EOSC-Life

EOSC-Life: Building a digital space for the life sciences

D14.2 – Report about technical implementation and validation of the COVID-19 portal

WP14 – Design, development, implementation and use of a repository for individual participant data from COVID-19 trials
Lead Beneficiary: ECRIN
WP co-leaders: Jacques Demotes (ECRIN), Gard Thomassen (UiO)

Authors of this deliverable: **Steve Canham (ECRIN), Sergey Gorianin (ECRIN), Milen Kouylekov (UiO)**
with contributions from: **Maria Panagiotopoulou (ECRIN), Christian Ohmann (ECRIN), Swarnalathaa Kichenassamy (ECRIN), Gard Thomassen (UiO), Pål Fugelli (UiO), Jacques Demotes (ECRIN)**

Contractual delivery date: **31 August 2021**
Actual delivery date: **16 May 2022**
H2020-INFRAEOSC-2018-2

Grant agreement no. 824087
Horizon 2020
Type of action: RIA

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Executive Summary

The present report is focused on the technical implementation and validation of the COVID-19 clinical research repository developed within the EOSC-Life project. The first section describes the functionality of the repository, split between its two main systems - the TSD infrastructure on the one hand, operated by the University of Oslo, and the Repository Management System (RMS), developed by ECRIN, on the other hand. The RMS is designed to support and record the workflows associated with managing the repository and its interactions with providers, secondary users and requesters. Subsequently, the two systems and their interface to support the repository's activity are described in detail, including the AAI infrastructure that will be used and shared by both the RMS and the TSD. Finally, the validation strategy that is currently applied to the RMS and to the new, repository-specific elements of the TSD is outlined.

Project Objectives

The objective of WP14 is to define the specifications, develop, implement and routinely operate a repository for individual participant data (IPD) from COVID-19 trials, compliant with European regulations and in particular with GDPR, allowing clinical trial data sharing after completion of the trial.

This deliverable marks the definition of the technical specifications for a secure and GDPR-compliant repository for the storage and sharing of data objects (including Individual Participant Datasets) from COVID-19 clinical studies. The development and implementation steps, as well as its validation strategy, are described in the following sections. With the creation and the routine operation of this repository, the project aims to render clinical research data more FAIR.

Detailed Report on the Deliverable

1. Introduction and Terminology

The EOSC-Life COVID-19 Data Repository - in this document referred to simply as 'the repository' - is designed to provide secure, file-based, storage for material generated by clinical research, including documents, individual participant datasets and metadata, making that material available to others within an appropriate ethical and legal framework.

Specifically, in the first instance, it is intended to store material from research related to COVID-19, though there is nothing inherent in the repository's design or planned operation that limits it to this particular area of research. The stored material will remain as discrete files - there is no intention at this stage to aggregate data from different studies into a single platform, or curate

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data into a single structure. The repository is therefore similar in architecture to other file-based systems, e.g. Vivli [1], CSDR [2], and Dryad [3].

The repository is being developed jointly by the European Clinical Research Infrastructure Network, ECRIN [4], and the University of Oslo, UiO [5]. UiO will provide a pre-existing secure infrastructure for storage and access control, called TSD, or the Service for Sensitive Data [6]. ECRIN will act as the main interface of the repository with the research community - i.e. negotiating with those providing the material and those requesting access to it, managing the processes of both data transfer and data access, ensuring the provision of adequate metadata, and monitoring compliance with legal and ethical obligations.

Several of the key terms used within this document can be interpreted in different ways. For clarity, their meaning as used here is described below. In particular:

A ***Digital Object*** (or, synonymously, a data object) is any file available in electronic form, of any type (document, data, media etc.). The repository will store and make available digital objects, not simply 'data' (or datasets, as defined below), because it is designed to contain protocols, analysis plans, consent forms, result summaries and other documents associated with a clinical research study, as well as individual participant data (IPD). Thus, throughout this document, reference is made to digital object transfer, digital object secondary use, digital object storage etc.

The term ***Dataset*** is used when referring to a digital object that contains only data – e.g., a spreadsheet, CSV, JSON or XML file, database dump, etc. In the context of the repository, 'dataset' (or datasets) will usually refer to the file or files of individual participant data derived from a clinical research study.

A Digital Object Provider, or more often simply the ***Provider***, is an organisation that provides digital objects to the repository, i.e. that enters into a Data Transfer Agreement with the repository. Unless those digital objects are already explicitly in the public domain, the Digital Object Provider is assumed to have the legal power to enter into that agreement, for instance, they would hold the copyright or intellectual property rights on the digital objects. For datasets of sensitive personal data, the Provider would be the Data Controller as defined under the GDPR.

Providers must be a legal entity, and thus able to enter into agreements such as a Data Transfer Agreement or Data Use Agreement (described below).

Individuals seeking to re-use data objects are called Digital Object Secondary Users, or simply the ***Secondary Users***. The organisation arranging such re-use on their behalf, normally their employer, is the digital object ***Requester***. Figure 1 illustrates the roles of the various groups involved in the repository schematically.

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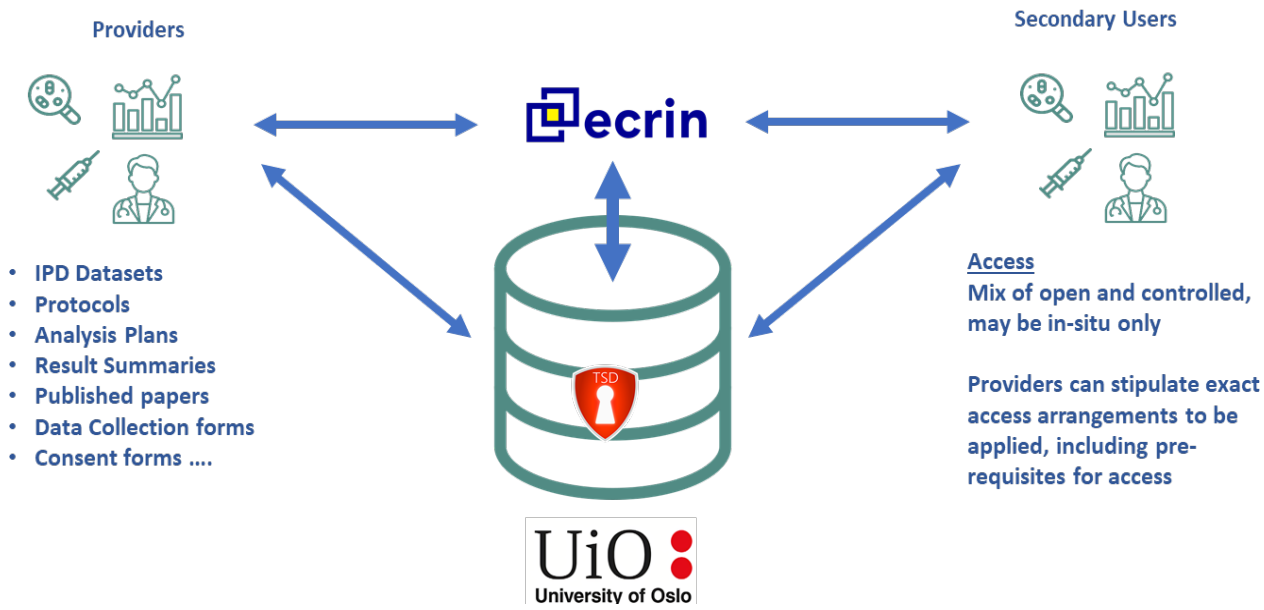

Figure 1: The main actors involved in the repository

The way in which the repository will be run, the options available to providers, e.g. the different access arrangements possible, the agreements that will be used for both depositing and accessing data, the metadata required, etc., have all been summarised in the repository's ***Data Sharing Policy*** [7]. The policy is intended to maximise the flexibility of access arrangements, reduce the burden to data providers of managing digital objects in the long term, and facilitate discovery of, and access to, those objects, all within the European legal framework.

The transfer of objects to the repository will be governed by a ***Data Transfer Agreement*** (DTA), with that document covering the transfer of all digital objects, including but not limited to datasets. Each DTA will include an appendix describing the digital objects to be transferred to the repository, and the access arrangements desired for each of them. Further details (e.g. prerequisites for secondary use, categorisation as anonymised or pseudonymised) will be required for objects under controlled access.

Some objects, chiefly documents like protocols or published papers, are likely to be available publicly. Others, chiefly datasets, will be under managed access. For managed objects, requester organisations will be asked to sign a ***Data Use Agreement*** (DUA) (also known as a Data Access Agreement) on behalf of the secondary users. The DUAs will constrain the use of the managed access objects, typically explicitly prohibiting any attempt to re-identify individuals within a dataset, stipulating that datasets should be stored securely and destroyed after use, and requiring that the providers and repository are notified of the results of the secondary use. In some cases, providers may stipulate that access can only take place 'in-situ', within the TSD infrastructure.

The available contents of the repository will be 'advertised' to potential users using ECRIN's global metadata repository, or MDR [8]. The MDR provides a single portal for searching for clinical research studies and locating the various digital objects associated with them. It currently covers all registered clinical studies (approximately 700,000) and lists well over a million digital objects. It therefore provides the most efficient mechanism for locating the material stored within the

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repository and can also link it to other relevant resources such as trial registry entries. Repository content may also be listed elsewhere (e.g., on the websites of UiO and ECRIN, within OpenAIRE, and within the COVID-19 Data Portal, but there will not be a specific 'portal' dedicated exclusively to the repository unless stakeholders indicate that they feel that this would be useful. (Note that the title of this deliverable reflects an earlier conception of the repository, which has since been developed).

This report is focused on the technical implementation and validation of the data repository. The first section describes how the functionality of the repository is split between two main systems - the TSD infrastructure on the one hand and a ***Repository Management System*** (RMS), developed by ECRIN, on the other. The latter is designed to support and record the workflows associated with managing the repository and its interactions with providers, users and requesters. The next section describes how these two systems are designed to work together to support the repository's activity. The following two sections then look at the RMS and the TSD infrastructure, respectively, in more detail. A short section describes the AAI infrastructure that will be used, and shared, by both the RMS and TSD, and a final section outlines the validation strategy to be applied to the RMS and to the new, repository-specific, elements of the TSD.

2. Functionality and workflows in the COVID-19 repository

As stated above, the repository's functionality is based upon the interaction of the RMS and the TSD infrastructure. There are two main processes or workflows that need to be supported:

- ➔ the data transfer process, when material is provided to the repository, and
- ➔ the data use process, when data is accessed for secondary use.

During the Data Transfer Process:

a) The initial information about the digital objects to be uploaded, and the people who will upload them, will be collected within the RMS. This includes all necessary study and data object metadata and the access arrangements, as stipulated by the digital object providers, required for non-public data objects.
b) Once this information has been collected a data transfer agreement can be constructed (based on a standard template) and agreed, and this too is recorded in the RMS. The ECRIN staff managing the RMS then need to inform TSD:
    - Who will be uploading the data objects, including their email addresses, parent organisations, and credentials within the RMS (if the latter can also be applied to TSD systems).
    - What data objects are to be uploaded.
c) The TSD staff can then arrange for access to be provided to the identified individuals, so that they can upload the material to a specific part of the TSD system. The TSD staff then inform the people uploading:
    - Of the credentials required for access.
d) At the same time, they should inform the RMS, via ECRIN staff:
    - That these arrangements have been put in place.
    - When the material has been uploaded.

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- Where ECRIN staff can locate the uploaded material, for quality checks.

e) The ECRIN staff then carry out quality checks on the uploaded data objects and associated metadata, the results being stored in the RMS. These checks make sure, for example, that descriptive metadata has been applied, and de-identification of the data has taken place. They need to inform TSD of the results of the quality checks.

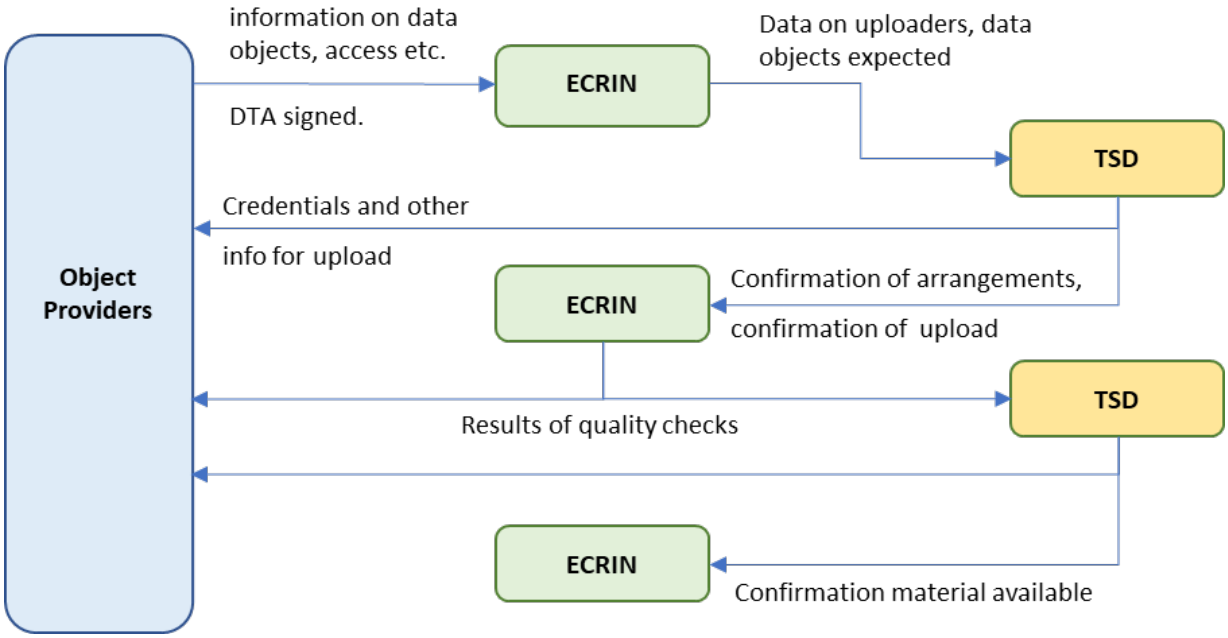

Figure 2: The Data transfer process

f) If checks are successful, ECRIN changes the status of the material so that it is advertised as available (even if under controlled access for some data objects). TSD makes any corresponding change in how and/or where they store the material, so that material designated as publicly available becomes so, and material designated as under controlled access is available for controlled access management.

g) If the check is unsuccessful, a dialog needs to occur between ECRIN and the provider staff, with the possibility of uploading revised versions of some data objects. ECRIN will record this process within the RMS and keep TSD informed, in case re-application or extension of upload permissions are required.

h) Once the material has been established within the repository as 'available', TSD inform:
   - ECRIN and the data uploaders that this is the case. The data transfer process is then complete.

During Data Use:

a) Initial information about the request – including the data objects sought, the people requesting and the reasons for their request – is collected by ECRIN within the RMS. Where prerequisites have been established by the data providers, these are also checked.

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b) Data Use Agreements are established between the data requesters and either the data providers directly or between the requesters and the repository acting on behalf of the data providers (depending on the providers' previously stated preferences).

c) Once the Data Use Agreement is agreed ECRIN informs TSD of:
   - The data objects that are to be made available.
   - The individuals (names, email addresses and organisations) to whom permissions for access in-situ and/or download should be provided.

