in e-services, and is meant to be affected in whichever access mode is in high demand at any moment in time.

2.5 Implementation of data interfaces (Deliverable 8.15)

An interface is a point where a user interacts with the software that he / she is using. User Interface Design in Information Technology refers to the design of the user interface for software or applications. It is about programming the look of things, with a view to facilitate usability and the user experience.

A good User Interface is important in the sense that it makes it easier for your target audience to clearly see what your products are. It is designed in a way to display the services that you offer without ambiguity, in order to draw your visitors' attention and keep them on your site.

2.5.1 Standards Requirements

In addition to the points offered in Deliverables 8.14 and 8.15, it is worthy to highlight the importance of working under some standards and common principles when it comes to developing a data interface. Some of these aspects have been considered and addressed with more detail in the supplementary templates.

The Service Integration Template explains the different fields that are considered necessary to develop an interface and the standards that must be followed. It is focused on data and metadata formats and provides some recommendations for the application of FAIR (Findable, Accessible, Interoperable and Reusable) principles. The template also includes some relevant information to be considered for the definition of the terms of use and licenses to be applied in each DANUBIUS service.

Data standards are a very important part of improving data quality for better decision making in environmental management programs. The use of data standards enables the reusability of data elements and their metadata, which can reduce redundancy between systems, thereby improving reliability and often reducing cost. Data standards ensure consistency in code set use by providing for the maintenance and management of permissible code sets.

A metadata standard is a requirement which is intended to establish a common understanding of the meaning or semantics of the data, to ensure correct and proper use and interpretation of the data by its owners and users. The only difference between metadata and data is mode of use. Metadata is not just for data, it is also for users, software services, computing resources. Metadata is not just for description and discovery; it is also for contextualisation (relevance, quality, restrictions (rights, costs)) and for coupling users, software and computing resources to data (to provide a Virtual Research Environment).

The FAIR Data Principles are a set of guiding principles in order to make data findable, accessible, interoperable and reusable. These principles provide guidance for scientific data management and stewardship and are relevant to all stakeholders in the current digital ecosystem. They directly address data producers and data publishers to promote maximum use of research data. Research libraries can use the FAIR Data Principles as a framework for fostering and extending research data services.

2.5.2 Design Requirements

In the data context, visualization is a form of communication that portrays dense and complex information in graphical form. The resulting visuals are designed to make it easy to compare data and use it to tell a story, both of which can help users in decision making. It can express data of varying types and sizes: from a few data points to large multivariate datasets**.** A good User Interface Design presents a seamless blend of visual design, interaction design, and information architecture:

Visual Design: improves a site's ornamental value by strategically implementing elements such as fonts, colours, and images among other things.

Interactive Design: looks at how users interact with technology. It then uses the understanding of such interactions to create an interface with behaviours that are well thought-out. Excellent interactive design not only anticipates how a person interacts with a system but also antedates and fixes problems in good time.

Information Architecture: is designed to help users find the info they need to complete various tasks. It, therefore, involves labelling, structuring, and organizing the web content in a manner that makes it easily accessible and sustainable.

Everything stems from knowing the users, including understanding their goals, skills, preferences, and tendencies. In the case of an interface oriented to the scientific community, visual design requirements are always less restrictive. Researchers are accustomed to functional and simple interfaces. For the design of the interface the following have been considered:

- Keep the interface simple and responsive.
- Create consistency and use common UI elements.
- Be purposeful in page layout.

- Make sure that the system communicates what's happening.
- Think about the defaults.

2.5.3 Example: The Guadalquivir Estuary DEMO Interface

In order to show the full potential of data interfaces and the usefulness of having a guide document common for all members (the service integration template), a DEMO interface has been developed with the information of one of the supersites that are part of the DANUBIUS community (The Guadalquivir Estuary Supersite. Port Authority of Sevilla, Spain) (example in Fig. 3).

Data and metadata standards as well as FAIR principles have been taken into account for its design. All the requirements and design tips listed above have been the basis of its image and functionality.

Considering the data, it has been used files in netCDF, a format mainly used for numerical models. The metadata standard associated with NetCDF is CF (Climate and Forecast).

The interface has been programmed in R. More specifically with the Shiny library, which mixes R and Rmarkdown, a markup language based on R. This customizable interface allows users to add interactive graphics, tables, text boxes, images, data filters and generally, everything that is necessary for the proper functioning of the respective virtual lab, repository or data model (as far as possible).

The functionalities of the pages of our DEMO are explained briefly in each of them. All graphics, maps and tables are responsive. The interaction buttons are easy to use and colour scales that favour the understanding of the representations are used. Below a screenshot of one page of the DEMO is showed.

Moreover, the DEMO interface developed by the University of Sevilla on behalf of the Authority Port of Sevilla (Spain) can be accessed through the following links:

https://alinan-gie-us.shinyapps.io/supersites/

https://alinan-gie-us.shinyapps.io/flexdashboard_merged_v5/

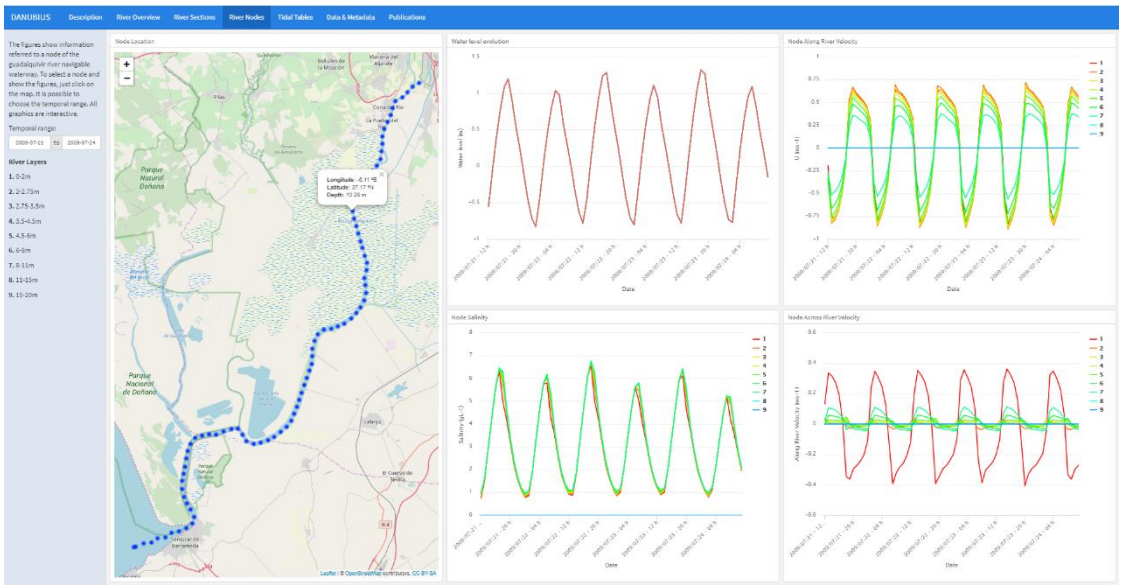

Fig. 3. Example of data interface for the Guadalquivir Estuary

2.6 Services (WP4)

The DANUBIUS-RI service line-up spans over a large range of disciplines which all are needed to address the major questions and challenges of River-Sea Systems. The services address five categories of users:

- “Researchers”, i.e. academic and scientific users
- “Businesses and professionals”, i.e. companies and charities
- “Students”, i.e. pupils and students
- “Authorities”, i.e. local, national and transnational authorities “Citizens” i.e. the public at large.

Seven categories of services have been developed: (1) Digital and Non-Digital Data, (2) Methods, Tools and Expert Support, (3) Study and Measurements, (4) Diagnostic and Impact, (5) Solution Development, (6) Tests, Audit, Validation and Certification, and (7) Training.

