TRINITY HEALTH
KIDNEY CENTRE

Rare Kidney Disease Registry and Biobank

Data Management Plan

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The Meath Foundation
Healthcare, Research and Education at the Hospital in Tallaght

Version 1.0_160620

A. Brief Description of RKD Biobank

Anti-Neutrophil Cytoplasmic Antibody (ANCA)-Associated Vasculitis (AAV) is a rare autoimmune disease that results in rapidly progressive kidney impairment, in addition to immune-mediated destruction of other organs. This affects about 20 per million population per year, as opposed to affecting a handful of people in the country, so is considered a “common-rare disease”. It causes severe multi-organ dysfunction, including irreversible kidney failure, lung haemorrhage, stroke and sino-nasal destruction. The prevalence is 300/million and hence can only be studied by a coordinated international network of centres. The Vasculitis Ireland Network was created in 2014 to harmonise care for vasculitis patients across Ireland. It is a member of ERN-RITA, the European Reference Network for rare immune disorders. Documenting and reporting on clinical outcomes and benchmarking against international norms using a dedicated registry are key components of ERN membership.

The primary aims of this initiative are to address fundamental questions about vasculitis epidemiology, facilitate conduct of phase II/III interventional studies by allowing easy identification of a suitable cohort, monitor use of novel biologic agents, compile sufficiently large cohorts to study immunogenetics, rapidly assess the clinical utility of new biomarkers for development in clinical trials as surrogate end-points, and to characterise ‘difficult to define’ disease subgroups including ANCA negative vasculitis and polyarteritis overlap syndromes.

DeCOmPRESS sub-study

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The DeCOmPRESS study will rapidly inform management of immunosuppressed patients who contract COVID-19 by comprehensively profiling immunological manifestations and defining the natural history and of the disease in these patients. This project aims to determine if COVID-19 is more or less severe in these immunosuppressed patients. We aim to determine whether immunosuppressant therapy for chronic autoimmune disease protects against the cytokine storm associated with COVID-19 and reduces the severity of the clinical syndrome, thereby paradoxically improving rather than worsening clinical outcome.

We will obtain a granular clinical dataset from RKD recruits contracting COVID-19, which will be linked to an existing clinical phenotype and blood samples analysed by flow cytometry and ELISA to define the immunophenotype and cytokine profile. Importantly, use of a FAIR COVID-19 dataset (designed to be interoperable with international data collection initiatives) and deposition of data in an open science repository will allow ready integration with other studies to maximise the impact of this project.

We will incorporate a broad range of potential data streams, including: the Rare Kidney Disease registry; immunophenotyping and serum cytokine data from the Central Pathology Laboratory at St. James' Hospital, clinical data derived from the registry database, and patient-derived data streams using smart phone and wearable technologies (if the participant has also consented to join the aligned AVERT study https://www.tcd.ie/medicine/thkc/avert/).

B. Information Governance Summary

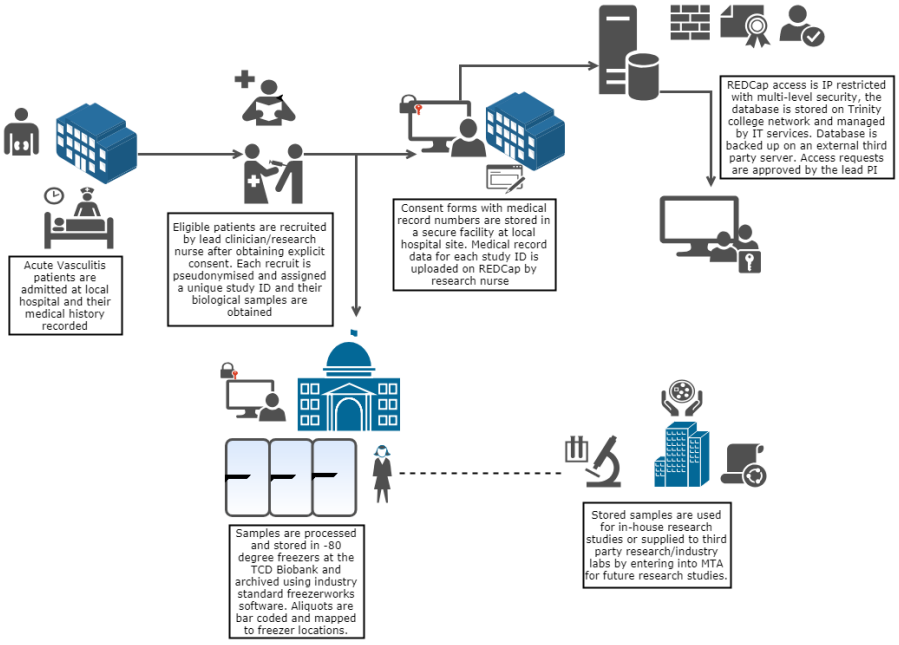

Figure X. Summary of key sites involved in the RKD registry and biobank.