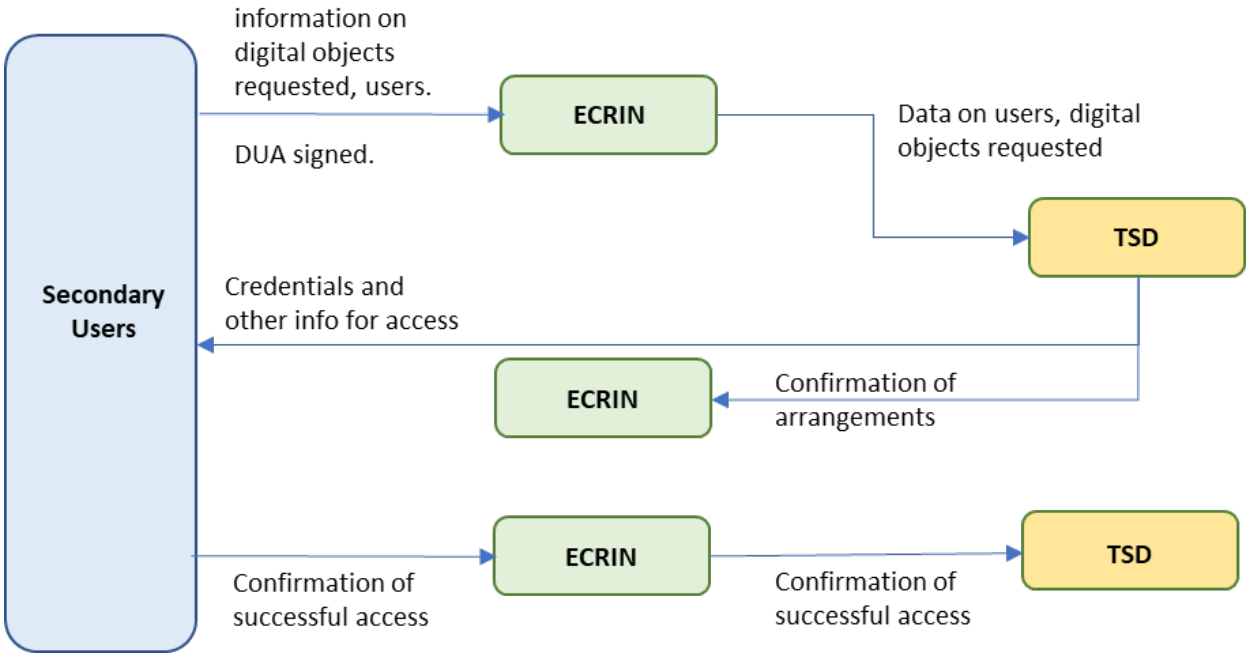

Figure 3: The Data use process

d) TSD staff then inform the people accessing/downloading the material
   - Of any credentials (or processes for establishing credentials) required for access.
   - The specific area within the system where the material can be found, (if this is not handled automatically by the system).
   - Time limits for access.

e) ECRIN is informed once these arrangements are put in place and the RMS is updated.

f) The users confirm successful access/download to ECRIN, and ECRIN then
   - Inform TSD that the Data use Process has been completed (so that permissions can be removed).

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3. The Repository Management System (RMS)

As the description of the repository's main workflows makes clear, the RMS has a central role in managing and recording the work of the repository. As shown in Figure 4, on the next page, the system must hold and process details of:

- Users of all types, their roles, and the particular process and objects with which they are concerned.
- Copies of the metadata associated with the studies and digital objects stored in the repository (though, once complete, that metadata is exported to ECRIN's metadata repository (MDR) for public viewing.
- Records of the Data Transfer Processes (DTPs), that lead to digital objects being deposited within the repository.
- Key details of the specific Data Transfer Agreements used within Data Transfer Processes.
- Records of the quality checks carried out on datasets and metadata once they have been uploaded.
- Key details of the Data Use Processes (DUPs), that lead to digital objects being accessed by secondary users.
- Copies of (or references to) the specific Data Use Agreements used within Data Use Processes.

The RMS will also be used to generate summary statistics and other 'management' information about the repository's functioning. Note that the digital objects themselves are never stored within the RMS - they are instead stored within the TSD's infrastructure.

The RMS Database

The RMS data is stored in a Postgres database, itself hosted on an external, commercial server provided by the French company OVH (physically located near Gravelines in Northern France). Its organisation reflects the list of entities above.

There are two main sets of tables, one with the details of the Data Transfer Processes (DTP) and the other with details of the Data Use Processes (DUP). Each of these are linked to the specific digital objects that are the subject of each transfer/use process, and the specific users involved in each process. ***Appendix A*** provides two summary entity-relationship diagrams of the relevant tables.

The RMS database also stores two sets of metadata. The first is the discovery-access-provenance metadata provided by the ECRIN metadata schema, for both data objects and the source studies. This will be exported to the global metadata repository, which uses exactly the same data model. ***Appendix B*** provides simplified entity-relationship diagrams for these tables.

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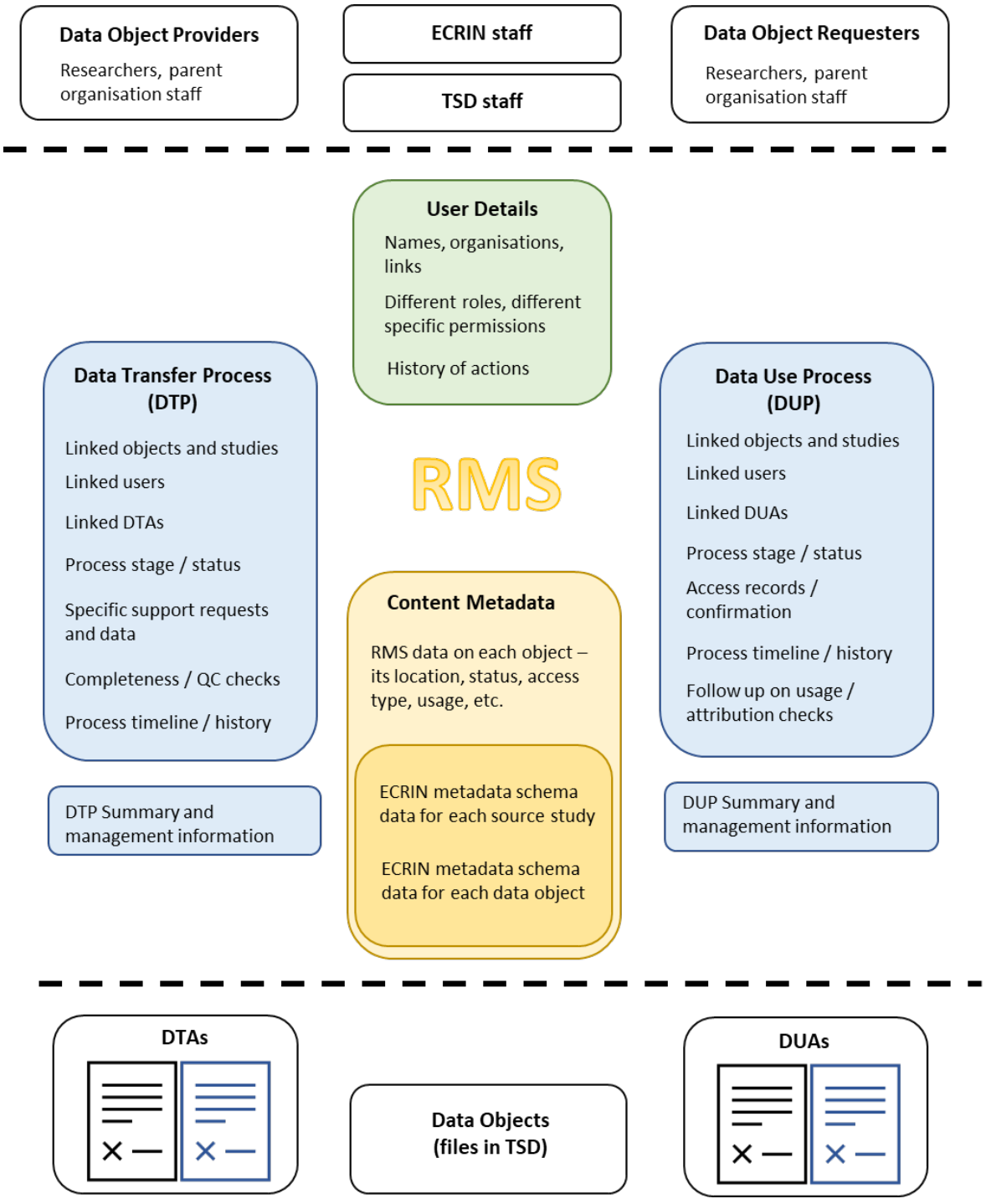

Figure 4: Main entities to be stored and processed within the RMS (entities in white outside the dashed lines are external to the RMS).

The second is the RMS specific metadata that describes the particular access requirements, (type, prerequisites, embargo periods etc.) and quality check results for controlled access objects. This

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data is part of the DTP/DUP tables - for example there is an access_prereqs table that stores the prerequisites stipulated by data providers for access to managed digital objects, like IPD datasets, and a dup_prereqs table for recording whether or not secondary users have met those prerequisites within a particular data use process.

More detailed specifications of the database, including a field by field metadata description, together with the SQL scripts that were written to create the tables and fill some of them with sample data, are available if required.

Technical implementation

The RMS system has been designed within a microservices model, i.e. it is one of several connected services maintained by ECRIN, all of which share the same basic architecture and technology stack, and all of which are hosted on OVH servers.

Figure 5 shows the overall configuration of this system. The RMS is exposed as a web-based 'RMS Portal', which forms the 'front-end' of the system. (The ECRIN MDR or metadata repository portal is currently the other front-end system). The 'back-end' RMS service, which controls the content of the displayed web page as the user navigates around the system, is one of several interconnected services in the system, and has the RMS database 'behind' it (actually located on a different server, accessible only by the RMS service).

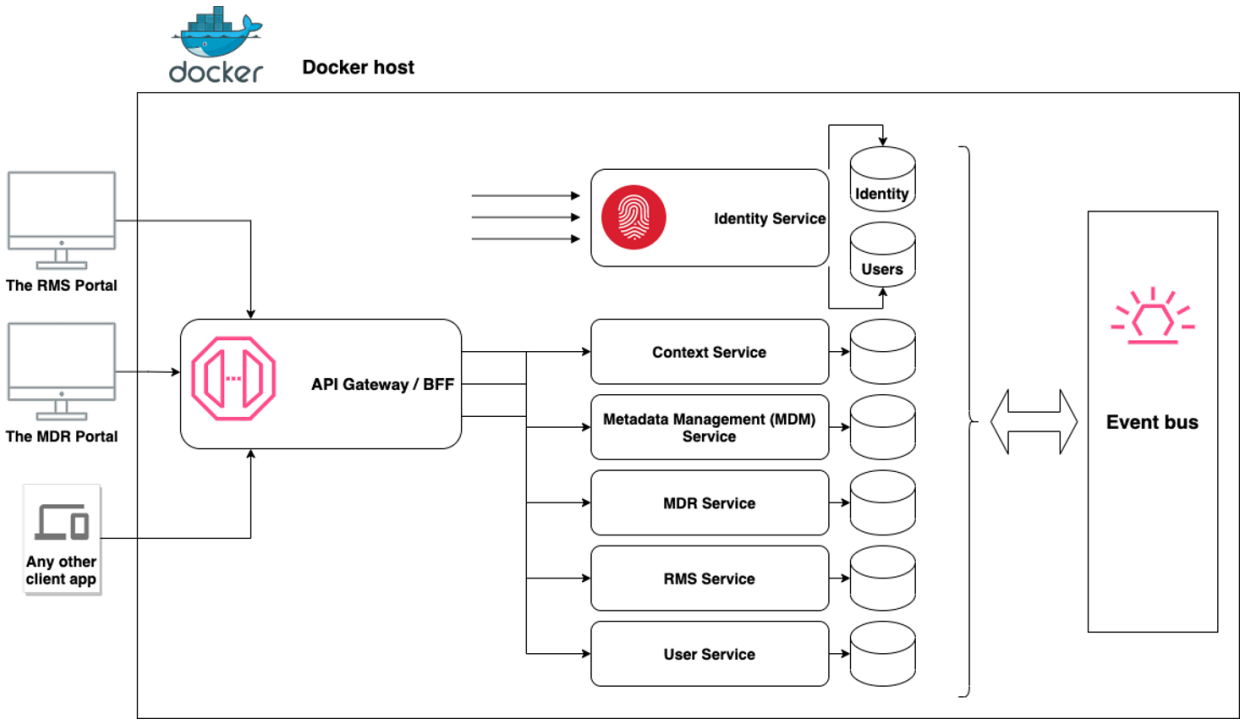

Figure 5: High level view of the ECRIN microservices architecture.

This architecture allows different services to focus on different areas and prevents unnecessary replication of both data and processing systems, making development and maintenance easier and more efficient. Thus, for example, the Context service handles contextual data (e.g about

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organisations), the User service user related data, and the RMS service handles only RMS specific data and tasks. Some of the specific components of the system are listed below:

- The ***API Gateway*** or ***BFF*** (Back-end for Front-end) is an API management tool which sits between a client-side portal and a collection of back-end services. It contains additional business logic implementation (e.g. users authentication and authorisation checking) which is common for all back-end services. An API gateway acts as a reverse proxy to accept all application programming interface (API) calls, aggregate the various services required to fulfil them, and return the appropriate result.
- The ***Identity service*** is simply the AAI service, whose role is to authenticate and authorise users within the RMS system (other ECRIN services do not currently need an AAI service). The Life Sciences AAI is used as an AAI provider (see section 5).
    - The Context service allows reading and updating of the context information, including:
    - Look up table information (eg. study types, statuses, access types etc.);
- People and organisations related information.
- The ***MetaData Management (MDM) service*** allows RMS users to add, edit, read and delete study and data object related metadata, based on the ECRIN Metadata Schema [9], including such information as contributors, identifiers, instances, titles, descriptions, etc.
- The ***MDR service*** is a service which provides a search API for the MDR and its related functionality.
- The ***RMS service***'s role is to allow users to manage information about the two core RMS processes: DTP and DUP.
- The ***User service*** works with user related information, including the user's profile, user's specific processes and metadata (studies, data objects, DTPs, DUPs), etc.
- The ***Event bus*** lets microservices subscribe to events, publish events and receive events to and from each other, to handle the distribution of information and tasks within the microservice collection.

System Development

The following technologies were used to develop the system:

- ***Front-end (client-side)***: Angular (v.11), Ngrx, Rxjs, Material design, Bootstrap, Webpack.
- ***Back-end (server-side)***: ASP.net Core (v.5), Entity Framework Core, IdentityModel (OpenID Connect Client), Identity Server (for AAI development and testing purposes), Dapper (Micro-ORM framework for complex database queries and migrations management), Npgsql (PostgreSQL library).
- ***API Gateway***: Ocelot.
- ***Event bus***: RabbitMQ.
- ***Caching support***: Reddis.
- ***Documentation***: Swagger.
- ***Containerization***: Docker.
- ***Version control***: Github.

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Screen Configuration

The screen configuration, i.e. the navigation available to users on the RMS portal is shown in Figure 6, where the arrows show the normal navigation available. Although there is a single 'landing page' for the application, the options available from it depend on whether the user is logged in as an 'internal user', i.e. is a member of ECRIN or TSD staff working with the RMS, or is an 'external' user, providing a particular set of digital objects, or requesting access to such a set.

Internal users can view and generally edit all data in the system - i.e. they can see all of the data transfer and data use processes. External users can only see the particular DTPs and/or DUPs with which they, or their organisation, are directly concerned. Thus, an internal user can see a series of 'summary' pages, each of which allows browsing of a system entity, be it DTPs, DUPs, studies, digital objects, or users, and can also access a report screen that provides summary data in various formats. They can also 'drill-down' from any of those summary pages to get to the details of a particular DTP/DUP etc.

External users, in contrast, can only access a single summary page, that lists only 'their' DTPs, DUPs, i.e. in which they or their organisation are participating in in some role, and the studies and objects linked to those processes. They can also drill down to the relevant details pages, but of course only from a much smaller set of entities. In a little more detail, the screens available are:

1. ***Landing page*** – the landing page for the system's URL. Contains a login panel, along with some explanatory text and logos.
2. ***Home page*** (internal) – Includes the navigation options for internal (ECRIN and TSD) users. Links are to the various different summary pages – one for each of the main entities. Also to be used to summarise current repository content and usage statistics, of access, transfer etc., in a 'dashboard' format.
3. ***Home page*** (external) – Has a welcome message and the navigation options for external (data provider or requester) users. Lists only the specific DTPs and/or DUPs that the user or their organisation is involved in and provides links to the summary pages for those processes. Also lists the data objects associated with DTPs and DUPs, and for DTPs provides links to the metadata detail pages. Also links to the details of that user's own user details page.
4. ***DTP summaries screen*** – Lists all past and ongoing data transfer processes. Data transfers are identifiable, for instance, by status (e.g. current versus completed), by provider organisation and by date. For each listed DTP, a link exists to the DTP summary screen.
5. ***DUP summaries screen –*** Lists past and ongoing data request processes, for objects with managed access. Data accesses are identifiable, for instance, by status (applied for, current, completed), by requester organisation and by date.
6. ***Reports list page*** – Lists the available reports in the system. Clicking on a specific report generates a spreadsheet or a PDF, depending on the report, and shows it in another tab, and makes it available for download (or causes a download automatically).
7. ***Study/data object summary page*** – a listing of the data objects that have been deposited, arranged under the relevant source study. Links allow a drill-down to the metadata details.
8. ***People/users summary screen*** – a listing of people known to the system (most of whom will be system users), with their associated organisation affiliation. The list is sortable by last name or by organisation. Links provide a drill-down into details of each individual.