1. **Digital and Non-Digital Data**: This category encompasses those services that consist in offering access to scientific resources, data and samples developed or collected by DANUBIUS-RI. Most of those services are e-services, but a few of them require a physical access, such as the sample and core repositories. DANUBIUS-RI platform or website, hosted by the Data Centre, is meant to offer users with raw and processed data from satellite observation, data obtained from models and simulations, data from biobanks, mineralogy samples and cores, geo- and hydrochemistry library and data used in publications co-authored by DANUBIUS-RI-affiliated authors and users in open access from the DANUBIUS-RI publication repository.
2. **Tools, Methods and Expert Support:** This category includes services that consist in providing access to facilities and equipment, specific methods and tools developed or made available by DANUBIUS-RI partners, as well as in providing expert support. Those tools and methods are related to information treatment (data processing tools, statistical filters, data visualization tools, etc.), DANUBIUS Commons-compatible scientific methodologies or technical assistance to users in the use of tools to exploit digital and non-digital data.
3. **Study and Measurements:** This category encompasses services that consist in carrying out analyses and measurements with users or on behalf of them. Most services in this category can be rendered on-site or remotely (38 out of 49 services in this case). The range of analyses and measurements is large and ranges from simple sample collection to advanced chemical, geochemical, geochronological, genotoxicological, xenotoxicological, radiogenic, ecotoxicological, biological, geo-hydromorphological, petrographic, chemostratigraphical, sedimentological, seismo-acoustic, and bathymetric analyses. The service range also includes assessments of bio/molecular markers, sediment and water quality assessment (concentration and nature of pollutants and nutrients), presence of microbial species with pathogenic potential, identification of transitional zone model organisms, population surveys for endemic and/or alien species, and the analyses of isotopes, magnetic

and gravity field variations (this list is non-exhaustive). This service category implies a collaboration with users beyond simple technical assistance but does not include work from DANUBIUS-RI experts on the interpretation of results.

4. **Diagnostic and Impact:** This category includes services that transition beyond measurements, an interpretation by DANUBIUS-RI specialists of analyses and measurements obtained e.g. from services. Interpretations can be done through the comparison of data with previous or expected results (diagnostic) or with forecasts (from models). This category range implies an involvement of DANUBIUS-RI beyond technical support and requires DANUBIUS-RI experts to assist users in drawing interpretations and conclusions from analyses and studies carried out in collaboration with users. This category of services is based on the expertise at DANUBIUS-RI in terms of modelling ecological assessment practice and impact assessment. This service range includes impact assessment of pollutants and nutrients on ecosystem services, impact of alien species on ecosystems and their services, and assessment of transient defense measures, among others.
5. **Solution Development:** This category consists of services addressing users – mostly from the private sector – looking for a scientific partner with wide-ranging expertise to develop solutions for the various challenges in River-Sea Systems. Unlike other service categories, this service category is defined in terms of development themes rather than data, tools, methods, methodologies and models, as the provision of this service is focused on the purpose of the service, rather than on the means employed.
6. **Tests, Audit, Validation and Certification:** This category completes the typical scientific methodology (observation and analysis, experimentation and/or modelling, diagnostic and/or forecasts) by the comparison of theoretic results with the reality. This category also includes the quality assurance and control of laboratories external to DANUBIUS-RI, e.g. in the context of DANUBIUS Commons accreditation or Accredited Service Providers certification.
7. **Training**: This category is not restricted to students and includes all the potential trainings and courses that DANUBIUS-RI can offer to e.g. companies and authorities in the four Areas of Expertise (Observation, Analysis, Modelling, and Impact). This service category also includes e.g. science communication training or the organization of ad hoc conferences or workshops.

2.7 Human Resources (Deliverables 9.4 & 9.6)

Researcher recruitment would follow the terms and conditions of the employer with respect to their national guidelines on recruitment and employment.

As DANUBIUS-RI partners define more precisely the works and services offered at DANUBIUS-RI, the need for qualified support staff is becoming more precise. The definition of support staff needed presented below took into account:

- a preliminary list of services offered to the user, and
- “internal” works, i.e. work considered necessary for the Supersite to remain fully operational;

The staff working at the Hub, at Nodes or Supersites (Fig. 4), were divided in three groups: administrative, research, technical, and are detailed onwards.

During the Preparatory Phase, some grey areas remain in terms of responsibilities between the Hub and the different limbs of the Research Infrastructures. Even though efficiency calls for a centralisation of most administrative functions, heavy constraints and difficulties caused by the existence of numerous national legal and fiscal contexts make it difficult to imagine that all administrative functions can be managed from a single location. There is therefore in each of the Nodes and Supersites a need for qualified administrative personnel. However, the fact that DANUBIUS-RI is a “brownfield” project, i.e. based on existing capacities and expertise developed by what DANUBIUS-RI partners call “hosting and leading institutions”, enables DANUBIUS-RI to count on the contribution of hosting/leading institution staff. For this reason, many Nodes and Supersites considered administrative profile FTEs to be less than 1.

This possibility to share the worktime of qualified personnel is, of course, not restricted to administrative personnel, and the Tables below show that the best-defined HR plans seize such an opportunity fully for research and technical staff as well. In the process, hosting/leading institutions with a sound HR plan seize the opportunity offered by DANUBIUS-RI to complete their range of expertise. This is certainly one of the best features of being a Member of a pan-European, distributed Research Infrastructure.

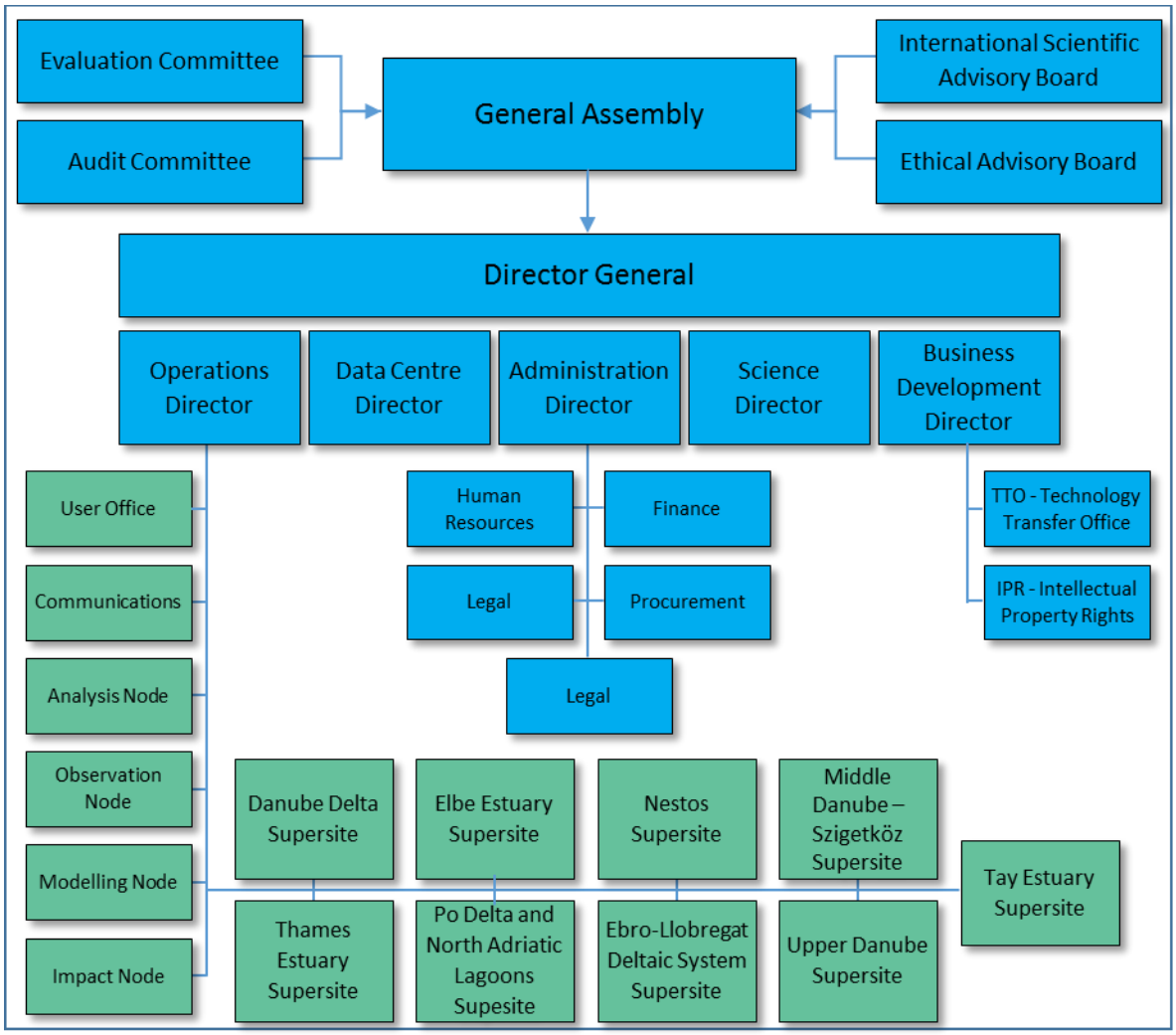

Fig. 4. DANUBIUS-RI Governance and Management Organogram

2.7.1 Employment categories (Table 1)

Category	Code	Short definition
Administration	A4	Director
Administration	A3	Third level administrative staff, with minimum bachelor or license, and responsibilities in the organisation, e.g. Head of department
Administration	A2	Second level administrative staff, with minimum bachelor or license, e.g. Accountant
Administration	A1	First level administrative staff, with low qualifications, e.g. Clerk
Research	R4	Leading senior researcher, e.g. Research fellow
Research	R3	Established senior researcher
Research	R2	Junior researcher, Post-doc researcher
Research	R1	PhD student

Category	Code	Short definition
Support	S4	Fourth level technical staff, with minimum Master level and responsibilities in the organisation, e.g. Engineer
Support	S3	Third level technical staff, with minimum Bachelor/License level
Support	S2	Second level technical staff, with professional qualifications
Support	S1	First level technical staff, with low or no qualifications

2.7.2 Recruitment status

The Human Resource needs for DANUBIUS-RI, as of May 2018, are summarised in Table 2, below.

Table 2 Summary of Human Resource Needs

DANUBIUS-RI component	Category of profile	# of FTEs
HUB		
Biological laboratories	Management	2
	Research	59
	Support	20
Non-biological laboratories	Management	
	Research	46
	Support	24
TOTAL Hub	Management	2
	Research	105
	Support	44
NODES		
Observation Node	Management	2.0
	Research	4.0
	Support	4.5
Analytical Node	Management	4.0
	Research	23.0
	Support	4.0
Modelling Node	Management	0.45
	Research	0.9
	Support	3.0
Impact Node	Management	0.9
	Research	2.7
	Support	0.5
TOTAL Nodes	Management	7.35
	Research	30.6
	Support	12.0
SUPERSITES		
Danube Delta Supersite	Management	1.0
	Research	15.0
	Support	32.0
Elbe-North Sea Supersite	Management	1.6
	Research	9.66
	Support	4.5
Thames Estuary Supersite	Management	1.0
	Research	1.7
	Support	2.8

Ebro Llobregat deltaic system Supersite	Management	3.0
	Research	25.9
	Support	4.0
Po delta and North Adriatic lagoons Supersite	Management	1.3
	Research	9.0
	Support	4.0
Middle Danube Szigetköz Supersite	Management	4.0
	Research	Not assessed
	Support	Not assessed
Nestos Supersite	Management	7.0
	Research	17.0
	Support	7.0
Upper Danube Supersite	Management	1.00-1.20
	Research	3.5
	Support	1.5
Tay Catchment (New)	Management	1
	Research	1
	Support	3
TOTAL Supersites	Management	20.9-21.1
	Research	82.76
	Support	57.3
OTHERS		
Technological Transfer Office	Support	9.0
NOT ASSESSED		
Data centre		
Guadalquivir Supersite (New)		
Rhine-Meuse delta Supersite (New)		
Middle Rhine Supersite (New)		
TOTAL		
	Management	29.25-29.45
	Research	171.46
	Support	110.3
TOTAL FTEs		311.1-311.3

2.8 Communications (including Identity and Branding)

A communications group will be established within DANUBIUS-RI, which will oversee the overall communication strategy of all the components of DANUBIUS-RI(ERIC, Hub, Nodes, Supersites, TTO & e-learning centre) by providing common tools and solutions, and recommendations on best practises. The DANUBIUS-RI Identity and Branding strategy will be at the core of the responsibilities as they are essential in executing a successful communication strategy. It will build on existing material such as logos, type sets, colouring and will be updated in order to be scalable and flexible, cohesive, easy to apply and relevant. The DANUBIUS-RI brand identity will be centred around the message: “making river-sea systems work”. It is perceived as distinct and memorable phrase, which will be closely associated with DANUBIUS-RI in the future. The unit will be also responsible for the coordination of communication activities between national components of DANUBIUS-RI such as national communities of users.

The communications strategy will target specific groups:

2.8.1 General public

To raise awareness and interest about DANUBIUS-RIand incite engagement of the general public, the communication strategy will use primarily digital media, familiar to the majority of the general public. The DANUBIUS-RI website will be the central medium of communication and dissemination activities. It will function as the starting point for requests for information and a repository of dissemination material for the general public. A strong social media presence will further enhance the visibility of DANUBIUS-RI. Since social media are rapidly changing, the DANUBIUS-RI communications group will assess current trends in social media usage and adopt the most appropriate channels. The efficiency of the digital communication will be regularly evaluated with the use of digital analytics tools. In addition, other media such as brochures and leaflets will be available in paper and digital form for dissemination in events and through the website and social media.

Engagement with the general public will be aided by the production of short 1-2 minute videos on the major topics relevant to DANUBIUS-RI (e.g. climate change, extreme events including floods and droughts etc) for distribution through the website, digital media and presentation in events.

DANUBIUS-RI will also be represented at popular science festivals, where exhibitions and displays will deliver the latest state of the art understandings, technologies and solutions relevant to River-Sea systems. Where appropriate, it is anticipated that the component institution local to the science festival will represent DANUBIUS-RI.

2.8.2 DANUBIUS RI

Coordinating all the internal communication between all the components of DANUBIUS-RI(ERIC, Hub, Nodes , Supersites etc) will be the task of the communications group. The group will also be responsible for organising the presence of DANUBIUS-RI in events (e.g. international exhibitions) and will oversee the production of communication/dissemination material (e.g. videos) ensuring that all relevant components are involved.

2.8.3 DANUBIUS-RI stakeholders

DANUBIUS-RI engagement with a variety of stakeholder (European and national funding agencies, policy makers, industry, academia) is crucial for the sustainability of the RI. It is also important for keeping stakeholders informed about the provided services and also receive feedback from stakeholders about their evolving needs. DANUBIUS-RI will organise regular stakeholder events/workshops, in collaboration with other environmental RI's in order to foster their engagement.

Communication material addressing specific groups of stakeholders will be produced and made available through the website.

2.8.4 Enhancing visibility of DANUBIUS RI

2.8.4.1 Participation in scientific conferences

DANUBIUS-RI core activity is the facilitation of scientific research thus organization of and participation in scientific conferences will be essential. Presentations of Danubius RI-related activities and research will help inform the scientific community about the available facilities,

services and capabilities and attract the interest for collaboration in scientific proposals and projects. Between 2018-2020 members of DANUBIUS have been co-organizing successfully an EGU session on river-sea interactions and plan to continue doing so in the future. In order to target international audiences, DANUBIUS-RI members or DANUBIUS_ERIC will participate in international conferences (eg. AGU in the US or conferences in Africa, Asia, South-America, Australia). In addition to formal scientific presentations, the communications group will assemble information on peripheral events organized during conferences and solicit the participation of DANUBIUS-RI members to these events.