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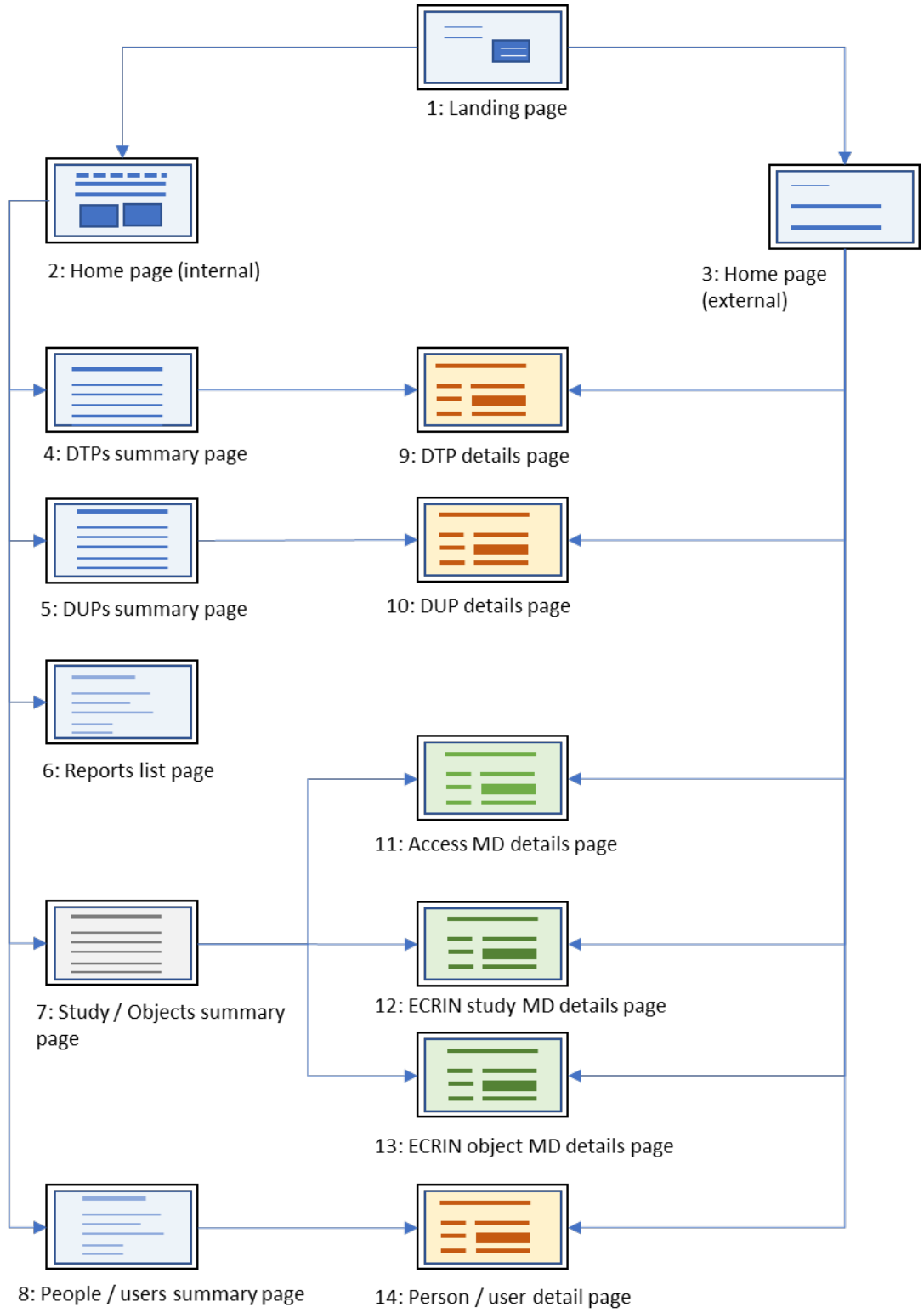

Figure 6: Main screens visible to external users (right hand side) and internal users (left hand side).

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9. ***DTP details page*** – Details of the Data Transfer Process, including linked organisations/people, objects and transfer agreement, dates of key stages in the DTP process, and overall status of the transfer.
10. ***DUP details page*** – Details of the Data Use Process, including linked organisations/people, objects and data use agreement, dates of key stages in the DUP process, and overall status of the transfer.
11. ***Access metadata details page*** – used for capture and editing of the system-specific metadata about each data object to be uploaded. Includes the exact access type required, any embargo period, any prerequisites for consideration of access requests (for managed data objects), requested use of a data access committee, etc. These data points are not part of the ECRIN metadata schema but are required for the repository to be clear about the data provider's requirements.
12. ***ECRIN study metadata page*** – used for the capture or more usually the editing of study metadata in the ECRIN metadata schema.
13. ***ECRIN data object metadata page*** – used for the capture and editing of data object metadata in the ECRIN metadata schema. Although the basic type and name of data objects will have been captured early in the DTP process, it will be necessary to complete the other metadata points to enrich the data in the MDR.
14. ***Person/user details page*** – used to capture and edit the details of people in the system. Contains name, affiliation and email address, plus the currently linked DTPs/DUPs. For users, the dates RMS and TSD system access was granted/revoked are also included.

4. TSD (Services for Sensitive Data)

Introduction to TSD

The TSD system was developed at the University Centre for IT (USIT), University of Oslo (UiO), and was set up to comply with the GDPR regarding policies for research on sensitive data. The majority of the research projects hosted use health information that is directly or indirectly identifiable. TSD is a centralised on-site cloud technology based-service. Storage, virtual machines, databases, private physical servers and High Performance Computing (HPC) is provided within this secure environment. Every project, including the repository, has its own set of virtual machines (VMs) inside TSD as a virtual workspace.

Users of TSD are normally required to access and work on their data via virtual workspaces, with technical and administrative restrictions regarding downloading data to local facilities. In the case of the repository, downloading will be allowed for publicly available digital objects, and - if the data provider has allowed it - for managed access material after all criteria have been met. All users must also comply with a general TSD code of conduct.

Sensitive data are kept within a virtual workspace including separated storage volumes. When data providers stipulate only in-situ access to their material, TSD can, by using VMs with sufficient computing power and high internal bandwidth, provide a flexible and familiar work environment to research projects.

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The firewall guards the system by allowing only authenticated and authorized access. All research projects reside within their own segmented network, either a Virtual Local Area Network (VLAN) or a micro-segmented network region. This gives the system several layers of security and it gives strict separation between TSD projects.

Gateways/jumphosts

There are two network gateway servers (aka jumphosts). These run FreeBSD and reside between the TSD internal network and the regular UiO outside network. All incoming traffic (except the Horizon view connections, see below) is routed by, and inspected by, the firewall servers. The Horizon View infrastructure has its own gateway, the gateway routes the incoming traffic and handles connections. Each project is separated from the other by automatically generated firewall rules set by the jumphosts. This ensures that a user from a given project can only access components and storage resources leased by that project. Routing and firewall rules are defined by the provisioning system, which is considered the master database of users, projects and all other resources. Further, the jumphosts also enable communication between computers on the inside and trusted computers on the outside (licenses, system-logging, reports etc). Port openings are strictly defined by protocol, port-numbers, target-computer on the outside/inside and direction of the traffic in the firewall. All firewall rules are auto-generated upon project creation.

Provisioning system

TSD has a specially developed IAM (Identity and Access Management) system that controls all users, and is the master-source of privileges etc. For computers TSD uses an instance of MREG (the UiO machine(computer) register).

The IAM feeds the Active Directory system with information about users and privileges, while MREG feeds the resource provisioning system with information about which resources a project and user should have available. Resource provisioning uses VMware tools, and IBM ESS API etc. The IAM is fed with data from the self-service system, and project-users are entitled to project membership by a project admin.

Network

The network inside TSD uses private RFC 1918 IPv4 addresses and the network is based on IPv4, while all machines also have a fully addressable dual stack IPv6 address.

At present the usable limit of VLANs before complexity issues arrive is approximately 2000 VLANs, ten of which are used for iDRAC (Integrated Dell Remote Access Controller, management, HPC, hypervisors and TSD administration and operations. Today projects are separated by VLANs internally inside TSD, in the near future TSD will introduce microsegmentation to allow more than 2000 projects.

TSD's network is strictly firewalled, and internal IP addresses are not published to external DNS services. TSD has a hierarchy of 3 different DNS servers, two running Unbound (resolvers for addresses inside TSD) and one running BIND, which is authoritative for queries from TSD and the

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UiO resolvers outside TSD (having only IPv6 addresses). TSD servers are not able to ping or do DNS lookups on addresses outside the main firewall, unless whitelisted by TSD.

Virtual machines

The virtualisation system used is based on VMware. The virtual machines are either Linux or Windows. In addition, the virtual hotel hosts some FreeBSD machines. Provisioning is done based on the master database of TSD and performed by standard VMware components. OS disks are either served from the TSD block storage on Fibre Channel or from the internal VSAN on the VM hosts.

Storage

Project storage for TSD is in a process of change. Currently it is the UiO storage resource named Astrastore. Astrastore is a SAN solution from Hitachi of ~2,8PB disk and 3.5PB tape. TSD has a part of these storage resources (~1,5 PiB) that is logically separated from the remainder. This disk is delivered to TSD in two ways. Block storage devices are provided to TSD servers via dedicated Fibre Channel infrastructure, and NFS or CIFS shared storage provided for project storage.

The block storage is used for the VM OS and as storage for the PostgreSQL databases, and represents a small part of the total storage resources used.

Secondly the main bulk of the TSD storage is delivered via Network File System (NFS) or Common Internet File System (CIFS). All access to the storage management system and the network switch between the Hitachi NAS Platform (HNAS) and TSD is behind Multi Factor Authentication (MFA). TSD has dedicated storage heads to separate it from all other usage. Physical access to the storage server room is very restricted, and few sysadmins can access the room.

Each project has the following standard folders:

- /data/no-backup/ (work area for temporary files)
- /data/durable/ (work area for data that must be backed up)
- /home/username[1-n] (only accessible by the single user)
- /data/durable/file-api (file API import and export)
- /data/durable/s3-api (file s3 API import and export)

There is one/shared directory that everyone can read, but only some selected admins and users admin can write to from the non-sensitive data project, this is for open data and software repositories. Failed disk drives are physically destroyed by a commercial disk crusher that makes reconstruction of data impossible.

The new TSD file storage is a physically separated IBM ESS of 6PiBs running General Parallel File System (GPFS) and exporting data to projects as NFSv4 with Kerberos and SMBv3 with Kerberos. Further the GPFS is presented directly to the Colossus cluster over infiniband. During early 2022 the storage will take over completely from the Hitachi system.

The File API is designed for file import and export and data streaming such as video recordings. The s3 API is a custom deployment of an open source web service that presents an object storage API compatible with Amazon Web Services (AWS) s3. The Storage/Retrieval API is a custom

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deployment of another open source component that creates a REST interface for JSON data based on PostgreSQL databases. TSD has developed and released an open source API client[1].

Backup

Backup is done with an isolated part of the UiO backup system based on Commvault that resides within TSD, but with the data (dedicated disk and shared tape) placed in a different building. The only part that is shared with UiO is the tape library, where TSD has its own partition. All data that is written to tape is encrypted, and the encryption is done inside TSD before data is written to the Commvault system.

Software, software provisioning and licensing

A number of software packages (open source or licensed) are offered in TSD. Deployment happens through the same methods used for UiO, namely the CFengine and System Center Configuration Manager (SCCM) to provision Linux and Windows VM respectively. Dedicated instances of CFengine and SCCM are running inside TSD.

The software portfolio available on the virtual machines includes basic office and statistical software on the servers: MS Office/Open Office, SAS, Matlab, Stata, SPSS, R, etc.

On windows computers Applocker is enabled to disable user software installation. Linux-users are able to install software in their /project or /home areas as long as this does not require administrative rights. Further, we strive to have the most used analysis tools on the cluster, such as HTS specific software (GATK, annovar, Picard, Tuxedo Tools) available by module load commands. In addition, we have a network folder that is read-only for all project users, this can be used as local repository for typical additional software (for instance the entire CRAN and Bioconductor libraries for R), and we provide a significant amount of non-sensitive common reference data on this shared directory. This network folder has subdirectories maintained by sysadmins or by project administrators, and it requires a separate MFA login to write to.

Self service portal

TSD has established a self-service portal where TSD will offer more and more self service-services. Today the following is possible:

- Apply for membership in a project
- Apply for a project
- Grant or deny users a membership in a project
- (Re)Set your password and one-time code
- Grant export rights
- Grant group privileges
- Generate download links
- Generate different grants for users

[1] https://github.com/unioslo/tsd-api-client

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Risk evaluation

TSD has been through a thorough evaluation by the chief of IT-Security at UiO. The risk assessment document is available on request. The security assessment of TSD is a continuous process and the risk evaluation is updated when a significant change has to be made in the infrastructure. TSD has also undergone penetration testing by an internationally recognized IT security expert. The penetration testing attempted i) an illicit login without valid user credentials and ii) illicit access to data of a given project operated by a licit user of another project. None of the targeted attacks were successful.

5. Roles, Users and AAI mechanisms

The management of user access is, at least in parts, a shared function that involves both ECRIN and UiO, and their respective systems, the RMS and TSD. It has therefore been described in this separate section.

Within the RMS there are two main groups of users: internal (System Administrator, ECRIN Repository Manager, TSD staff) and external (data providers and data requestor staff).

Internal users

System Administrators have access to all parts of the system, all data and all functions. A role only given to the system's developers.

ECRIN Repository manager(s) or co-ordinator(s) – the main direct users of the system. Their functions include the following:

- Setting up Data Transfer Processes (DTPs) and Data Use Processes (DUPs) within the system. This includes ensuring that the correct users, objects, agreements etc. are linked to each process.
- Resolving any issues with user details or their authorisations to view specific process/object details. Even if most of these authorisations can be set up automatically, this role therefore needs access to, and edit capability within, user detail screens.
- For DTPs, carrying out, and recording the results of, quality control (QC) checks on the supplied ECRIN metadata.
- For DTPs, carrying out, and recording the results of, QC checks on the system specific (access requirements) metadata.
- Recording the location and other details of DTAs, once agreed.
- Signalling to TSD that the objects in a specific DTP can be uploaded so that the specified users can be given the necessary rights.
- For DTPs, carrying out, and recording the results of, QC checks on the uploaded data objects.
- If and when necessary, recording the nature and completion of additional services requested by data providers (e.g. support in de-identification).
- Indicating the 'acceptance' by the repository of objects, so that their presence becomes publicly available, and liaising with TSD to confirm this has happened (if the latter cannot be done automatically).

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- For DUPs, carrying out, and recording the results of, pre-requisite checks against access requests.
- For DUPs, carrying out, and recording the results of any requested input from a Data Access Committee.
- Recording the location and other details of DUAs, once agreed.
- Indicating to TSD that the specified users have been granted access to specified objects, so that access can be arranged (if the latter cannot be done automatically).
- For DUPs, carrying out, and recording the results of, secondary usage and attribution checks used material.
- Running reports that provide a description of objects and/or activity within the repository, e.g. for management purposes.

TSD staff are also direct users but they should not be directly involved in most of the activities listed above. Their access should therefore be largely a read-only version of that provided to the ECRIN RMS coordinators, with a few exceptions to allow them to indicate that they have carried out one of 3 tasks:

- Provided access for file upload, for specified users and specified objects, as part of a DTP (this message is also sent to the external users concerned).
- Made uploaded files available for access (i.e. after all checks have been successfully completed), as part of a DTP.
- Provided access for on-screen access and/or download to managed access files, as part of a DUP (this message is also sent to the external users concerned).