2.8.4.2 Participation in international events

DANUBIUS-RI, as an international centre for the study of river sea systems, aims to become a research infrastructure for the international scientific community, policy makers and industry. Participation in international events is essential in increasing the visibility and promoting the services of DANUBIUS-RI. DANUBIUS will continue its participation in the International Conferences, including for example those on Research Infrastructures, Limnology, and European maritime days. The communications team will suggest further participation in other international events, which will further enhance DANUBIUS-RI presence internationally and will build demand for its services.

2.9 Measures of Performance (KPIs; Deliverable 6.6)

2.9.1 Introduction to KPIs

Key Performance Indicators (KPIs) are defined as a measurement of performance. KPIs evaluate the success of an organization or of a particular activity (e.g. projects, programs, products and other initiatives) in which it engages. Together with Core Impact Indicators (CIIs) they are the framework to develop the Risk Management Plan for DANUBIUS-RI, during the Implementation Phase.

CIIs are generic indicators that can provide a general picture of the impact at a given time and that can be used by most RIs whatever their type and discipline (OECD 2019).

Key Performance Indicators and CIIs were developed through workshops, meetings of the BGR and attendance of the ESFRI workshops, which provided the opportunity for an ongoing robust review in the development and tuning of the DANUBIUS-RI KPIs. The KPIs were developed for each category of benchmarking relevant for DANUBIUS-RI based on impact of science (excellence) and society (impact and visibility), policy (legal relevance) and economy (innovation stimulation).

To ensure effectiveness and implementation, each of the proposed KPIs were developed in line with the following five principles (source: CERIC 2018): relevant, accepted, credible for non-experts, easy-to-monitor, and robust.

KPIs provide an indispensable tool to ensure that DANUBIUS-RI is delivering on its core mission and enable evidence-based decision making (remedial actions/investments) for management, whilst also providing the evidence to develop future management priorities, strategies and business plans. KPIs aid in transparent communication both internally and externally, illustrating the performance of the RI within the international research landscape

and helping to deliver the sustainability of the individual component parts that contribute to the overall distributed research infrastructure. All publicly funded bodies are obliged to report on their performance.

The following list of objectives were used as a framework around which the DANUBIUS-KPIs were defined:

(i) Deliver Scientific Excellence in River Sea-System Understanding
(ii) Deliver Societal impact
(iii) Secure DANUBIUS-RI sustainability

2.9.2 Key Performance Indicators

The draft list of KPIs highlight the priority areas for engagement, growth and impact, and are useful for both management purposes and target setting as well as public reporting on the return of the investment in the KPI (complete list in Annex 1). The data for the KPI's will be collected annually using metrics collected from across the RI and captured through standardised application and reporting procedures to the RI. Metrics will be reported in absolute numbers as well as percentages to reflect proportions within sub-categories, e.g. the number and percentage of publications with industry and policy partners. These KPIs and their change with time will form part of the DANUBIUS-RI review that will take place on a five-yearly cycle.

The KPIs reflect the world-leading ambition of research in RSS along with the one-stop-shop for researchers, policy makers, industry and society more broadly in all matters relating to RSS. Fundamental to the success of tackling global and intractable challenges is the need for interdisciplinarity and this is a relatively unique KPI to DANUBIUS-RI. Access to DANUBIUS-RI digital and non-digital data will adhere to the principles of FAIR (Findable, Accessible, Available, Interoperable and Reusable) and is currently the focus of another H2020 programme ENVRI/FAIR in which DANUBIUS is an active participant. Promotion of DANUBIUS-RI and triggering interest to grow its global impact and reach, along with education and training at every level, informing policy and promoting innovation and industrial development are all priorities for DANUBIUS-RI and reflected in the following ten draft external KPIs (Table 3).

Table 3. External and Internal KPIs (see Annex 1 for detail)

No	External Indicator	No	Internal Indicator
1	Scientific production	1	Implementation of Commons in the RI
2	Number of Users	2	Adoption of Commons by labs
3	RI access	3	Adoption of Commons by individual users
4	Interdisciplinarity	4	Adoption of Commons by International Community
5	FAIRness data	5	Operational Collaboration
6	Industrial impact	6	Financial Sustainability

7	Promotion of education outreach	7	Service Use
8	Inform public policies	8	Success of national auditing
9	Facilitate international agendas (SDGs, European DGs)		
10	Trigger Interest		

In addition to the external KPIs, we have also identified a series of KPIs (Table 3) that are required for management purposes to identify resource requirements and management priorities. These will be especially important in the implementation phase of DANUBIUS-RI and may well eventually become external KPIs, especially as for example, more Supersites become compliant with the DANUBIUS Commons.

2.9.3 Core Impact Indicators

Making River-Sea Systems work is the overarching ambition of DANUBIUS-RI. This big impact orientated ambition is multidimensional in its scope and by necessity provides an interdisciplinary approach that crosses geographical and geopolitical boundaries. This distinguishes the difference between performance, quantified by KPIs, and impact quantified by CII. In this case the CII will be evaluated by *Impact Case Studies*, which will be developed to evidence the reach and significance of DANUBIUS-RI, and may comprise qualitative as well as quantitative information around the benefits that DANUBIUS-RI has had on RSS. Such Impact Case Studies may be specific to individual River-Sea-Systems and collectively across geographical regions highlighting the impact on the state of the environment and might include one or more of: policy, industry and society including behavioural change and the economy. Given the scope, it is anticipated that such impact case studies will contribute to the review of DANUBIUS-RI on a 5/10 year-time scale. Given its nature, it is anticipated that the CII will be reviewed independently and a report submitted to the RI for management and reporting (Table 4).

Table 4. Summary of the Core Impact Indicator (CII)

CII	Indicator	Content
1	Making River Sea Systems Work	Evidenced from Case Studies Reports on RS status every 5/10 years (state of the environment) to show how DANUBIUS-RI Contributed to *making RS Systems work again*.

2.10 Stakeholders Engagement (Deliverable 6.7 & Deliverable 9.11)

It is anticipated that stakeholder engagement within continuing development and operation of DANUBIUS-RI will manifest itself in many forms for multiple purposes. Fundamentally, stakeholder engagement shall be a central activity and must be resourced appropriately within the operation of the RI in the first instance.

Understanding the drivers for engagement is a fundamental first step in planning stakeholder engagement. Identifying what the benefits may be to the stakeholder as well as to the researcher is perhaps obvious but often overlooked. Careful analysis and identification of the *value proposition* at an early stage and which *structural drivers* (e.g. climate change, economic need, social needs, technological opportunities) they address is important to the process of identifying and engaging stakeholders. At the same time, identifying the potential benefits and impacts of the engagement, *conjunctural drivers* (e.g. policy reforms, crisis and emergency situations, political pressures, business innovation) along with the longer term *policy implications* will help shape the rationale for stakeholder engagement, its longevity and the direct (fulfilling the research needs) and indirect (reputational) benefits and sustainability to the RI. For DANUBIUS-RI, the spectrum of stakeholders surveyed identified *Environmental Stability and Resilience* as a key priority for their operations along with access to *data and facilities* to help evidence the need for *policy reform and better management.* This is a useful starting point for the RI.

Having identified the drivers and opportunities for engagement, the next key step is to identify and map the stakeholders to the opportunity. This requires an understanding of how the river-sea management sector is organized in terms of functions and responsibilities and to determine who should be engaged. Here it is important not only to map to existing established actors in the field of water management but also promote an inclusive agenda which facilitates newcomers to develop new opportunities for research and innovation that will benefit the environment and society, and promote sustainable growth.

Within the river-sea management sector, there are many levels to the complexity of stakeholders involved in decision making within the context of Integrated Water Resources Management (IWRM) and/or WFD River Basin Management Planning including engineering (e.g. navigation/energy/abstraction), chemical, manufacturing, agriculture and fisheries (including aquaculture); conservation and environmental protection (statutory agencies); and SMEs implementing new ideas and technologies. This complexity can also be compounded further by fragmentation in decision making within policy and governance and an awareness of which institutions and actors are able to focus on the promotion of research and innovation and can help facilitate the research agenda and infrastructure development with appropriate resources and through influence and leverage in the wider stakeholder and policy landscape. Within the RI, this process can be time consuming and appropriate resource should be provided to ensure that this is managed and executed effectively.