This role should therefore provide edit access to the relevant indicator fields in the DTP/DUP records, and any associated textual comment fields. Authorisation mechanisms would need to be in place to allow these features – which might need to be applied at the level of individual items to allow the edit capability described above.

External users

Data Provider external users are the staff from a data provider organisation that are involved in one or more DTPs. Any member of staff from a data provider could be given this role, on request, though a brief explanation of why access was required would be expected. It should also be possible to add people to the system who are not direct 'users', e.g. a legal representative who signed the DTA (and whose basic details should be recorded) but who had no interest in using the system themselves. A DTP would therefore have several linked people listed.

Where one of these people is a user, they should only see the details of DTPs and the details of the agreements and objects linked to DTPs, that are linked to their own organisation. Access to the DTP and agreement details should be read-only (these are updated by the RMS co-ordinators) but access to the object metadata should be read/write, as the users will be expected to provide or update much of this data.

Data Requester external users are the staff from a data requester organisation that are involved in one or more DUPs. The role includes both researchers and central administrative roles within the organisation, and it can include people who are not direct users but for whom it is useful for the system to store their personal details. Where access is required it needs to be limited to the

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details of the specific DUPs, the linked agreements and the details of the data objects (e.g. specific prerequisites) linked to their organisation. The access need only be read-only, as little or no direct input is required. A possible exception might be to confirm successful receipt, or on-screen access, of the requested material.

TSD login

TSD offers different login functions to enable secure Graphical User Interface (GUI) access to the project VMs inside TSD, according to the operating system (OS) of the remote client.

For access to projects VMs TSD provides the VMware PCoIP protocol with 2-factor login as the primary login protocol. TSD supports VMware Horizon View Client and the VMware html5 BLAST protocol. This enables 2-factor login to TSD windows computers from any modern browser or the client if preferred. The login methods use TSD Active Directory (AD) with Kerberos for password verification and the TSD FreeRadius server for the second factor.

Giving access to projects and users

All users in TSD are registered as a PERSON and one person has one or more USERNAME(s), one for each project they are a member of. Each person is given a combination of a one-time code and a password to access the system. The combination projectname-username is used to guide the user to the desired project.

The Authorisation API supports three authentication methods: 1) basic authentication by means of a persistent API key (coupled with IP whitelisting), 2) SAML and Open ID Connect using Difi's ID-porten service, and 3) authentication using TSD identities. Authorization is based on group membership.

The RMS login

The Life Science (LS) AAI is now used to authenticate users within the RMS system, though for much of the system's development the ELIXIR AAI was used. The ELIXIR AAI has now been incorporated within the Life Science AAI and all system details have been migrated to the newer service.

The first step was registering the RMS as a client service with the AAI. After setting up a personal ELIXIR account[2], the client registration was carried out[3]. This involved registering a "New service", and in the case of the RMS selecting "OpenID Connect" as the protocol to be used from the dropdown menu, then following the several steps asking for relevant information to be completed for service registration.

The ELIXIR AAI administrators reviewed and approved the registration. The registration system also generated *client_id* and *client_secret* values for the RMS service. The Life Science (originally

[2] at https://www.elixir-europe.org/register/
[3] using: https://spreg.aai.elixir-czech.cz/spreg/

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ELIXIR) AAI service then needs to be integrated into the RMS portal code as an external authorisation service.

When an individual logs in to the RMS the authorisation step is 'passed off' to the external service, the Life Science AAI, that requests the user's credentials. These may have been originally set up with another external service (e.g. ORCID) in which case that external service will be contacted for the credentials. If authorisation is successful, an access code is obtained.

Internally the request takes the form of a 'redirect' (http code 302) from the RMS to the external service:

```
HTTP/1.1 302 Found
Location: https://login.elixir-czech.org/oidc/authorize
    ?response_type = code
    &scope = openid profile email
    &client_id = client
    &state = StAtE
    &redirect_uri = https://your.host.org/callback
```

Here:

- ***response_type*** is always "code"
- requested scopes must be a subset of what has been registered
- ***client_id*** which has been received after the registration is completed
- state is a randomly generated secret which will be received and checked after redirection (Protection against cross site request forgery (CSRF) attack)
- ***redirect_uri*** must match one of the URIs that have been registered.

After user authentication, the user is redirected back to the RMS client, specifically to the defined redirect URL. The ***code*** param represents successful user authentication:

```
HTTP/1.1 302 Found
Location: https://your.host.org/callback
    ?code = AuThOrIzAtIoNcOdE
    &state=StAtE
```

The next step is to exchange the access code for an access token, with the RMS system sending:

```
POST https://login.elixir-czech.org/oidc/token HTTP/1.1
Content-Type: application/x-www-form-urlencoded
Authorization: Basic clientId:clientSecret

grant_type = authorization_code
    &code = AuThOrIzAtIoNcOdE
    &redirect_uri = https://your.host.org/callback
```

and the response being something like:

```
HTTP/1.1 200 OK
Content-Type: application/json
{
"access_token": "ToKeNhEaD.AcCeSsToKeNbOdY.ToKeNsIgN",
"expires_in": 3600,
"scope": "openid profile email"
```

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```
"id_token": "ToKeNhEaD.IdToKeNbOdY.ToKeNsIgN"
}
```

The response body is a JSON object which includes an ***access_token*** key. This is a JWT (json web token) which already contains some useful information such as the unique user identifier.

expires_in is in seconds. The JWT is saved till that time so there is no need to obtain a token each time the user or the system needs to request info.

scope is a collection of available user attributes or claims.

id_token is another JWT token with some other useful info. Tokens are normally signed.

The final stage is to obtain some user information and/or claims (roughly equivalent to 'rights' within the system) by sending a GET request to the userinfo endpoint (within the external authorisation service), with the authorization header containing the access token as shown below.

```
GET https://login.elixir-czech.org/oidc/userinfo HTTP/1.1
Authorization: Bearer ToKeNhEaD.AcCeSsToKeNbOdY.ToKeNsIgN
```

The JSON object with standard OpenID Connect claims will be received. The exact content will depend on the scopes previously established for the service.

```
HTTP/1.1 200 OK
Content-Type: application/json

{
"sub": "5d16d564135a4363ada44b809169275ead3244bf@elixir-europe.org",
"name": "Ondrej Velisek",
"given_name": "Ondrej",
"family_name": "Velisek",
"email": "ondrejvelisek@gmail.com"
}
```

The same authorisation token is sent in requests to the RMS system whenever authorisation is required to view or edit a page, which it is for almost all pages.

When the user logs out from the system, the endsession endpoint is used. Parameters for this endpoint are id_token_hint and post_logout_redirect_uri. The first parameter should be set to the ***id_token*** that has been issued for the user. The second parameter specifies the URI to which the user will be redirected after completing the logout. This URI has to be registered in the client configuration. A template for the end session request is shown below.

```
GET https://login.elixir-czech.org/oidc/endsession HTTP/1.1
id_token_hint = {id_token}
    &post_logout_redirect_uri = {post_logout_redirect_uri}
```

The user is redirected to the endsession endpoint where he/she is asked to confirm the logout. After successful logout, the user is redirected back to the URI specified in parameter ***post_logout_redirect_uri***. Appendix C provides further details of the OpenID Connect implementation within the RMS system and includes some of the C# functions involved in the authentication process.

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Accessing the TSD system by transferring RMS credentials

One of the features of the system allows users to be transferred 'seamlessly' from the RMS to the relevant part of the TSD infrastructure, without having to re-enter credentials. When the various prerequisites have been established for either data transfer (object deposition) or data access (secondary use) the RMS system will enable a button that activates this transfer. When the user clicks the button, the RMS will send a JSON payload to the relevant TSD end-point. This json object contains both user details and information about the object(s) to be uploaded/accessed. Properties include:

User details

Token – access token of the authorized via Life Science AAI user,

AAI ID – unique ID of the user in Life Science AAI.

Entity details

Type – type of the entity the user wants to attach/upload document(s) to,

ID – the unique identifier of the entity,

Access type – type of access of the entity.

An example of such a json object is shown below:

```
{
   "user":
         {
      "token": "eyJhbGciOiJSUzI1NiIsInR5cCI6IkpXVCIsImtpZCI6Ik1FTTNOa0k1UmtGQ01VWk …
         … … … … …
         (several hundred characters in total)
         … … … … …
         … l4cTLZVwWl3xZDCWjeLVAX0otzP3G-EJJrULVPBtMjdag",
      "aai_id": "lifescience_user_unique_id"
         }
   "type": "data_object",
   "id": "RMS-300001",
   "access_type": "public, non-public"
}
```

Once TSD receives this payload, the system first validates that the token is valid and was generated by the Life Science AAI.

If the token is valid, the TSD system redirects the user, for example to the uploading section where he can upload necessary files to the system and link them with the specific entity. Also, based on the transferred access details, the TSD system sets a specific access type for the uploaded file(s).

Once the uploading process is done, the user is able to return to the RMS.

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If the token is invalid, the user will be redirected to the RMS login page and be asked to sign into the system again, to repeat the procedure, or advised to seek assistance.

6. Validation strategy

The proposed validation strategy is designed to ensure that, to a high level of confidence, the repository's various systems are fit for purpose, and that the system will therefore be able to meet the needs of its user community. Validation needs to take place in two stages. Initially we intend to implement a detailed verification process, which focuses on whether the system meets its specification. This will be followed by a structured assessment of the system by users, to provide a fuller validation of functionality and 'fitness for purpose'. Although informal ad hoc testing will take place throughout system development, a more formal, systematic approach is required for verification, to provide the necessary level of evidence. The general approach is to use 'integration tests' to test the system as a whole, rather than rely on unit tests of individual functions and processes.

Any verification exercise can take place, however, only against a fixed 'target', i.e. once the system has been fully completed. What is described here, with the system still in development, is therefore a proposal for validation rather than a summary of validation results. Because the TSD architecture has been tested successfully already, and is an established system, most of the validation will be focused on the RMS - though any entirely new components or operations within TSD will also be checked.

Verification will require both a set of dummy data (already constructed), and a detailed functional specification. A high-level system specification already exists and was the basis of the development work, but as that work is completed a more detailed document will be required and is being developed - the current version of the validation plan template is provided as Appendix D. This reflects a detailed functional specification, at the level of individual system components, and forms the basis of a detailed set of integration tests, examining all the different RMS screens. These check (for example) that:

- Log-in processes work as expected, with users with different roles in the system being allocated those roles accurately, with inaccurate credentials properly trapped, etc.
- The navigation available to any user matches their role within the system.
- All expected navigation from any screen is present and works as expected.
- There is correct placement of screen 'widgets', across different screen sizes and scrolling.
- That the data viewable on screen matches the known sample data that has been added to the test system.
- That the drop-down options available within on-screen selection boxes include the correct options.
- Attempts to input incorrect or implausible information are trapped.
- Adding new entities to the system works as expected.
- Editing existing entities within the system works as expected.
- Deleting entities, where allowed, works as expected. Prohibition of deletion, when appropriate, should also work correctly.
- 'Apply changes' and 'Cancel' (or equivalent) buttons work as expected, in all situations.
- Reports are constructed accurately and formatted correctly.

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- Interactions between the RMS and TSD systems function as expected

As can be seen from Appendix D, this provides a very detailed, mechanistic set of tests, but this is the standard approach to system validation.

It will also be necessary to ensure proper database and system maintenance plans are in place - i.e. to develop and implement backup plans and check that the associated restore mechanisms operate correctly.

A specific validation required relates to the need to check the auditing functionality within the database - as it will be important to know (especially of the external users) who is making what changes to what fields within the system.

The second stage of validation will involve end users and focus on the system's usability and overall fitness for purpose. We do not expect end users to carry out detailed verification checks, but feedback from users is very valuable. Once the system is fully established, therefore, we plan to do a more formal set of user tests, asking a representative group of users to go through a set of specified tasks and documenting their assessment of the system's functionality and ease of use. It is foreseen to report this work in *D14.3 Report about use and user satisfaction of COVID-19 repository including a maintenance and sustainability plan*.

7. Next steps

At this stage the technical implementation of the repository is well advanced but still ongoing as the first extensive validation of the system (as described in Appendix D) revealed few technical issues that need to be corrected before its public launch. We see fit to provide at the end of the project an updated document describing the changes in the technical implementation and validation strategy after the system can be considered stable and the feedback of potential users and other stakeholders has been taken into consideration. The repository and its capabilities will then need to be 'advertised' to the research community. The level of initial use is likely to be low, especially since the sustainability of the repository beyond the project duration remains to be discussed with funders. This discussion and proposed solutions will be outlined in *D14.3 Report about use and user satisfaction of COVID-19 repository including a maintenance and sustainability plan*. Within some COVID-19 vaccine trials the repository has already been identified as the platform to be used for long term storage of data and documents. In the meantime, we will continue to promote the use of the repository across a range of COVID-19 or other related activities.

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Abbreviations

AAI	Authentication and Authorization Infrastructure
API	Application Programming Interface
AWS	Amazon Web Service
BFF	Back-end for Front-end
CIFS	Common Internet File System
CSDR	Clinical Study Data Request
DTA	Data Transfer Agreement
DTP	Data Transfer Process
DUA	Data Use Agreement
DUP	Data Use Process
ECRIN	European Clinical Research Infrastructure Network
FAIR	Findable, Accessible, Interoperable, and Reusable
GDPR	General Data Protection Regulation
GPFS	General Parallel File System
GUI	Graphical User Interface
HPC	High Performance Computing
IAM	Identity and Access Management
IP	Internet Protocol

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IPD	Individual Participant Data
JWT	JSON Web Token
MDM	MetaData Management service
MFA	Multi Factor Authentication
NFS	Network File System
OS	Operating System
QC	Quality Control
RMS	Repository Management System
SCCM	System Center Configuration Manager
TSD	Service for Sensitive Data
UiO	University of Oslo
VLAN	Virtual Local Area Network
VM	Virtual Machine

Delivery and Schedule

The delivery of *D14.2 Report about technical implementation and validation of the COVID-19 portal* has been delayed (initially due in August 2021). This delay is linked to the addition of the Repository Management System (RMS) in the overall architecture of the COVID-19 repository (see details above), which was not initially foreseen. This system had to be designed and developed by ECRIN from scratch and integrated with the TSD secure storage platform. Minor technical difficulties in the system implementation (e.g. for embedding the ELIXIR AAI) have also been encountered. In addition, it has been proven difficult to recruit additional human resources with development/data management skills during the COVID-19 pandemic.

The above led to the submission of this report in May 2022.

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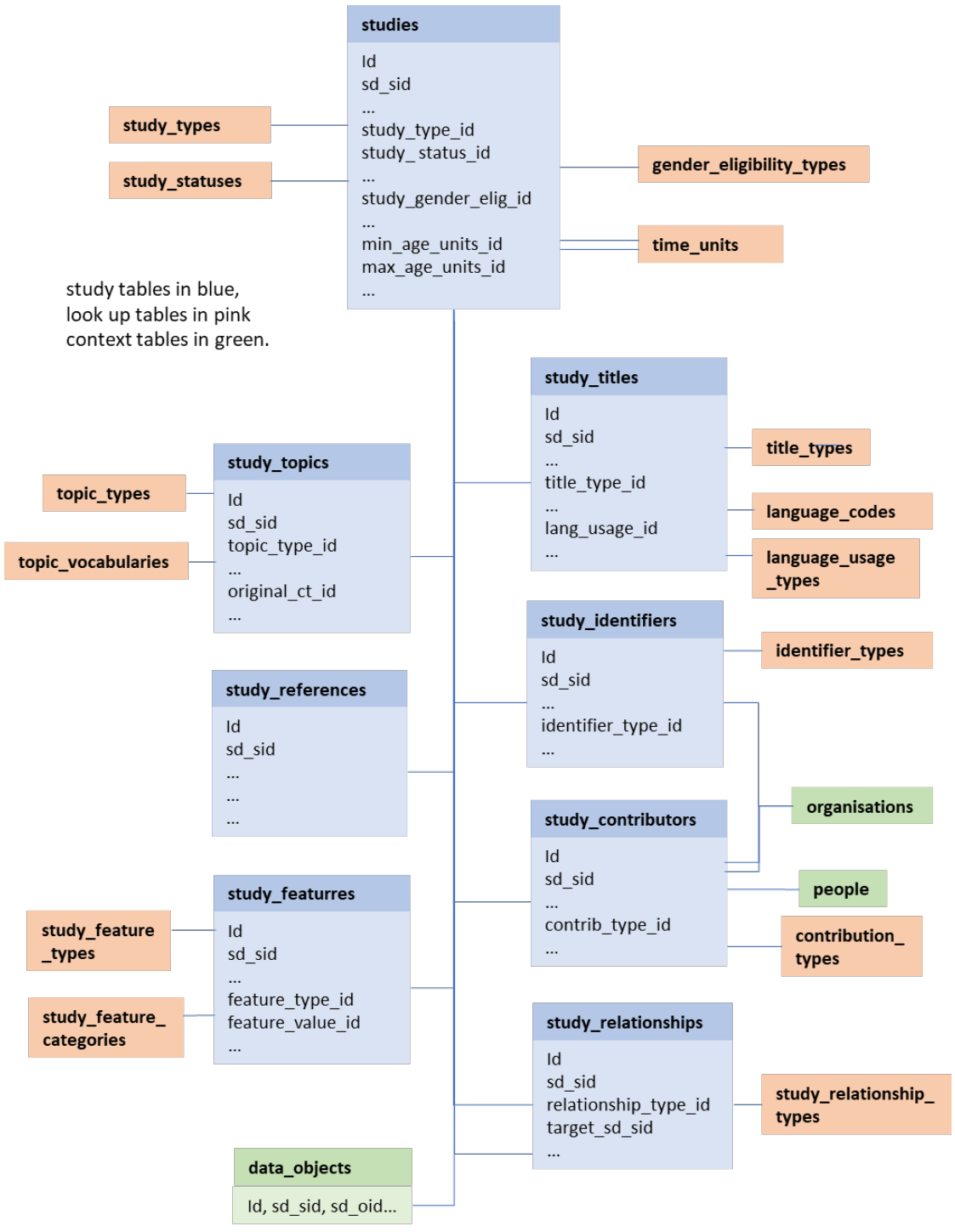
Appendix A: E-R Diagrams for Data Transfer/ Data use Processes



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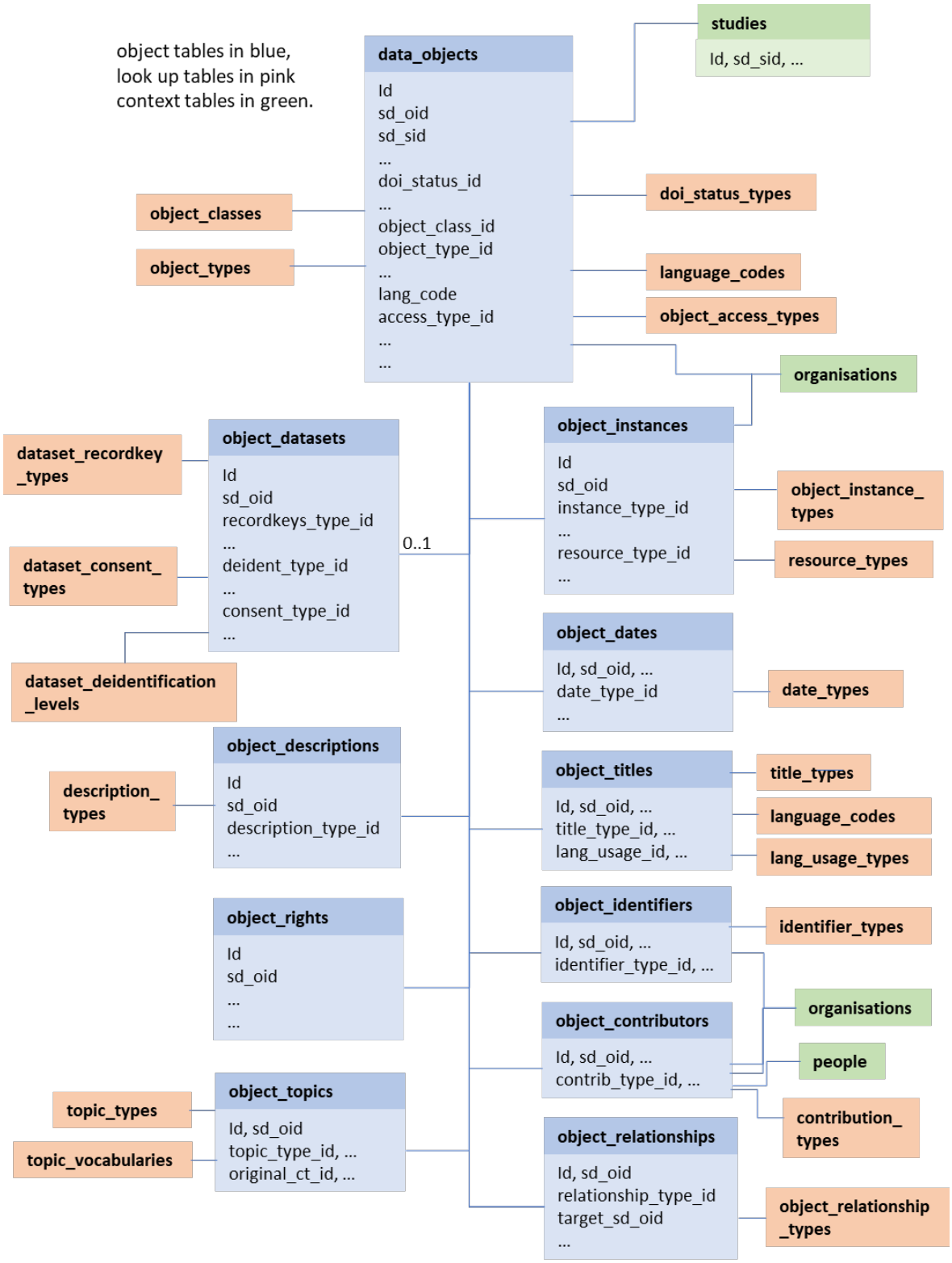

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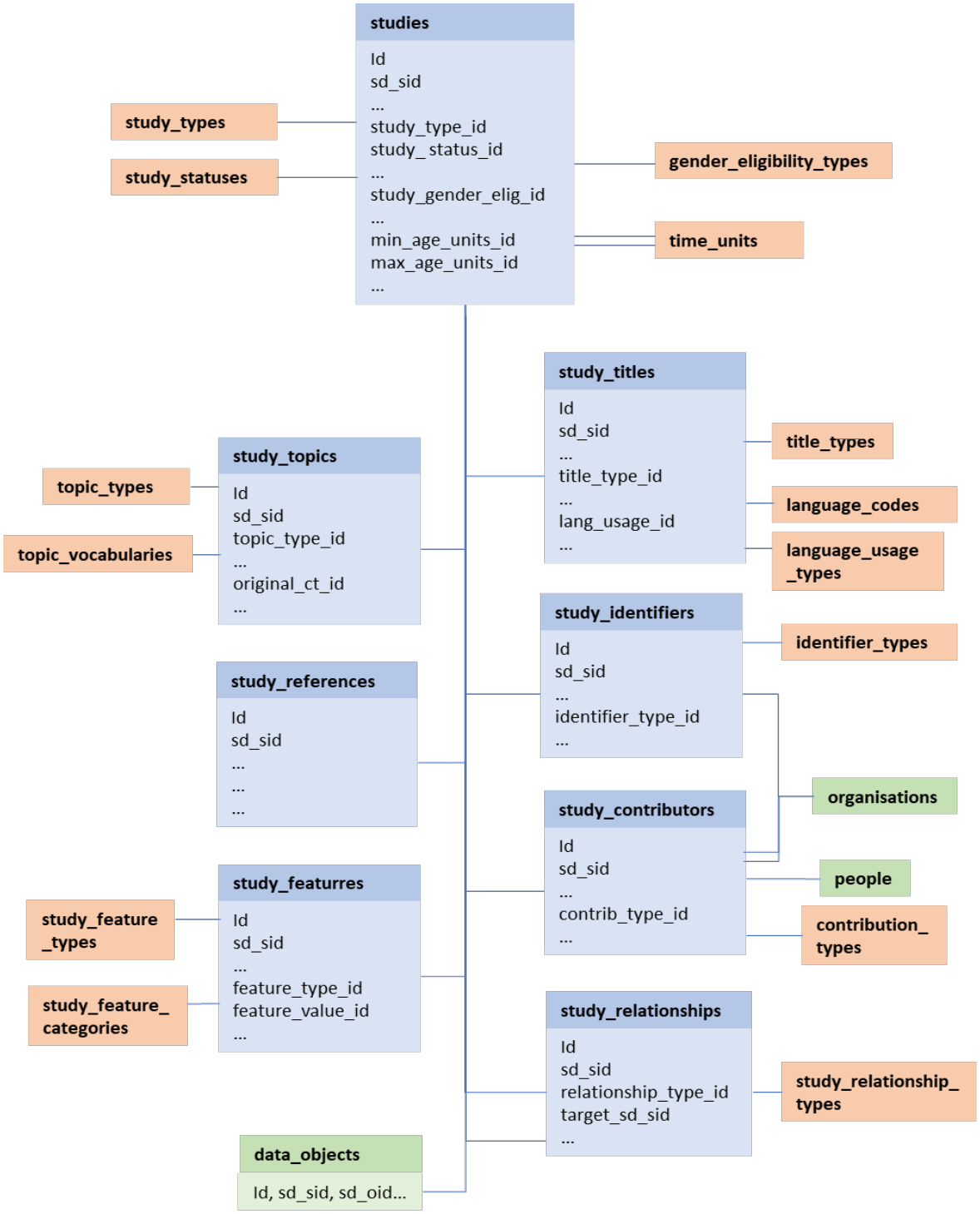
Appendix B: E-R Diagrams for Study/Object Metadata



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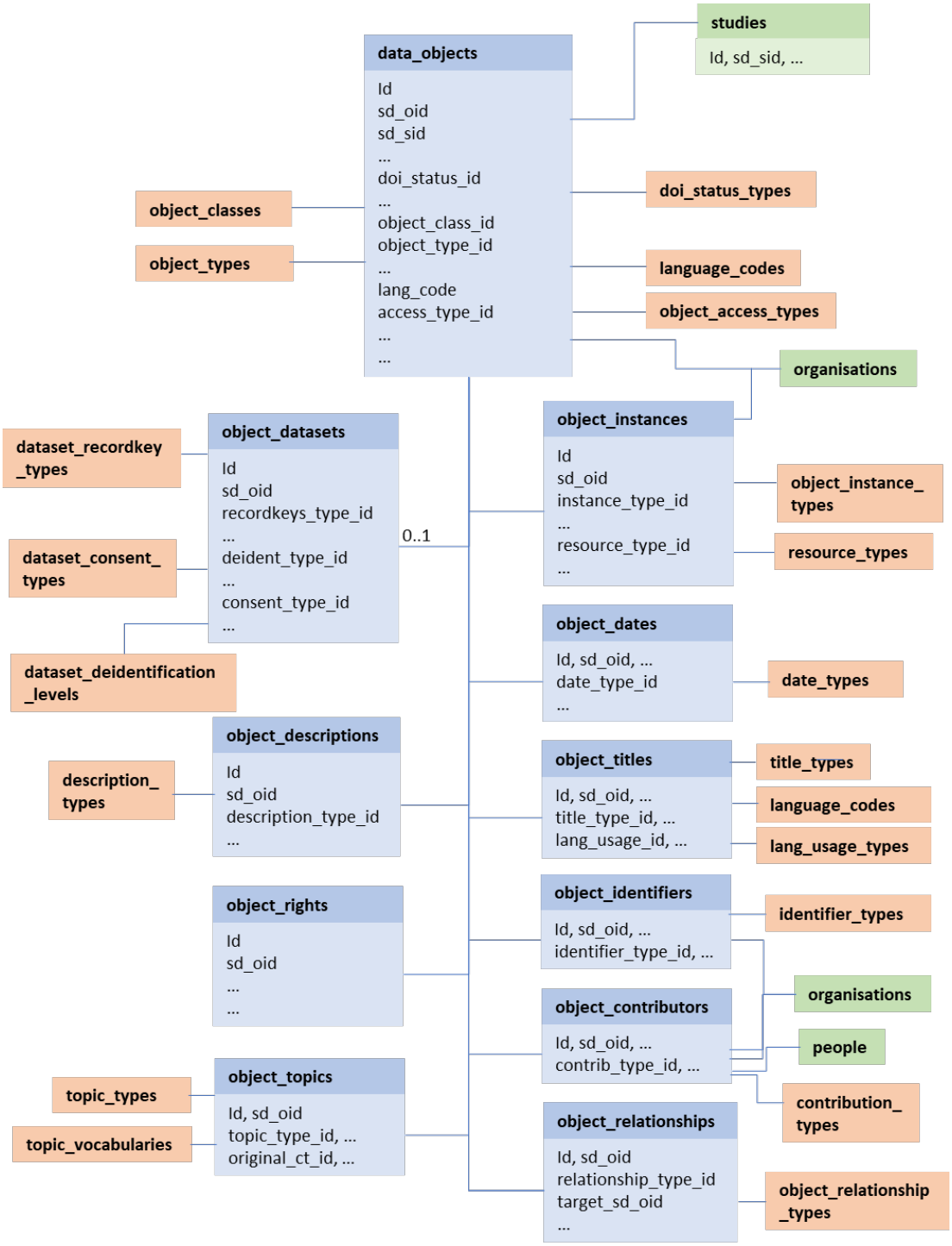

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Appendix C: OpenID Connect Implementation

To implement the OIDC part the IdentityModel (https://identitymodel.readthedocs.io/en/latest/) library is used. It contains a lot of built-in methods which can be used to implement OIDC on the RMS side.

Below you can see examples of how the token and user claims endpoints have been implemented.

The Token endpoint:

```
[HttpPost("refresh-token")]
[SwaggerOperation(Tags = new []{"The Elixir AAI endpoints"})]
public async Task<IActionResult> GetRefreshToken([FromBody] RefreshTokenBodyRequest refreshTokenBodyRequest)
{
    var client = new HttpClient();

    var response = await client.RequestRefreshTokenAsync(new RefreshTokenRequest
    {
        Address = ElixirIdentityConfigs.TokenUrl,
        ClientId = ElixirIdentityConfigs.ClientId,
        RefreshToken = refreshTokenBodyRequest.RefreshToken,
        GrantType = "refresh_token"
    });

    if (response.IsError) return Ok(response);

    return Ok(new ApiResponse<JsonElement>()
    {
        StatusCode = 200,
        Messages = null,
        Total = 1,
        Data = new List<JsonElement>(){response.Json}
    });
}
```

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The user claims endpoint:

```
public class UserElixirApiController : BaseElixirApiController
{
    [Authorize]
    [HttpGet("user-info")]
    [SwaggerOperation(Tags = new []{"The Elixir AAI endpoints"})]
    public async Task<IActionResult> UserInfo()
    {
        var accessTokenRes = await HttpContext.GetTokenAsync("access_token");
        var accessToken = accessTokenRes?.ToString();

        var client = new HttpClient();

        var response = await client.GetUserInfoAsync(new UserInfoRequest
        {
            Address = ElixirIdentityConfigs.UserInfoUrl,
            Token = accessToken
        });
        if (response.IsError) return Ok(new ApiResponse<UserInfoResponse>
        {
            Total = 0,
            Messages = new List<string>{response.Error},
            StatusCode = 403,
            Data = null
        });
        return Ok(new ApiResponse<JsonElement>()
        {
            Messages = null,
            Total = 1,
            StatusCode = 200,
            Data = new List<JsonElement>(){response.Json}
        });
    }
}
```

As the response from the user claims endpoint, the system can receive the following information about the user (depends on the information the user decided to share and scopes):

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```
{
  "total": 1,
  "size": null,
  "page": null,
  "statusCode": 200,
  "messages": null,
  "data": [
    {
      "sub": "sub@elixir-europe.org",
      "name": "Full name",
      "preferred_username": "username",
      "given_name": "First name",
      "family_name": "Last name",
      "email": "mail@gmail.com",
      "email_verified": true,
      "phone_number_verified": false,
      "eduperson_scoped_affiliation": "affiliate@elixir-europe.org",
      "schac_home_organization": [
        "linkedin",
        "google"
      ],
      "perun_api": "TRUE"
    }
  ]
}
```