Being aware of the obstacles of engagement is important to ensure that the stakeholder engagement process is resourced appropriately from the start. Obstacles to engagement can manifest itself in many ways and can include: (i) the lack of political will; (ii) the lack of available resource within the stakeholder organisation; (iii) the lack of understanding of the

priority or opportunity; (iv) institutional fragmentation which might be accompanied by weak legal frameworks; (v) perceived competition rather than an opportunity for collaboration; (vi) perceived duplication of existing structures; (vi) lack of clarity on how to use stakeholder's inputs; and (vii) miscommunication of information and bottlenecks to information flow.

These issues all highlight the need to have an effective communication plan to ensure the value of the opportunity is understood by the stakeholder, the context of the opportunity with the research and innovation landscape is clear, the RI is proactive in bringing together key influential stakeholders to promote, add value and snowball the opportunity. Properly secured funding is therefore critical in sustaining the engagement process and to diminish the risks associated with the many obstacles to effective stakeholder engagement.

Experience tells that early engagement builds deeper, trusted and more sustainable relationships with stakeholders who then also become advocates and ambassadors within their industry for the research and innovation opportunities presented. The feedback from the stakeholder survey highlights the importance of research institutions in informing industry and policy makers in the science. The co-development and co-creation of research programmes and infrastructures provide immediate benefits including a mutual understanding of realistic expectations and responsibilities, timelines for delivery and resource requirements.

Mechanisms for engagement are likely to vary with the stakeholder and the specific opportunities as well as the different role stakeholders (see D9.11) have in engaging with DANUBIUS-RI.

The stakeholder questionnaire is especially useful in understanding how stakeholders might wish to engage with the governance of DANUBIUS-RI and this plays especially well to the strengths of a pan-European distributed research infrastructure in two specific ways:

(i) The distributed nature of the RI enables stakeholders to engage with an international operation through local offices at the Nodes and the hosting institutions for the Supersites.

(ii) As a research infrastructure, it provides the opportunity for stakeholder engagement beyond the lengths of conventional 3-5 year cycle of research projects and political electoral cycles. This enables stakeholders to build long-term relationships, enable continuity of approach for long term data sets, and provide an effective and efficient pathway(s) for impact for projects undertaken within the RI or related to the RI. This provides very real mutual benefits to both the stakeholders and researchers.

The delivery of products and services, including the effectiveness of the engagement process as a whole, presents many challenges and ensures stakeholder satisfaction is central to a sustainable relationship that is both adaptive as circumstances change and responsive to need. The evaluation should take account of both the *process* of stakeholder engagement and the *outcomes*. The feedback should be seen to be implemented within the RI management process and ensure continuing improvement of management and execution of the stakeholder engagement experience. Effective evaluation can also help in the management of risk associated with the various engagement events.

Rather than overcomplicate the evaluation and feedback process, simple generic assessments should suffice to capture the necessary information and should be at the level of the individual events. Continuous evaluation with stakeholders leads to the most cost effective and improved engagement which can lead to more effective implementation of data and services whilst also providing opportunities of greater influence. Stakeholder evaluation will also provide an important input into the KPIs (Deliverable 6.6) of DANUBIUS-RI.

3 Structure for the Quality Assurance Procedures

3.1 Quality Management System

The ISO/IEC 17025 standard is used to implement a quality management system on laboratories and infrastructures which can include multiple labs utilising first, second or third party laboratories. These laboratories might include within the RI: testing and/or calibration labs, customer engagement (key aspects of ISO 9001), testing organisations, regulatory authorities, accreditation bodies and organizations and schemes using peer assessment. It applies to all organisations performing laboratory activities regardless of size or number of personnel.

Compliance with the standard is designed to confirm competence, impartiality and consistent operation of laboratories and has the added advantage of using national accrediting bodies for the monitoring and maintenance of compliance with this standard. Whilst seeking accreditation to this standard may be a longer-term ambitious goal, formulating the quality management system around the structure of ISO17025 (2017) provides immediate benefits in the management and operation of the RI and does not represent a rigid system hindering research, innovation and development, but provides a system that ensures that any new developments implemented with DANUBIUS-RI are fit for purpose before the resulting services or improvements and delivered.

This section although, not explicitly mapped onto the requirements of ISO17025, covers the key components required to deliver on its Commons framework to ensure that a suitable Quality Management system is in place for the operation of the RI to enable it to deliver world class data and services.

3.1.1 RI Management structure

This section outlines (i) the legal operating framework for the RI, i.e. ERIC which includes the senior management structure; (ii) the structure of the RI which describes the activities undertaken in the different components, including the Hub, Nodes, Supersites, The Technology Transfer Office, the Data Centre and the E-Learning Office; and (iii) the Commons requirements for the Management System.

3.1.1.1 Structure of the ERIC (WP3)

The **legal entity DANUBIUS-ERIC** has the aim to establish and operate the pan-European distributed research infrastructure in the area of RS systems. DANUBIUS-ERIC shall be supported by the DANUBIUS Partners, who shall provide major scientific equipment or sets of instruments, research facilities, resources and related services to the DANUBIUS-RI Components and through them to Users, enabling the conduct of top-level research in their respective fields.

DANUBIUS-ERIC shall provide an effective governance framework, coordinate and harmonize the activities carried out by the DANUBIUS Components in relation to RS systems.

Through its Components, DANUBIUS-RI shall provide effective access to facilities, services, advice and data to promote and drive interdisciplinary research and innovation across RS systems.

DANUBIUS-ERIC shall pursue its main task on a non-economic basis, however it may carry out limited economic activities, provided that they are closely related to its main task and that they do not jeopardize the achievement thereof.

The statutory seat of DANUBIUS-ERIC is in Romania.

The **General Assembly** shall be the governing body of DANUBIUS-ERIC and shall be composed of representatives of the members and observers of DANUBIUS-ERIC. Each member shall have one vote with all votes being of equal value. Representatives to the General Assembly may be accompanied by up to two experts per delegation with the sole purpose of advising the delegation.

General Assembly shall establish an independent **Scientific Advisory Committee**, whose representatives shall be appointed by the General Assembly, and which shall report to it. The Scientific Advisory Committee shall monitor scientific quality of the activity of DANUBIUS-ERIC and the DANUBIUS-RI Components and provide feedback and make recommendations on actions to improve the effectiveness of DANUBIUS-ERIC and DANUBIUS-RI Components outcomes and output and science strategy and provide recommendation accordingly.

The **Director General** of DANUBIUS-ERIC, appointed by the General Assembly and based in the Hub, shall be employed by DANUBIUS-ERIC and shall be the legal representative of DANUBIUS-ERIC. The Director General is responsible for the implementation of the decisions by the General Assembly, including annual work plan and yearly budget as well as five years strategy and financial plan, and he/she shall actively contribute to the community building and fostering external relations and strategic partnerships. In his day-to-day management he/she is supported and assisted by the Executive Office.

The **Research Infrastructure Committee**, composed of one representative from each DANUBIUS-RI Component, shall support the Director General for all general matters including drawing up proposals for the General Assembly in establishing and modifying annual work plans related to the DANUBIUS-RI Components to ensure consistency, quality, coherence and stability of the services offered, coordinate procedures, tools and practices, procurements, and make proposals to the General Assembly to improve the quality and efficiency of the services

DANUBIUS-ERIC and each DANUBIUS-RI Component shall sign a **Service Level Agreement** (SLA) which sets out the terms and conditions on which the DANUBIUS Component shall provide resources and services to the DANUBIUS-ERIC, to other DANUBIUS Components and to Users. A Service Level Agreement may be signed by a lead DANUBIUS Partner on behalf of a DANUBIUS Component in cases where the DANUBIUS Component lacks legal personality.