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Appendix D: COVID-19 Repository Validation Plan Template

Action	Expectation	Result	
Initial Log-in and Navigation			
Navigate to the RMS home page (https://ecrin-rms.org/login)	Clinical Research Repository page should appear, with logos, explanatory text, and buttons or links to 'Sign in', 'Information', 'MDR', and 'Contact us'.		
Contract page along horizontal axis	Logins and links should remain visible (switch to lie under logos and graphics rather than to the right of them).		
Contract page along vertical axis	Logins and links adjust vertical position but fall outside of visible screen area when screen height reduced below a (quite small) set value		
Click on login button	User should be sent to LS AAI page to login using previously selected method (e.g. using ORCID sign-in). On successful login should be directed to internal home page for ECRIN and TSD staff, external home page for external staff. The system should distinguish between the types of users by querying a user database – the user should not have to select which login link or system to use. On unsuccessful login should be returned to the landing page.		
Click on 'Contact Us' link/button	User should be redirected to the contact page in a new tab		
Complete details on 'Contact us' page	User should be able to complete details of who they are, why they are seeking contact and the nature of their query/request		
Click on Send button	Email should be received by group account (to be setup) for the RMS User should receive a confirmation that the email has been sent		
Click on MDR link/button	User should be redirected to the MDR home page in a new tab		

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Action	Expectation	Result	
Click on Information link/button	User should be redirected to an information 'repository summary' page in a new tab		
Click on ECRIN logo	User should be redirected to the ECRIN web site in a new tab		
Click on TSD logo	User should be redirected to the TSD web page in a new tab		
Click on EOSC-Life logo	User should be redirected to the EOSC-Life web site in a new tab		
Click on EOSC logo (if decided to add this)	User should be redirected to the EOSC web site in a new tab		
Navigate to the RMS home page having recently (within token expiration length) logged into a service using the Life Science AAI	User should be transferred automatically to the appropriate home page, as described below (this being part of the rationale for the LS AAI)		
Overall result/Comments		**Initials/ Date**	
System navigation			
Inspect page elements visible on all pages	A fly-out main navigation should be visible on the left edge of the screen, initially as a narrow icon-only strip, a header bar should span the top of the screen and a footer bar span the bottom (but see comments on footer below). A scroll bar should appear to the right of the screen when required.		
Contract page along horizontal axis	Below a set width left hand main menu should be transformed into a 'hamburger' icon at top right and the user details panel becomes a vertical row of three dots.		
Contract page along vertical axis	Little adjustment possible or necessary in most situations – footer should jump to base of viewport – but easier to lose the footer! (see below)		
Check footer should only be	If a footer is present it should either provide		

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Action	Expectation	Result	
visible if needed	useful additional information or useful links. The current footer provides a link to ECRIN (already present on the home page), a link to the MDR (already present on the home page), a link to the MDR wiki (not relevant), a 'Terms' link that goes nowhere, and a Contact us link that goes to the MDR 'team' (not relevant). The copyright notice is meaningless for an open source project.		
Mouse over left hand navigation bar	Bar should expand to show text as well as icons. Top expand/contract arrow icons reverses direction to indicate clicking it will contract menu.		
Click on top left arrow to expand/ contract navigation bar	Bar expands/contracts according to direction of arrow		
Check expanded navigation bar shows relevant and functional links	Icons and text for the following links should be shown: Home, Data Transfers, Data Usage, Study Metadata, Object Metadata, Users Reports, Contact Us, Help		
Check navigation bar icons are clear	Icons should be visible and meaningful.		
Click on links in the navigation bar	User navigates to the relevant screen, Navigation bar contracts, title of selected page is highlighted (when the bar is re-expanded) N.B. Selected page will need to differ between internal and external users For internal users, page should be the summary list pages. For external users, navigation will be to the relevant ***section*** of the single summary page (i.e. for their organisation), which may only have a single entry (study, data transfer process) on it.		
Check Navigation bar does not	The navigation bar should expand/contract		

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Action	Expectation	Result	
obscure header bar details	*below* the header bar, which should span the entire viewport, or 'push' the header bar to the right.		
Check Header bar retains ECRIN logo and system title	The ECRIN logo, the system title ('RMS Portal') and the version should be displayed in the header. If not in production the status should also be clearly shown.		
Check Header bar includes language indicator	The two letter code for the current language should be displayed to the right of the header bar		
Check Language indicator allows change of language for on-screen labels, possible help files	Clicking on the language indicator should provide a list of available languages. Selecting one of these should change the on-screen labels and prompts to the selected language. Help files, if available in translation, could also be presented in the selected language.		
Check Header bar includes a 'user' button for accessing user details and options, including signing out of the system. The button should clearly indicate it relates to the user	The user button should be shown at the right hand end of the icon bar. Clicking on it should show a panel with various options. The button could show the user's name and an avatar, the user's name and a conventional icon for a user, or just the name.		
Click on close button in User panel	User panel disappears		
Click on system outside User panel	User panel disappears		
Click on Sign Out button in User panel	User should be transferred to the Life science log out page		
Click on mail icon in User panel	User should go to the Contact us page or open up their email client		
Click on My Profile in User panel	User should be transferred to the user details screen, to edit their own details		
When screen is constricted horizontally check placement of new icons matches the original	The navigation menu should become a hamburger menu at the top left of the screen, the language/user details menu should become a menu at top right.		
Check Scroll bar spans only scrollable portion of viewport	The top and bottom of any scroll bar should correspond to the area to be scrolled		
Overall result/Comments		**Initials/**	

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Action	Expectation	Result	
		Date	
Dashboard Home page (internal users)			
Inspect Dashboard display at top of page	4 circular icons, representing Data Transfer Processes, Data Use Processes, Study Metadata, Object Metadata should be arranged across the top of the page. Data Transfer and Data Use Processes = total number of transfers and data user processes in the system (could change later) Study and object metadata = total number of studies and objects in the system.		
Assess need for welcome/ organisation message	The user name will be at the top right of the header bar and therefore does not need another welcome message. For internal users the totals will be for the whole system, and there is no need to state any particular organisation. External users will not see this screen, and the listings of each type will be small in number – however an organisation header will be necessary on the equivalent summary screen for external users (see below)		
Click on any of the circular icons or text underneath at the top of page	Transfers user to the relevant section of the dashboard page		
Inspect screen after navigating to Data Transfers section I	On the left hand side is a panel with a) Number of Data Transfers active this month (whatever stage) b) Completed Data Transfers so far – all time c) Total Data Transfers in system – all time, whatever stage d) Generate a ?? report – if present at all should be a single named summary report, other reports available from the Reports screen		
Inspect screen after navigating to	On the right hand side a table with the basic details of recent data transfer processes – id,		

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Action	Expectation	Result	
Data Transfers section II	organisation, name, and status, and for each View and Edit buttons. Table designed to hold the 10 most recent DTPs		
Inspect screen after navigating to Data Transfers section III	Add and See more buttons above table on RHS Add should go directly to the Add Data Transfer screen See more should go to the DTP summary screen where all DTPs can be searched		
Click on View button in Data Transfers table	User should be transferred to the view page for that DTP, with the relevant data for the selected DTP being automatically filled into the on-screen boxes		
Click on Edit button in Data Transfers table	User should be transferred to the edit page for that DTP, with the relevant data for the selected DTP being automatically filled into the on-screen boxes		
Inspect screen after navigating to Data Use processes section I	On the left hand side is a panel with a) Number of Data Use processes active this month (whatever stage) b) Completed Data Use processes so far – all time c) Total Data Use processes in system – all time, whatever stage d) Generate a ?? report – if present at all should be a single named summary report, other reports available from the Reports screen		
Inspect screen after navigating to Data Use processes II	On the right hand side a table with the basic details of recent data use processes – id, organisation, name, and status, and for each View and Edit buttons. Table designed to hold the 10 most recent DTPs		
Inspect screen after navigating to Data Use processes III	Add and See more buttons above table on RHS Add should go directly to the Add Data Use Process screen See more should go to the DUP summary screen where all DUPs can be searched		
Click on View button in Data Use processes table	User should be transferred to the view page for that DUP, with the relevant data for the		

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Action	Expectation	Result	
	selected DUP being automatically filled into the on-screen boxes		
Click on Edit button in Data Use processes table	User should be transferred to the edit page for that DUP, with the relevant data for the selected DUP being automatically filled into the on-screen boxes		
Repeat of Total Studies and Total Objects graphics	Non interactive copies of the study and data object graphics appear after the Data Use table and before the studies table. Not sure if they add any value, as navigation to the relevant sections will by-pass them, and they are simply a repeat of information at the top of the page.		
Inspect screen after navigating to Recent Studies section I	Displays a table with the basic details of recent studies entered into the system – id, title, type, and status, and for each View and Edit buttons. Table designed to hold the 10 most recent added studies		
Inspect screen after navigating to Recent Studies section II	Add and See more buttons above table on RHS Add should go directly to the Add Study screen See more should go to the Study summary screen where all Studies can be searched		
Click on View button in Recent Studies table	User should be transferred to the view page for that study, with the relevant data for the selected study being automatically filled into the on-screen boxes		
Click on Edit button in Recent Studies table	User should be transferred to the edit page for that study, with the relevant data for the selected study being automatically filled into the on-screen boxes		
Inspect screen after navigating to Recent Data Objects section I	Displays a table with the basic details of recent Data Objects entered into the system – id, title, and access type and for each View and Edit buttons. (Linked study usually obvious from the title) Table designed to hold the 10 most recent added objects		
Inspect screen after navigating to Recent Data Objects section II	Add and See more buttons above table on RHS Add should go directly to the Add Data Object screen		

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Action	Expectation	Result	
	See more should go to the Object summary screen where all Objects can be searched		
Click on View button in Recent Data Objects table	User should be transferred to the view page for that data object, with the relevant data for the selected object being automatically filled into the on-screen boxes		
Click on Edit button in Recent Data Objects table	User should be transferred to the edit page for that data object, with the relevant data for the selected object being automatically filled into the on-screen boxes		
Navigate to User table	There should be a similar icon to the other 4 at the top of the page allowing easy navigation to the Users table		
Inspect user table	Should show the most recent users (?5) – and include their name, **role**, email, location (or organisation)		
User table buttons	Add and See more (or See All) buttons should be added at the top of the table, as with the other tables		
User table row buttons	Vied and edit buttons (or perhaps just edit) should be available for each row		
Overall result/Comments		**Initials/ Date**	
Home page (external users)			
Inspect header display at top of page	This page should have a header that specifies which organisation's details are displayed below. There is no need for any dashboard type graphics as numbers for any specific organisation are likely to be so low		
Check only user organisation's activity and entities only are visible	The page should have 5 tables with a) Data Transfer Processes b) Data Use Processes c) Studies d) Data Objects e) Users Linked to this organisation. Table headers should indicate if there are none of any of the above in the system, in which case		

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Action	Expectation	Result	
	the table itself should not be shown. Otherwise, table headers should indicate the total number (linked to this organisation) in the system of each type.		
Inspect summary tables, design and functionality	Tables should have the same buttons associated with each row as in the internal users' screen, which should function in the same way, but NOT the See more/See all button and Add buttons at the top of each table. In general external users should not be able to see entities not linked to their organisation, and the linkage between entities should be done by the RMS manager ort other internal users, not external users.		
Check effects of menu navigation	The main menu should only move the user around this page, i.e. to the relevant section.		
Overall result/Comments		**Initials/ Date**	
Data Transfers list			
Inspect Data Transfers list page	Table of data transfers in the system should be visible, showing id, organisation, title and status for each, along with standard 'items per page' and page navigation functionality. A search facility should be available above the table (search by title) along with search and reset buttons A '+ New Data Transfer' button should be visible above the table. View, edit and delete icons should be visible to the right of each table row.		
Click on New Data transfer button	User should be transferred to a new blank 'Add new data transfer screen'		
Select Search by title option, insert known title fragment in search box and click 'Search'	List should be filtered to contain only those entries that contain the search box text.		
Change title fragment text case so that it no longer matches original	Search should be case insensitive and retain the same filtered list as before		
Change title fragment to a string known not to be present in any	The unsuccessful search should return an empty list		

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Action	Expectation	Result	
title.			
Click 'Reset' Search	The search text should clear and the list restored to its initial unfiltered state		
For a selected Data Transfer process, click on View	The user should be transferred to a read only view details screen for the selected Data Transfer, with the relevant details shown		
For a selected Data Transfer process, click on Edit	The user should be transferred to a read only view details screen for the selected Data Transfer, with the relevant details shown		
For a selected Data Transfer process, click on Delete	Dialogue appears asking the user if they are sure they want to delete the record		
Click Cancel in the Delete confirmation dialogue	The dialog is dismissed and no change occurs in the list		
Click Delete in the Delete confirmation dialogue	The dialog is dismissed, record is deleted and the revised list is displayed		
Click page navigation buttons	Navigation should occur through the set a page of records at a time		
Change number of items displayed per page	Number selected should be reflected in the resized table		
Overall result/Comments		**Initials/ Date**	
Data Transfer - view			
Inspect header on page	Header on page should indicate the DTP being viewed, e.g. <DTP Name> details (read only)		
Inspect data available to view	Data should include the associated organisation, the status, **the linked data objects**, (i.e. the material DTP is about), ideally arranged by or referencing the study, and include the object access type (public, or managed download, or managed TRE), including or with a link to detailed pre-requisites for managed access objects, any embargo period etc., the external users associated with this DTP		
Status should be clear and fixed	The visual representation of the status should		

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Action	Expectation	Result	
	be clear and fixed		
Status related data should be clear	When any of the enabled, completed stages are clicked the relevant data should be shown. Disabled type images should not respond at all		
Click on Edit button at top right of screen	User should be transferred to the corresponding edit screen, with the same data being displayed but in an editable form		
Click on Print button at top right of screen	Print preview, usually of a constructed pdf, should be shown to allow printing to take place, or a print command sent automatically (with confirmation dialogue)		
Click on JSON button at top right of screen	A download of a JSON file with the displayed data should take place, with a confirmation dialogue for the user		
Overall result/Comments		**Initials/ Date**	
Data Transfer – Add new			
Inspect Add New Data Transfer screen	Header should say Add New Data Transfer Basic details – organisation, display name and status should be visible The Initial contact date should show the current date by default but be editable		
Type into the organisation selection box	The available organisations should be filtered to those including the typed characters, as an aid to selecting the organisation		
Inspect status data	The overall status should be 'In Set Up'. The Initial contact date should show the current date by default but be editable, (by selecting the Creation icon). **Other status icons should stay disabled.** It does not make sense for the DTP to be added to the system in a later 'phase'. Those phases can and will be reached within the DTP edit screen.		
Type a date later than today in the Initial Contact date	This should be rejected by the system as impossible		
Click on the Save button	A popup should confirm the addition of the new DTP. The user should be returned to the		

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Action	Expectation	Result	
	screen that they were last at, normally the DTP list screen, to see the new DTP in the list		
Click on the Save button with no display name entered	The system should prevent the addition and post a message asking the user to enter a display name		
Click on the Save button with no organisation selected	The system should prevent the addition and post a message asking the user to select an organisation		
Click on the Cancel button	The user should be returned to the screen that they were last at, normally the DTP list screen		
Click on the Add Study button	An Add study dialog should appear, with a list of studies in the system and Add and Cancel buttons		
Click on the Cancel button in the Add Study dialog	The Add Study box should be dismissed		
Click on the Add button in the Add Study dialog after selecting a study	The selected study should be added to the DTP details. Associated data objects should be then used in the Add Data Object process		
Click on the Add Data Object button	An Add Data object dialog should appear, with a list of the objects in the system and Add and Cancel buttons		
Click on the Cancel button in the Add Data Object dialog	The Add Data object box should be dismissed		
Click on the Add button in the Add Data Object dialog after selecting an object	The selected object should be added to the DTP details. There should be an indication of the access type required, if known.		
Click on the Add User button	An Add User dialog should appear, with a list of the users in the system and Add and Cancel buttons		
Click on the Cancel button in the Add User dialog	The Add User box should be dismissed		
Click on the Add button in the Add User dialog after selecting a user	The user name should be added o the DTP details as one of the associated users		
Overall result/Comments		**Initials/ Date**	