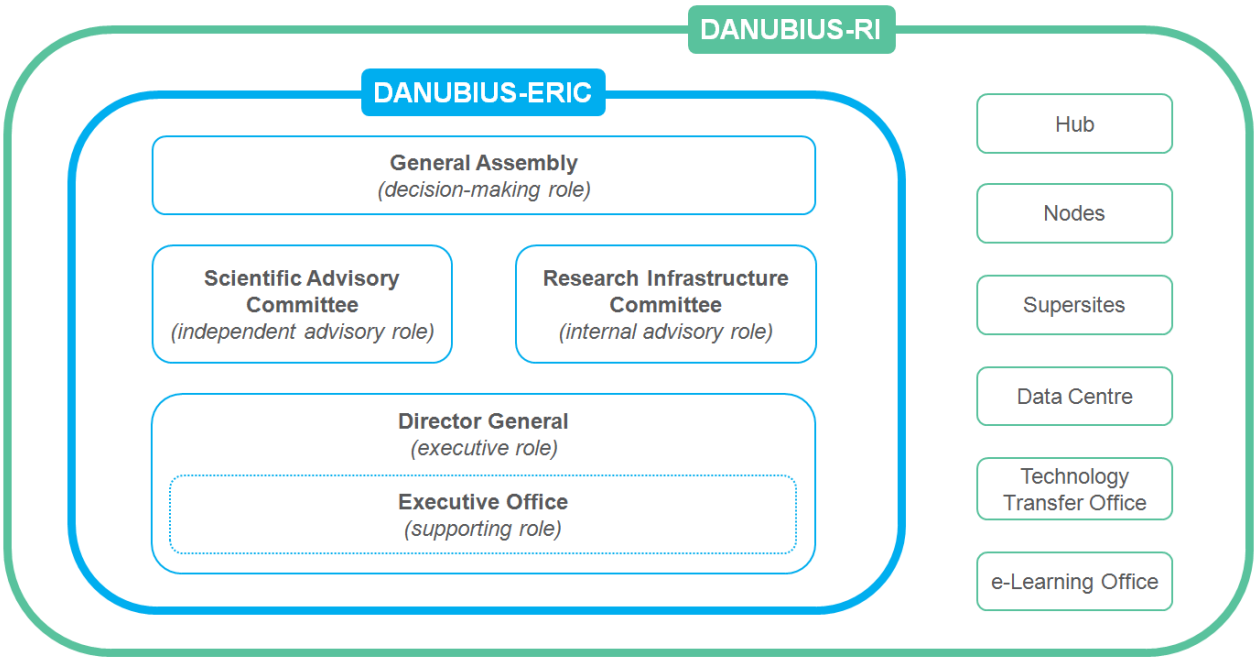

Fig. 5. The proposed Management and ERIC structure of DANUBIUS-RI

3.1.1.2 Structure of the RI (WP5)

The International Centre for Advanced Studies on River-Sea Systems (DANUBIUS-RI) will be a distributed research infrastructure (RI) bringing together world leading expertise and providing access to a range of river-sea (RS) systems, facilities and expertise.

The initial plan of DANUBIUS-RI structure included: the Hub; four Nodes; twelve Supersites; the Data Centre; and the Technology Transfer Office. During the Preparatory Phase, an e-learning Office has been added. All components will be of equal status and work together as a unified research infrastructure.

The Hub is based at Murighiol at the edge of the Danube Delta in Romania. It performs the headquarters functions of DANUBIUS-RI and provide a range of research, training and educational facilities. The Hub will provide management to coordinate the activities of the Nodes, Supersites and other components of DANUBIUS-RI.

The Nodes in concert with the DANUBIUS-RI Hub and Supersites, will enable sustainable programmes of R&I to be promoted and exploited across Europe and internationally, that balance the needs of environmental protection, economic development and wider societal needs and pressures.

The four Nodes are:

The Observation Node will comprise operational data processing (PML) and calibration, validation and training facilities (Stirling) and will facilitate world-leading research in conjunction with the DANUBIUS-RI consortium and other partners.

The Analysis Node: will facilitate access for the DANUBIUS-RI user community to state-of-the-art scientific expertise and highly innovative methodologies that enable the biotic and abiotic conditions and their associated interactions to be characterised.

The Modelling Node: Based in Italy it will provide access to a range of services, from modelling tools to expert support for modelling activities and associated techniques that will be applied in each of the (existing and future) Supersites.

The Impact Node: will facilitate scientific knowledge development at the interface between natural and social sciences; develop methodologies and tools that will help to solve problems in highly complex dynamic RS systems; and transfer scientific output and practical tools derived from DANUBIUS-RI to those engaged in the sustainable management and use of RS systems (to solve problems and to strengthen business in this area).

Also *Accredited Service Providers* (ASP) are developed under the coordination of the Specific Node Leading Institution. They are entities (e.g. university, knowledge institute or company) located in an ERIC Member State; that deliver scientific expertise or knowledge or technical capacity and capability to, and demanded by a Node Leading Institution; and that in their delivery are capable and obliged to apply the DANUBIUS Commons. Nodes are, therefore, composed of Leading Institutions and specific ASPs.

Supersites are study sites, true natural laboratories, which provide the focus for observation, analysis, research and modelling at locations of high scientific importance and opportunity across RS systems, from source to coastal sea. They will be the place for testing new ideas, concepts, methodologies, where theories will be put to test. Supersites will provide support not only for research but also for education and training. Supersites will be the main generators of DANUBIUS-RI data and the flow of data between them, the other components parts of the RI and the Data Centre will be the lifeblood of DANUBIUS-RI.

The Data Centre, in Romania, is the main site for managing and analyzing DANUBIUS-RI data. The Data Centre of the DANUBIUS-RI will be the central point of the ICT infrastructure providing single point of access for the users to all available services. Data Centre will house the DANUBIUS-RI Data Portal, providing access to metadata and data by users and stakeholders. The Data Centre is the DANUBIUS-RI portal to the community of users and the connection with other major e-Infrastructure initiatives in Europe and elsewhere. In this respect it will be the ‘front door’ of the RI.

Technology Transfer Office will coordinate actions concerning the intellectual property (IP) of RI numerous outputs (Cork). The TTO will provide a distributed model with a Technology Transfer Secretariat, governed by national policies, providing insight on national approaches to ownership and assignment of IPR.

E-learning Office: Another component of the RI concerns e-Learning, an internet-based teaching system. For a distributed RI, such as DANUBIUS-RI, involving many people working in different locations across Europe while following the same DANUBIUS Commons, a system of e-Learning is not an option but a requirement. It additionally provides a means of offering to institutions and research communities access to data from databases or experimentation sites located all around the world. The design of such a system requires a defined platform to organise all related tasks such as the material content, the student-system-teacher communication protocols, the deliveries, the evaluation process and administration.

3.1.1.3 Commons requirements

The management system must contain and maintain Commons which include protocols, procedures, forms and test results (referred to collectively as *documents*) that are appropriate to the scope of the RI. A Quality Policy that is defined and agreed by all contributors to the DANUIUS-RI will provide the benchmark against which the operation can be assessed for compliance and should include, for example, a commitment to professional practice, the standard service that is expected including the objectives of the management system and a commitment that staff are familiar with the relevant components of the quality management and technical management system.

Management and Management Review: The RI has defined its management structure but should have a Commons that describes the roles and responsibilities of the individuals within the management structure across all components of the RI, the communication and reporting mechanisms including key agenda items that should be covered by the different components of the RI from the General Assembly to local laboratory meetings to ensure clear lines of communication throughout the RI. This should also include an annual review of the management operation which includes feedback opportunities to ensure continual improvement.

Identity and Communication: Critical to the success of the RI is the consistent experience by the user community, which can only be achieved by ensuring that all branding is used consistently and all mechanisms of communication are well defined and adhered to.

Stakeholder Engagement: Commons that will govern the approach to stakeholder engagement that takes account of the need for flexibility with specific stakeholder needs and ensure maximum benefit to the stakeholder and RI. Stakeholder engagement must also include a process of continuous review to ensure improvement and benefit to the stakeholder.