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Action	Expectation	Result	
Data Transfer - edit			
Inspect header on page	Header on page should indicate the DTP being viewed, e.g. <DTP Name> Edit		
Inspect DTP data available to view	Editable Data should include the associated organisation, the DTP name the status, Expectations of viewing the linked data objects, studies and objects are discussed below		
Inspect status related date data	The relevant data points required for the completion of each phase of the DTP should be visible and editable when the corresponding status icon is clicked. The icon representing the current status should be selected when the page loads.		
Edit status related date data	For each data a date picker should allow easy selection of the date to be entered		
Enter dates out of sequence or in the future	a) Dates should not normally be allowed to be entered in a phase later than the current phase (see page 14/15) b) Dates entered in one phase should not normally be before dates in an earlier phase c) Dates should not normally be later than today The system should either prevent any of these three things or at least post a warning message and ask the user to confirm that this is their intention		
Display, add, edit or remove associated studies	The studies associated with this DTP should be listed in the editable details screen. Suitable buttons to add or delete additional studies should be present		
Display, add, edit or remove associated objects	The objects associated with this DTP should be listed in the editable details screen. Suitable buttons to add or delete additional objects should be present		
Display, add, edit or remove	The users associated with this DTP should be		

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Action	Expectation	Result	
associated users	listed in the editable details screen. Suitable buttons to add or delete additional users should be present		
Display, add, edit or remove object access details	The main access type required will be included in the EDCRIN metadata for the data objects, but should also be displayed here once known, or added here and displayed in the ECRIN metadata (this may require some adaptation or renaming of the available categories). Specific *pre-requisites* for managed access material cannot easily be captured by the ECRIN metadata schema, although there is some overlap with consent types. It should be at least displayed, if not necessarily edited, here, with any object having – potentially – multiple associated prerequisites.		
Click on the Apply Changes button	A popup should confirm the successful edit of the DTP.		
Click on the Apply Changes button with no display name entered	The system should prevent the addition and post a message asking the user to enter a display name		
Click on the Apply Changes button with no organisation selected	The system should prevent the addition and post a message asking the user to select an organisation		
Click on the Cancel button	The user should be returned to the screen that they were last at, normally the DTP list screen		
Click on the Add Study button	An Add study dialog should appear, with a list of studies in the system and Add and Cancel buttons		
Click on the Cancel button in the Add Study dialog	The Add Study box should be dismissed		
Click on the Add button in the Add Study dialog after selecting a study	The selected study should be added to the DTP details. Associated data objects should be then used in the Add Data Object process		
Click on the Add Data Object button	An Add Data object dialog should appear, with a list of the objects in the system and Add and Cancel buttons		
Click on the Cancel button in the Add Data Object dialog	The Add Data object box should be dismissed		

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Action	Expectation	Result	
Click on the Add button in the Add Data Object dialog after selecting an object	The selected object should be added to the DTP details. There should be an indication of the access type required, if known.		
Click on the Add User button	An Add User dialog should appear, with a list of the users in the system and Add and Cancel buttons		
Click on the Cancel button in the Add User dialog	The Add User box should be dismissed		
Click on the Add button in the Add User dialog after selecting a user	The user name should be added o the DTP details as one of the associated users		
Overall result/Comments		**Initials/ Date**	
Inspect Data Use Processes list page	Table of data use processes in the system should be visible, showing id, organisation, title and status for each, along with standard 'items per page' and page navigation functionality. A search facility should be available above the table (search by title) along with search and reset buttons A '+ New Data Use' button should be visible above the table. View, edit and delete icons should be visible to the right of each table row.		
Click on New Data Use button	User should be transferred to a new blank 'Add new data use screen'		
Select Search by title option, insert known title fragment in search box and click 'Search'	List should be filtered to contain only those entries that contain the search box text.		
Change title fragment text case so that it no longer matches original	Search should be case insensitive and retain the same filtered list as before		
Change title fragment to a string known not to be present in any title.	The unsuccessful search should return an empty list		

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Action	Expectation	Result	
Click 'Reset' Search	The search text should clear and the list restored to its initial unfiltered state		
For a selected Data Use process, click on View	The user should be transferred to a read only view details screen for the selected Data Use, with the relevant details shown		
For a selected Data Use process, click on Edit	The user should be transferred to a read only view details screen for the selected Data Use, with the relevant details shown		
For a selected Data Use process, click on Delete	Dialogue appears asking the user if they are sure they want to delete the record		
Click Cancel in the Delete confirmation dialogue	The dialog is dismissed and no change occurs in the list		
Click Delete in the Delete confirmation dialogue	The dialog is dismissed, record is deleted and the revised list is displayed		
Click page navigation buttons	Navigation should occur through the set a page of records at a time		
Change number of items displayed per page	Number selected should be reflected in the resized table		
Overall result/Comments		**Initials/ Date**	
Inspect header on page	Header on page should indicate the DUP being viewed, e.g. <DUP Name> details (read only)		
Inspect data available to view	Data should include the associated organisation, the status, **the linked data objects**, (i.e. the material DUP is about), ideally arranged by or referencing the study, and include the object access type (managed download, or managed TRE), including or with a link to detailed pre-requisites for managed access objects, and whether or not those pre-requisites have been met in this DUP, the external users associated with this DTP		
Status should be clear and fixed	The visual representation of the status should		

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Action	Expectation	Result	
	be clear and fixed		
Status related data should be clear	When any of the enabled, completed stages are clicked the relevant data should be shown. Disabled type images should not respond at all		
Click on Edit button at top right of screen	User should be transferred to the corresponding edit screen, with the same data being displayed but in an editable form		
Click on Print button at top right of screen	Print preview, usually of a constructed pdf, should be shown to allow printing to take place, or a print command sent automatically (with confirmation dialogue)		
Click on JSON button at top right of screen	A download of a JSON file with the displayed data should take place, with a confirmation dialogue for the user		
Overall result/Comments		**Initials/ Date**	
Data Use Process – add new			
Inspect Add New Data Use Process screen	Header should say Add New Data Transfer Basic details – organisation, display name and status should be visible The Initial contact date should show the current date by default but be editable		
Type into the organisation selection box	The available organisations should be filtered to those including the typed characters, as an aid to selecting the organisation		
Inspect status data	The overall status should be 'In Set Up'. The Initial contact date should show the current date by default but be editable, (by selecting the Creation icon). **Other status icons should stay disabled.** It does not make sense for the DUP to be added to the system in a later 'phase'. Those phases can and will be reached within the DUP edit screen.		
Type a date later than today in the Initial Contact date	This should be rejected by the system as impossible		
Click on the Save button	A popup should confirm the addition of the new DUP. The user should be returned to the		

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Action	Expectation	Result	
	screen that they were last at, normally the DUP list screen, to see the new DUP in the list		
Click on the Save button with no display name entered	The system should prevent the addition and post a message asking the user to enter a display name		
Click on the Save button with no organisation selected	The system should prevent the addition and post a message asking the user to select an organisation		
Click on the Cancel button	The user should be returned to the screen that they were last at, normally the DUP list screen		
Click on the Add Study button	An Add study dialog should appear, with a list of studies in the system and Add and Cancel buttons		
Click on the Cancel button in the Add Study dialog	The Add Study box should be dismissed		
Click on the Add button in the Add Study dialog after selecting a study	The selected study should be added to the DUP details. Associated data objects should be then used in the Add Data Object process		
Click on the Add Data Object button	An Add Data object dialog should appear, with a list of the objects in the system and Add and Cancel buttons		
Click on the Cancel button in the Add Data Object dialog	The Add Data object box should be dismissed		
Click on the Add button in the Add Data Object dialog after selecting an object	The selected object should be added to the DUP details. There should be an indication of the access type required, if known.		
Click on the Add User button	An Add User dialog should appear, with a list of the users in the system and Add and Cancel buttons		
Click on the Cancel button in the Add User dialog	The Add User box should be dismissed		
Click on the Add button in the Add User dialog after selecting a user	The user name should be added to the DUP details as one of the associated users		
Overall result/Comments		**Initials/ Date**	

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Action	Expectation	Result	
Data Use Process - edit			
Inspect header on page	Header on page should indicate the DUP being viewed, e.g. <DUP Name> Edit		
Inspect DTP data available to view	Editable Data should include the associated organisation, the DUP name the status, Expectations of viewing the linked data objects, studies and objects are discussed below		
Inspect status related date data	The relevant data points required for the completion of each phase of the DUP should be visible and editable when the corresponding status icon is clicked. The icon representing the current status should be selected when the page loads.		
Edit status related date data	For each data a date picker should allow easy selection of the date to be entered		
Enter dates out of sequence or in the future	a) Dates should not normally be allowed to be entered in a phase later than the current phase (see page 23/24) b) Dates entered in one phase should not normally be before dates in an earlier phase c) Dates should not normally be later than today The system should either prevent any of these three things or at least post a warning message and ask the user to confirm that this is their intention		
Display, add, edit or remove associated studies	The studies associated with this DUP should be listed in the editable details screen. Suitable buttons to add or delete additional studies should be present		
Display, add, edit or remove associated objects	The objects associated with this DUP should be listed in the editable details screen. Suitable buttons to add or delete additional objects should be present		
Display, add, edit or remove	The users associated with this DUP should be		

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Action	Expectation	Result	
associated users	listed in the editable details screen. Suitable buttons to add or delete additional users should be present		
Display, add, edit or remove object access details and pre-requisite checks	The access type allowed will be included in the ECRIN metadata for the data objects, but should also be displayed here (this may require some adaptation or renaming of the available categories). Specific *pre-requisites* for managed access material cannot easily be captured by the ECRIN metadata schema, although there is some overlap with consent types. They must be displayed, together with confirmation that they have been met, here, with any object having – potentially – multiple associated prerequisites.		
Click on the Apply Changes button	A popup should confirm the successful editing of the DUP.		
Click on the Apply Changes button with no display name entered	The system should prevent the addition and post a message asking the user to enter a display name		
Click on the Apply Changes button with no organisation selected	The system should prevent the addition and post a message asking the user to select an organisation		
Click on the Cancel button	The user should be returned to the screen that they were last at, normally the DUP list screen		
Click on the Add Study button	An Add study dialog should appear, with a list of studies in the system and Add and Cancel buttons		
Click on the Cancel button in the Add Study dialog	The Add Study box should be dismissed		
Click on the Add button in the Add Study dialog after selecting a study	The selected study should be added to the DUP details. Associated data objects should be then used in the Add Data Object process		
Click on the Add Data Object button	An Add Data object dialog should appear, with a list of the objects in the system and Add and Cancel buttons		
Click on the Cancel button in the Add Data Object dialog	The Add Data object box should be dismissed		

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Action	Expectation	Result	
Click on the Add button in the Add Data Object dialog after selecting an object	The selected object should be added to the DUP details. There should be an indication of the access type required, if known.		
Click on the Add User button	An Add User dialog should appear, with a list of the users in the system and Add and Cancel buttons		
Click on the Cancel button in the Add User dialog	The Add User box should be dismissed		
Click on the Add button in the Add User dialog after selecting a user	The user name should be added to the DUP details as one of the associated users		
Overall result/Comments		**Initials/ Date**	
Studies list			
Inspect Studies list page	Table of studies in the system should be visible, showing id, organisation, title and status for each, along with standard 'items per page' and page navigation functionality. A search facility should be available above the table (search by title) along with search and reset buttons A '+ New Study' button should be visible above the table. View, edit and delete icons should be visible to the right of each table row.		
Click on New Study button	User should be transferred to a new blank 'Add new study screen'		
Select Search by title option, insert known title fragment in search box and click 'Search'	List should be filtered to contain only those entries that contain the search box text.		
Change title fragment text case so that it no longer matches original	Search should be case insensitive and retain the same filtered list as before		
Change title fragment to a string known not to be present in any title.	The unsuccessful search should return an empty list		
Click 'Reset' Search	The search text should clear and the list		

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Action	Expectation	Result	
	restored to its initial unfiltered state		
For a selected Study, click on View	The user should be transferred to a read only view details screen for the selected study, with the relevant details shown		
For a selected Study, click on Edit	The user should be transferred to a read only view details screen for the selected study, with the relevant details shown		
For a selected Study, click on Delete	Dialogue appears asking the user if they are sure they want to delete the record		
Click Cancel in the Delete confirmation dialogue	The dialog is dismissed and no change occurs in the list		
Click Delete in the Delete confirmation dialogue	The dialog is dismissed, record is deleted and the revised list is displayed		
Click page navigation buttons	Navigation should occur through the set a page of records at a time		
Change number of items displayed per page	Number selected should be reflected in the resized table		
Overall result/Comments		**Initials/ Date**	
Inspect header on page	Header should clearly indicate the study being viewed On scrolling the study title should stay in prominent view		
Inspect main study data available to view	Study status, type, start month and year, brief description, data sharing statement, gender eligibility, enrolment, min and max ages should be visible.		
Inspect study identifier data available to view	Each identifier should be indicated by the top bar of a drop down panel, with the bar showing the identifier type and value. Opening the panel should show the same data, plus also identify the organisation that applied the identifier and if known the date		
Inspect study title data available to view	Each title should be indicated by the top bar of a drop down panel, with the bar showing the		

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Action	Expectation	Result	
	title text. Opening the panel should show the same data, plus also identify the title type and the language of the title.		
Inspect study feature data available to view	For Interventional studies the value of the 5 possible features, or 'Not given' if the data is missing . Should be labelled text – not drop down boxes in an expanded panel. No top bar is required. For interventional studies the same for the 3 expected features.		
Inspect study topic data available to view	Each topic should be indicated by the top bar of a drop down panel, with the bar showing the topic type and value. Opening the panel should show the same data, plus also identify the controlled terminology, if any, to which the topic belongs, and the code of that term within that technology		
Inspect study relationship data available to view	Each relationship should be indicated by the top bar of a drop down panel, with the bar showing the relationship type and value of the target study – using just its study (registry) ID Opening the panel should show the same data, and provide the full title of the target study		
Inspect study contributor data available to view	Each contributor should be indicated by the top bar of a drop down panel, with the bar showing the contributor type and name. Opening the panel should show the same data, plus also explicitly identify if the contributor is an individual or an organisation, give the names and any ORCID identifier for a person, plus their departmental and organisational; affiliation, while for organisations simply provide their name.		
Click on Back button	User should be transferred back to the most recent screen, usually the studies list screen		
Click on Edit button at top right of screen	User should be transferred to the corresponding edit screen, with the same data being displayed but in an editable form		
Click on Print button at top right	Print preview, usually of a constructed pdf, should be shown to allow printing to take		

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Action	Expectation	Result	
of screen	place, or a print command sent automatically (with confirmation dialogue)		
Click on JSON button at top right of screen	A download of a JSON file with the displayed data should take place, with a confirmation dialogue for the user		
Overall result/Comments		**Initials/ Date**	
Study details – add new			
After completing study main data values and at least one of study identifiers, titles, topics, contributors, plus all of requested features, click Save	The study should be saved to the system, a dialog confirming this should be shown to the user, and the system should return to the study list page to show the new study.		
Before initial save of the study it should **not** be possible to add study identifiers, titles, contributors, etc. Too complex!	The Add new Study page should just include the main study fields – i.e. that would be stored in the Study table. Other data can be added later in the edit study screen.		
Add a study using the MDR	It should be possible to add a study by putting in a trial registry (selected from a drop down) and trial registry id, and then interrogating the MDR – retrieving all the study data directly. This feature could perhaps be at the top of the Add Study page, with the main study details pages below, to be used only as necessary.		
Click on Cancel button	User should be transferred back to the most recent screen, usually the studies list screen		
Overall result/Comments		**Initials/ Date**	
Study details – edit			
Inspect header on page	Header should clearly indicate the study being viewed On scrolling the study title should stay in prominent view		
Edit main study data	Changing any field and clicking Apply changes allows those values to reappear when the study is refreshed, viewed or edited.		

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Action	Expectation	Result	
Check section of the data is clearly demarcated	The boxes and buttons associated with a particular attribute type should be clearly grouped together.		
Check addition process is guided	When the user clicks on Add new … something, the relevant panel should open below the existing list and should be highlighted as the current focus. If there is any guidance required it should be present on screen		
Add new study identifier data	If there is no unsaved panel, clicking on Add new study identifier causes a new panel to be opened. If identifier type and value are added, plus optionally identifier organisation and date, then clicking Save saves the input identifier data to the database, and it reappears when the study is viewed or edited.		
Edit study identifier data	Changing any field and clicking Save on the panel allows those values to reappear when the study is viewed or edited.		
Remove study identifier data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the study is viewed or edited.		
Add study title data	If there is no unsaved panel, clicking on Add new study title causes a new panel to be opened. If type type and text are added, with en as the default language code, then clicking Save saves the input title data to the database, and it reappears when the study is viewed or edited.		
Edit study title data	Changing any field and clicking Save allows those values to reappear when the study is viewed or edited.		
Remove study title data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the study is viewed or edited.		

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Action	Expectation	Result	
Edit study feature data	Changing any field and clicking Save on the panel allows those values to reappear when the study is viewed or edited.		
Add study topic data	If there is no unsaved panel, clicking on Add new study topic causes a new panel to be opened. If topic type and value are added, with optionally controlled terminology and the CT code, then clicking Save saves the input topic data to the database, and it reappears when the study is viewed or edited.		
Edit study topic data	Changing any field and clicking Save on the panel allows those values to reappear when the study is viewed or edited.		
Remove study topic data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the study is viewed or edited.		
Edit study relationship data	Changing any field and clicking Save on the panel allows those values to reappear when the study is viewed or edited.		
Add study relationship data	If there is no unsaved panel, clicking on Add new study relationship causes a new panel to be opened. If relationship type and target study are selected, then clicking Save saves the input relationship data to the database, and it reappears when the study is viewed or edited.		
Remove study relationship data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the study is viewed or edited.		
Add study contributor data	If there is no unsaved panel, clicking on Add new study contributor causes a new panel to be opened. If topic type and value are added, with optionally controlled terminology and the CT code, then clicking Save saves the input topic data to the database, and it reappears when		

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Action	Expectation	Result	
	the study is viewed or edited.		
Edit study contributor data	Changing any field and clicking Save on the panel allows those values to reappear when the study is viewed or edited.		
Remove study contributor data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the study is viewed or edited.		
Click on Cancel button	User should be transferred back to the most recent screen, usually the studies list screen		
Overall result/Comments		**Initials/ Date**	
Data Objects - list			
Inspect data objects list page	Table of data transfers in the system should be visible, showing id, organisation, title and status for each, along with standard 'items per page' and page navigation functionality. A search facility should be available above the table (search by title) along with search and reset buttons A '+ New Data Transfer' button should be visible above the table. View, edit and delete icons should be visible to the right of each table row.		
Click on New Data object button	User should be transferred to a new blank 'Add new data object screen'		
Select Search by title option, insert known title fragment in search box and click 'Search'	List should be filtered to contain only those entries that contain the search box text.		
Change title fragment text case so that it no longer matches original	Search should be case insensitive and retain the same filtered list as before		
Change title fragment to a string known not to be present in any title.	The unsuccessful search should return an empty list		
Click 'Reset' Search	The search text should clear and the list restored to its initial unfiltered state		
For a selected Data object, click	The user should be transferred to a read only		

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Action	Expectation	Result	
on View	view details screen for the selected Data object, with the relevant details shown		
For a selected Data object, click on Edit	The user should be transferred to a read only view details screen for the selected Data object, with the relevant details shown		
For a selected Data object, click on Delete	Dialogue appears asking the user if they are sure they want to delete the record		
Click Cancel in the Delete confirmation dialogue	The dialog is dismissed and no change occurs in the list		
Click Delete in the Delete confirmation dialogue	The dialog is dismissed, record is deleted and the revised list is displayed		
Click page navigation buttons	Navigation should occur through the set a page of records at a time		
Change number of items displayed per page	Number selected should be reflected in the resized table		
Overall result/Comments		**Initials/ Date**	
Data Object details - view			
Inspect header on page	Header should clearly indicate the data object being viewed On scrolling the object title should stay in prominent view		
Inspect main object data available to view	Display title, DOI, Version, Object class and type, Publication year, Language, Managing Organisation, Access Type, EOSC category, Access details and URL should all be visible, If not given or available that should be clearly indicated.		
Inspect object dataset data available to view, for dataset objects only	The dataset data (all one-to-one per dataset) should be clearly laid out, with explanatory material to clarify the various boolean statements for de-identification and consent type. Using clear subheadings – information should be arranged with the following field names **Dataset Record Key Types** Type		

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Action	Expectation	Result	
	Details **Dataset Deidentification Levels** Type Direct IDs? HIPAA applied? Dates rebased? No Narrative? K-anon applied? Details **Dataset Consent** Type Non Comm only? Geographic restrictions? Research type related? Genetic research only? No methods? Details		
Inspect object instance data available to view	Each instance should be indicated by the top bar of a drop down panel, with the bar showing the repository organisation and the resource type. Opening the panel should show the same data, plus whether or not direct access is possible, the URL if it is, the instance size if available and any further details comments.		
Inspect object title data available to view	Each title should be indicated by the top bar of a drop down panel, with the bar showing the title text. Opening the panel should show the same data, plus also identify the title type and the language of the title.		
Inspect object date data available to view	Each date should be indicated by the top bar of a drop down panel, with the bar showing the date type and the start date in ISO format – YYYY-MM-DD (or European format?? DD/MM/YYYY) Opening the panel should show the same data, plus also identify whether or not the date is a range (and if it is the end date), whether or not the date is classed as partial, and the date as a string – all should be available in the database.		
Inspect object identifier data available to view	Each identifier should be indicated by the top bar of a drop down panel, with the bar showing the identifier type and value. Opening the panel should show the same data, plus also identify the organisation that applied		

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Action	Expectation	Result	
	the identifier and if known the date.		
Inspect object description data available to view	Each description should be indicated by the top bar of a drop down panel, with the bar showing the description type and the label if there is one. Opening the panel should show the same data, and provide the full text of the description as well as its language.		
Inspect object rights data available to view	Each rights record should be indicated by the top bar of a drop down panel, with the bar showing the rights name. Opening the panel should show the same data, and provide the URL of the rights definition, plus any additional comments		
Inspect object relationship data available to view	Each relationship should be indicated by the top bar of a drop down panel, with the bar showing thew relationship type and the object id. Opening the panel should show the same data, and provide the full title of the target object		
Inspect object topic data available to view	Each topic should be indicated by the top bar of a drop down panel, with the bar showing the topic type and value. Opening the panel should show the same data, plus also identify the controlled terminology, if any, to which the topic belongs, and the code of that term within that technology		
Inspect object contributor data available to view	Each contributor should be indicated by the top bar of a drop down panel, with the bar showing the contributor type and name. Opening the panel should show the same data, plus also explicitly identify if the contributor is an individual or an organisation, give the names and any ORCID identifier for a person, plus their departmental and organisational; affiliation, while for organisations simply provide their name.		
Click on Back button	User should be transferred back to the most recent screen, usually the studies list screen		
Click on Edit button at top right of	User should be transferred to the corresponding edit screen, with the same data		

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Action	Expectation	Result	
screen	being displayed but in an editable form		
Click on Print button at top right of screen	Print preview, usually of a constructed pdf, should be shown to allow printing to take place, or a print command sent automatically (with confirmation dialogue)		
Click on JSON button at top right of screen	A download of a JSON file with the displayed data should take place, with a confirmation dialogue for the user		
Overall result/Comments		**Initials/ Date**	
After completing object main data values click Save	The object should be saved to the system, a dialog confirming this should be shown to the user, and the system should return to the object list page to show the new object.		
When saving a data object to the system the associated study should be indicated	The Add new object page should include a drop down for the studies in the system, and this should allow the associated study to be stored in the system		
Before initial save of the object it should **not** be possible to add object identifiers, titles, contributors, etc. Too complex!	The Add new object page should just include the main object fields – i.e. that would be stored in the Data Objects table. Other data can be added later in the edit object screen.		
Click on Cancel button	User should be transferred back to the most recent screen, usually the studies list screen		
Overall result/Comments		**Initials/ Date**	
Inspect header on page	Header should clearly indicate the data object being viewed On scrolling the object title should stay in prominent view		
Check section of the data is clearly demarcated	The boxes and buttons associated with a particular attribute type should be clearly grouped together.		
Check addition process is guided	When the user clicks on Add new … something,		

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Action	Expectation	Result	
	the relevant panel should open below the existing list and should be highlighted as the current focus. If there is any guidance required it should be present on screen		
Edit main object data available to view	Changing any field in the main data object specific data and clicking Apply changes allows those values to reappear when the object is refreshed, next viewed or edited.		
Edit dataset data for dataset objects	Changing any field in the dataset specific data and clicking Apply changes allows those values to reappear when the object is refreshed, next viewed or edited.		
Add object instance data	If there is no unsaved panel, clicking on Add new object instance causes a new panel to be opened. If the repository organisation and resource type are added, with optionally direct access? (default No), access URL, resource sized and comments (resource details), then clicking Save saves the input instance data to the database, and it reappears when the object is refreshed, viewed or edited.		
Edit object instance data	Changing any field and clicking Save on the panel allows those values to reappear when the object is refreshed, next viewed or edited.		
Remove object instance data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the object is refreshed, next viewed or edited.		
Add object title data	If title type and text are added, with optionally the language code (default aet as 'en'), then clicking Save saves the input title data to the database, and it reappears when the object is refreshed, viewed or edited.		
Edit object title data	Changing any field and clicking Save on the panel allows those values to reappear when the object is refreshed, next viewed or edited.		
Remove object title data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which		

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Action	Expectation	Result	
	should not reappear when the object is refreshed, next viewed or edited.		
Add object date data	If the date type and a start date are added, with optionally an end date, then clicking Save saves the input date data to the database, and it reappears when the object is refreshed, viewed or edited.		
Edit object date data	Changing any field and clicking Save on the panel allows those values to reappear when the object is refreshed, next viewed or edited.		
Remove object date data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the object is refreshed, next viewed or edited.		
Add object identifier data	If identifier type and value are added, plus optionally identifier organisation and date, then clicking Save saves the input identifier data to the database, and it reappears when the object is refreshed, viewed or edited.		
Edit object identifier data	Changing any field and clicking Save on the panel allows those values to reappear when the object is refreshed, next viewed or edited.		
Remove object identifier data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the object is refreshed, next viewed or edited.		
Add object description data	If a description type and descriptive text are added, with optionally a descriptive label and language code ('en' is the default here), then clicking Save saves the input description data to the database, and it reappears when the object is refreshed, viewed or edited.		
Edit object description data	Changing any field and clicking Save on the panel allows those values to reappear when the object is refreshed, next viewed or edited.		
Remove object description data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the object is		

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Action	Expectation	Result	
	refreshed, next viewed or edited.		
Add object rights data	If an object rights name and URL are added, with optionally Further comments, then clicking Save saves the input instance data to the database, and it reappears when the object is refreshed, viewed or edited.		
Edit object rights data	Changing any field and clicking Save on the panel allows those values to reappear when the object is refreshed, next viewed or edited.		
Remove object rights data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the object is refreshed, next viewed or edited.		
Add object relationship data	If a relationship type and target object are added, then clicking Save saves the input instance data to the database, and it reappears when the study is viewed or edited.		
Edit object relationship data	Changing any field and clicking Save on the panel allows those values to reappear when the object is refreshed, next viewed or edited.		
Remove object relationship data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the object is refreshed, next viewed or edited.		
Add object topic data	If are added, with optionally , then clicking Save saves the input instance data to the database, and it reappears when the study is viewed or edited.		
Edit object topic data	Changing any field and clicking Save on the panel allows those values to reappear when the object is refreshed, next viewed or edited.		
Remove object topic data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the object is refreshed, next viewed or edited.		

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Action	Expectation	Result	
Add object contributor data	If are added, with optionally , then clicking Save saves the input instance data to the database, and it reappears when the study is viewed or edited.		
Edit object contributor data	Changing any field and clicking Save on the panel allows those values to reappear when the object is refreshed, next viewed or edited.		
Remove object contributor data	Clicking on Remove and then confirming the deletion in the query dialog should immediately remove the containing panel of data, which should not reappear when the object is refreshed, next viewed or edited.		
Click on Cancel button	User should be transferred back to the most recent screen, usually the studies list screen		
Overall result/Comments		**Initials/ Date**	
Users - list			
Should be able to go to a 'Users' summary screen	The simplest options for accessing user details would be a link/button on the home screen to a screen listing all users, accessible like all the summary list screens to internal users only. N.B. This is in addition to users being able to view and edit their **own** details through the user panel in the header bar One issue is whether external users should be divided into two groups – a subset of 'super users' who can add and edit people in their own organisation, and 'ordinary' users who cannot do this.		
Inspect user table	Should show all users – and include their id, name, **role**, email, location (or organisation), along with standard 'items per page' functionality		
User table buttons	Add new user button should be above table		
Search functionality added	Search by name (either given or family name) capability should be added above table, with Search and Reset buttons		

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Action	Expectation	Result	
User row buttons	View, edit and delete buttons (? Need for view button/screen) should send user to user details screen.		
Overall result/Comments		**Initials/ Date**	
Should be able to access user details from relevant locations	User details should be accessible from any selected row in the users list screen (not yet implemented). They should also be available from a selected row in the 'recent users' table in the home screen for (internal users All users should be able to view and edit their ***own*** details through the user panel in the header bar.		
Click on View Details in user summary list (home screen)	The details of that particular user should be displayed in the user details screen If the user has the necessary rights, e.g. is a system administrator or the RMS manager, they should also be able to edit those user details.		
Navigate to user details screen from My Profile in User Panel	User details screen should fill with details of current user		
Essential fields of user details should be obvious	The fields that are essential to capture for a user should be clearly marked or labelled as such. Given and family name (not first and last name) and email address should be essential. Contact telephone should be optional but if given should include the international dialling code and explicitly ask for this. Country should be optional. Job title could be useful but should also be optional. In the user table Location is included but is not in the user details. If required should be included as an optional (City) field.		
Username only if necessary	In most systems the email can also act as the username and it is simpler to do so. Would need checking with SG, but if a separate username is not required this can and should		

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Action	Expectation	Result	
	be dropped from the user details		
User fields should be useful	Not clear to me if an image file or avatar is useful. In most cases I think users would ignore it.		
User screen should be RMS specific	At the moment the screen includes 'If you want your invoices addressed to a company. Leave blank to use your full name'. This makes no sense but does indicate the entire screen is just a placeholder copied from somewhere		
Click 'Save Changes' in the User screen	The changes should be confirmed by an explicit message or clearly visible in a revised user details list on screen		
Click 'Cancel' in the User screen	User screen should be closed and the user should be returned to the screen where they were when they navigated to the user details screen		
User role needs to be managed by RMS manager or other internal staff	The role of the user is a critical attribute. Options available include: a) System administrator b) RMS manager c) Other ECRIN staff d) TSD staff e) Internal person – ECRIN/TSD staff but not a user** f) External user – super-user g) External user – ordinary user h) External person – personal details in system but not a user** ** May be useful to include in system, e.g. details of signatories to legal agreements Users should not in general be able to determine their own roles. Only System administrators and the RMS Manager(s) should have this ability. The 'Role' box should therefore be a read only text box for most users, and an editable drop down box for a few users		
Overall result/Comments		**Initials/ Date**	

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Action	Expectation	Result	
Reports (internal users only)			
Navigate to Reports screen	A listing of available reports should be shown Creating and deleting reports should not be possible from within the system (see comments below). Less important than the author/date of a report is a brief description of what it does and/or the parameters it might need. Each report just needs to be accompanied by a 'Select' or 'Run' button. All other buttons can be dropped.		
Click 'Run' on a selected report	If the report has no parameters the report should be generated, shown on screen and made downloadable as a PDF, CSV file or JSON. If the report has parameters (e.g. an organisation name, start and end dates for a time period) then some form of dialogue box/panel needs to appear to collect those parameters. Assuming valid parameters, the report can be run, shown on screen and made downloadable as a PDF, CSV file or JSON.		
Overall result/Comments			

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