User Service and the handling of complaints: includes ensuring the user requirements are understood, communication requirements with the customer and the handling of complaints

Document Control: The Commons will require a system for approving, issuing and reviewing documents (See QAP), which includes a mechanism for ensuring the effective distribution of the latest authorised versions of the documents and removal of obsolete documents from the system.

Review of applications, requests, tenders and contracts: The Commons will require a system that deals with applications to the RI for access as well as review of applications/tenders/contracts made in the name of DANUBIUS-RI. This should include a review not only of the science and content, but also ensuring that the capability, capacity and resource are available, including use of ASPs; identification and resolution of conflicts of interest, and any negotiations required. This Commons should include a mechanism for documenting this information.

Purchasing: Commons should include policies and procedures for purchasing to ensure consistency in service delivery across the RI. This might include minimum specification of

equipment and consumables and an assessment of continuity of supply. However, national laws and regulations still have to be respected.

Handling of non-conforming activities and improvement: inevitably things go wrong, but a management procedure needs to be in place to capture incidents to ensure that the impact is assessed, causation identified and corrected and/or mitigated against, and corrective actions are fed back into the Commons for continuous improvement.

Auditing: a programme of regular internal auditing is required to check compliance against the Quality and Technical Management System. This can cover method witnessing, audits of specific commons around a given analytical procedure, or tracing the documentation from user application to data delivery and customer feedback. The findings should also feedback into the Quality System for continuous improvement.

Measures of Performance: As an ESFRI the DANUBIUS-RI will set up a performance monitoring system based around the proposed set of KPIs and CIIs. This will feed directly into the management review of the RI to help decision making and resourcing to meet the user requirements and in response to opportunities for development an innovation.

3.1.2 Quality Assurance Panel

Principles and Commons can be created by any member (both users and staff) of the DANUBIUS-RI community. The approval, update, and removal of Principles and Commons will be executed by a quality assurance panel (QAP). During the implementation phase of DANUBIUS-RI an interim QAP is formed. The interim QAP comprises one representative each of DANUBIUS-RI Nodes, Hub, TTO, e-learning office, and Data centre and three elected persons will represent all supersites. It should be taken into account that each supersite should delegate a representative once in a while. It is suggested that the election period for all interim QAP members by the General Assembly will be three years and each position within the interim QAP has to be filled by a different person. To form the interim QAP it should be strived for a balanced representation of genders, scientific disciplines and scientific experience. The composition of the final QAP will be defined in the ERIC statutes.

One task of the (interim) QAP will be the critical testing of the (interim) QAP structure and, if necessary, the adaptation of its rules of procedure. The adopted rules must be approved by the (ERIC) General Assembly. The main task of the (interim) QAP is the review of submitted Commons and, if necessary, a further clarification of Common structure. Additionally, the QAP needs to administrate the collection of obligatory Commons

To handle these tasks the QAP will assign a handling officer. The handling officer initiates the evaluation of Commons based upon assessments (short advisory opinion) from respective/ impacted Structures or Components. The handling officer or the QAP is further authorized to request review(s) for a Common. All RI participants are asked for assessment by formal suggestions and objections. The QAP decides on the suggested Commons and Principles by majority vote based upon the handling officer´s suggestion, (scientific) reviews, the comments of the RI community members and the impacted/requesting Components of DANUBIUS-RI. The QAP may also demand minor or major revisions of the proposal and can decide on the need for reviews about the respective Common from independent experts (for details see deliverable 6.4 and its supplement).

3.2 Technical Implementation

3.2.1 General Requirements for the Commons

The quality of the data and services delivered by DANUBIUS-RI are dependent on consistency of approach and compliance against the Commons. At the first level, this quality is influenced by both the human and environmental factors under which the data and services are being produced. Commons must be in place to support these requirements.

Personnel: The Commons should ensure the competence of individuals operating within a given set of procedures for which they are responsible. Appropriate training and supervision by competent individuals should be available and training records should demonstrate competency for individuals who are given the responsibility and authority to perform specific procedures. Goal setting, training and skills setting can also be covered by the Commons to ensure an equitable experience across the RI. These should already be in existence within existing local management structures.

Accommodation and environmental conditions: The laboratory facilities and operating conditions shall be adequate to ensure the correct performance of sample preservation and sample analyses. Where specific environmental conditions are required, monitoring should be in place to ensure compliance against these requirements to avoid test results or services being compromised. These might include: biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, or others,. Where conflicts of purpose might exist, sufficient separation or division shall exist.

Methods and method validation: Commons shall be available on the appropriate methods, instructions and procedures that are within the scope of DANUBIUS-RI. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test data. These commons are defined, reviewed and updated via the QAP. Thereby, methods used must meet the requirements of the user, whether specified by the user or not. Methods developed in-house for sample testing or calibration must be validated against appropriate standards or references prior to roll-out across the RI and used. Use of non-standard methods must be in agreement with the user and the QAP. Uncertainty estimation must include all components which are of importance in a given situation.

Equipment: All equipment used for the purposes of DANUBIUS-RI whether within or outside its direct control (i.e. shared equipment not for the sole purpose of DANUBIUS-RI) shall be tested or checked to ensure that the equipment is fit for purpose and operating within the tolerance levels expected. The equipment used shall be of sufficient quality to achieve the accuracy and detection requirements needed by the science. The equipment is used only be authorized personnel. Appropriate calibration programmes and checks shall be in place before being used and records kept. Maintenance records shall also be kept.

Measurement traceability: Commons must be in place to ensure calibration and testing of equipment is in place at the appropriate frequency for the relevant environmental matrices. Reference standards should also be traceable and where possible from

organizations accredited to ISO17025. The development of internal standards can also be used for intermediate checks and testing.

Sampling, storage and transport: The Commons should include sampling plans including locations, substances and materials being sampled. Sampling procedures shall be documented and forms used to record all relevant information. The procedures should also include the transportation, receipt, handling, storage, retention and disposal of samples. A *chain of custody* provides a useful approach to auditing the sample from collection to disposal and identifying individuals responsible at each stage of its journey, processing, analysis and reporting.

Reporting: results shall be provided in the format agreed with the user at the time of user application and review.

3.2.2 Data (Digital/Non-Digital) FAIR (ROEDU)

Data Transfers: Large volumes of data will be transferred between institutions and appropriate tests should be in place to ensure data integrity is maintained

Computer software, models and calculations: Appropriate checks should be in place to ensure that systems are delivering the expected outputs. Documentation should be in place to describe software and model development with adequate detail to be of value to the user. Data protection details shall also be in place that maintain the integrity and, where appropriate, the confidentiality of the data during storage, transmission or processing.

Hardware: Commons shall ensure that equipment is maintained and used within appropriate environments to ensure effective functioning.

Non-Digital Data: the commons should detail the methodology and environments for which samples are preserved and stored for benefit and use of future generations of scientists.

4 Summary for Implementation Phase

4.1 A framework for the Quality Management System

The inputs to the Quality Management framework have been developed throughout the preparatory phase of DANUBIUS-RI and are summarised in Chapters 2 and 3. Whilst core components have been developed in WP6, WPs 3 to 10 have each provided valuable outputs that contribute to either the Management or Technical requirements of the DANUBIUS RI, as summarised in the framework presented in Fig. 6. This framework will ensure the highest standards of engagement and communication between partners and stakeholders, and data and service delivery that is required to fulfil the Science and Innovation Agenda described in WP2 and to grow and enhance the global reputation of DANUBIUS-RI.

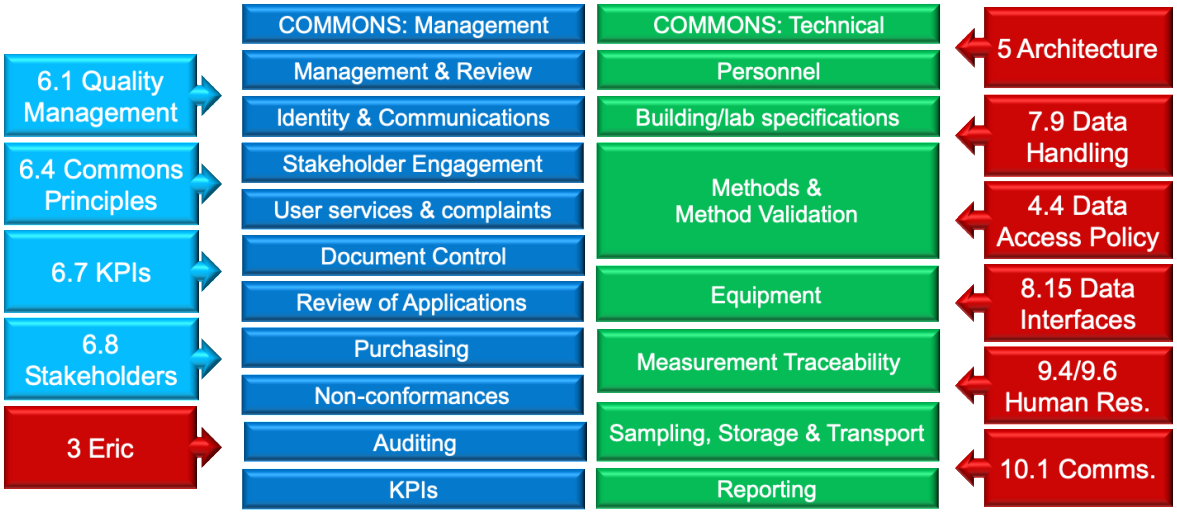

Fig. 6. Summary of the Quality Management Framework with inputs from WPs and a summary of the Commons requirements for the Management and Technical requirements for DANUBIUS-RI.

The Commons for the Management of the RI (Fig. 6) highlights the areas where Commons are required and are described in Chapter 3.1. Adherence to this structure will ensure the smooth management of the RI and when the functioning fails, it ensures appropriate processes can be brought into place to allow these to be managed effectively to ensure corrective and preventative measures are brought into place. Failure of any component can have wide ranging impacts within the RI operation including timely and quality assured data and service delivery, in addition to impacts on reputation. A programme of auditing of the Commons and its implementation will also help to prevent operational failures from occurring in both the management and technical aspects of the RI operation.

The comprehensive range of parameters, technologies and techniques implemented by DANUBIUS-RI, required to drive the knowledge requirements in River-Sea systems, and complex data flows through the different components that comprise the RI, will necessitate

a significant amount of effort for the effective implementation and monitoring of the Commons, including agreement and buy-in. This will be managed through the Quality Assurance Panel. The Commons framework also has the advantage of ensuring that any new methods or instrumentation are properly tested before implementation into the data and service delivery plan.

A phased approach for the implementation of the technical aspects of the Commons must also follow a prioritisation of the DANUBIUS-RI services, which can then be phased in over a realistic timescale to ensure that the minimum specifications are implemented by Supersites across the RI. This will require, for example:

- The minimum specifications for Supersites to be defined
- Harmonisation of data and tools
- Clear definitions and prioritisation for service delivery
- The development of a longer-term delivery plan

Having the Commons framework in place, will not only ensure a traceable and quality assured management structure, data and service delivery, but also the opportunity for seeking accreditation to ISO 17025:2017. Accreditation allows for annual performance review from national accreditation bodies, which provides an extra level of quality assurance review. Such accreditation also offers opportunities for further research, development and innovation in the support of industry and policy sectors, especially where legal accountability becomes a reporting requirement.

4.2 A framework for the Quality Management System

The KPIs provide a framework for monitoring the performance of the RI. These will be reviewed as ESFRI continue their process of defining and agreeing the final set of generic KPIs for RIs on the ESFRI roadmap. It is envisaged that the final set of KPIs will be implemented immediately and reviewed annually and reported to ESFRI as DANUBIUS-RI becomes operational. Equally, following the first year or two of operation, and DANUBIUS-RI becomes established, the benchmark targets should be set of each KPI both collectively for the whole RI, but also devolved to each component part of the RI. Five-year cycles of performance management can then be based on the KPI targets to ensure growth, effective data and service delivery and demonstrate the operational success, impact and therefore value to the research community across Europe and globally.

5 References

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DANUBIUS-PP Deliverable 6.4. Final report on DANUBIUS Commons principles

DANUBIUS-PP Deliverable 6.6. Concept for benchmarking system and performance monitoring

DANUBIUS-PP Deliverable 6.7. Report on standards and rules to integrate stakeholders from European policy and European industry

DANUBIUS-PP Deliverable 7.7. Final - Interconnectivity design: Data Centre, sites, storage capacities, transfer requirements and protocols, options and technologies

DANUBIUS-PP Deliverable 8.15. Implementation of application interfaces - final version

DANUBIUS-PP Deliverable 9.4. DANUBIUS-RI strategy on Human Resources for Researchers – final

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6 Annex 1

External KPIs

No	Indicator	Content
1	Scientific production	Number of publications crediting DANUBIUS-RI; Number of citations; Number of papers using data /knowledge provided by DANUBIUS; Number of publications in database from RI users published within Q1 journals
2	Number of Users	Number of scientific users; Number of non-EU users; Number of non-ERIC users using RI facilities for world-wide sites; number of non-scientific users; Number of MSc and PhD students using the RI; Number of individuals trained who are not RI staff.
3	RI access	Number of successful applications (worldwide) for using the RI; Total number of applications (incl. rejected); Research user fees for competitive access; Research user fees for on demand access.
4	Interdisciplinarity	Number of disciplines involved in research – integrating natural and social science, breaking the disciplinary and geographical boundaries.
5	FAIRness data	Data Findable, Accessible, Available, Interoperable and Reusable; Data Openness; Digital resource openness; Non-Digital resource openness.
6	Innovation and knowledge transfer including industrial impact	Patents; Co-patenting with companies; Joint technology development projects between RI and industry; Industrial technology development projects funding RI research; Students collaborating with industry; Number of publications based on research using the RI together with an industrial partner.
7	Promotion of education outreach	Openness to public; Web Access; Knowledge sharing and improvement including the number of scientific conferences and workshops organised; Total number of people trained in academia and industry; Number of educational and outreach activities including numbers

		attending; Career path of students trained within the RI; Number of students trained and their distribution
8	Stimulate research to inform public policies	Production and co- production of advice in support of public policies; Production of resources, experiments, data, biobanks or informatics resources in support of public policies; Contribution to policy - expert reports, conferences, articles in regulatory or legal texts etc.
9	Facilitate international agendas through research (SDGs, European DGs)	Links between DANUBIUS-RI scientific agenda and international agendas. The number of times DANUBIUS-RI is mentioned in reports and policy documents. Number of consultation / workshop events DANUBIUS-RI members attend.
10	Trigger Interest	Public visibility – Number of occurrences of the RI in regional, local and global online media; Internet popularity – number of followers on social media channels

Internal KPIs

KPI	Indicator	Content
1	Implementation of Commons in the RI	Internal auditing of labs providing the number of labs and list of parameters and systems (including management) successful operating under the DANUBIUS Commons following performance testing trials.
2	Adoption of Commons by labs external to the RI	Number of certifications granted to laboratories operating outside the RI and demonstrating global reach.
3	Adoption of Commons by individual users	Number of trained individuals, *See also external KPI 2.* (This may eventually become an external KPI to demonstrate the level of internal/external training)
4	Adoption of Commons by International Community	Contributions to ISO standards. Number of individuals represented on National Standards Institutes; number of standards developed or modified due to DANUBIUS Commons.

5	Operational Collaboration	Number of Memoranda of Understanding
6	Financial Sustainability	Upgrade/reuse of national pre-existing investments that acquired European/international dimension in the RI New Investments; Investment value compared with the business plan; Income from commercial activities expressed as a percentage of the total.
7	Service Use	Performance/Percentage of use for each service provided by the RI; User satisfaction; Stakeholder satisfaction (see Deliverable 6.7)

DANUBIUS-PP

Preparatory Phase for the pan-European Research Infrastructure DANUBIUS–RI "The International Centre for advanced studies on river-sea systems"

European Commission

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