This data management policy will be followed by all collaborators on the RKD project and complemented by standard operating rules and codes of practice for the diverse research and technical actors in the project. It should be read in conjunction with the RKD data protection impact assessment. A uniform base standard for information security will apply across the project (designed to interface with the existing policies and practices at TCD), which will provide a consistent assurance of privacy protection.

TCD is the **data controller** of RKD registry and biobank data. The relevant hospitals are the **data controllers** of clinical data before it is pseudonymised and entered into the registry database. The basic RKD data governance principles are summarised in Table 1.

Table 1 RKD Data Governance Principles

Integrity	We will practice integrity with their dealings with one another; we will be truthful and forthcoming when discussing constraints, options, and impacts for data-related decisions.
Transparency	Data Governance and Stewardship processes will exhibit transparency; it should be clear to all participants and auditors how and when data-related decisions and controls were introduced into the processes.
Auditability	Data-related decisions, processes, and controls subject to Data Governance will be auditable; they will be accompanied by documentation to support compliance-based and operational auditing requirements.
Accountability	Data Governance will define accountabilities for cross-functional data-related decisions, processes, and controls.
Stewardship	Data Governance will define accountabilities for stewardship activities that are the responsibilities of individual contributors, as well as accountabilities for groups of Data Stewards.
Checks-and-Balances	Data Governance will define accountabilities in a manner that introduces checks-and-balances between recruitment and analysis teams as well as between those who create/collect information, those who manage it, those who use it, and those who introduce standards and compliance requirements.
Standardization	Data Governance will introduce and support standardisation of data to maximise potential for sharing.
Change Management	Data Governance will support proactive and reactive Change Management activities for reference data values and the structure/use of master data and metadata. This will allow us to track reliably where changes were made.

All coded experimental data pertaining to the DeCOmPRESS sub-study will be stored on TCD's Microsoft OneDrive service. OneDrive is Microsoft's cloud-based file storage service, which allows syncing and sharing of files between computers and mobile devices, and is the cloud computing service of choice of TCD. These files can be accessed from anywhere you have an internet connection. Data hosted on OneDrive will be securely hosted by Microsoft in Europe in compliance with relevant legislation[1] (see **TCD Data Protection Procedural Guidelines**). TCD is the data controller of DeCOmPRESS data.

At times, cross-centre research collaborations will require data sharing, potentially between European countries. RKD data management and sharing policies will be applied to such data transfers, which are detailed in the data sharing policy.

[1] **https://www.tcd.ie/info_compliance/data-protection/documents/TCD_Data_Protection_Procedural_Guidelines.pdf**

C. Documentation and Metadata

Each data document generated as part of the RKD study (see **Section D.1**) will include a metadata descriptor. Metadata and data field descriptors for REDCap data exports are available and have already been incorporated into the RDF uplift process, where this approach to data integration is employed. Benefits of this approach include data storage in an interoperable format, quicker and more intuitive querying of the data, consistent combination of diverse data sources, and ease of reporting.

D. Data Collection

D.1 Types of Data Collected and Created

All data will be collected according to the FAIR data principles; findability, accessibility, interoperability, and reusability. Data are pseudonymised by use of the **RKD Main Study ID** primary identifier; this is assigned as the next available ID on the REDCap database. Access to relevant data sources will be controlled by the PI. The key data files generated are:

- A site **recruitment log,** which incorporates identifiable data that allows local re-identification of recruits.
- Pseudonymised **clinical characteristics** of patients and controls. These are stored in the central RKD REDCap database.
- Pseudonymised **experimental data**, e.g. immunophenotyping and serum cytokine results from CPL analysis, biomarker data, flow cytometry data.
- Pseudonymised **biobank data**, describing the provenance, status and location of biobank aliquots. These are stored in a Freezerworks database.
- Uplifted Resource Description Framework (RDF) data, comprising **fused clinical and experimental data** and held in a dedicated triplestore database.

The RKD registry database is hosted by TCD IT service providers, as its security and access permissions are managed by them. This database is periodically backed up on an external third-party server located in Dublin.

The DeCOmPRESS sub-study also incorporates a data stream from the patientMpower vasculitis support app in those participants who have consented to inclusion in the aligned AVERT project (DMP for this study located here: **https://www.tcd.ie/medicine/thkc/assets/pdf/Data%20Management%20Plan_v1.1.pdf**). As a sample sub-study, the data streams for DeCOmPRESS are summarised in figure x.

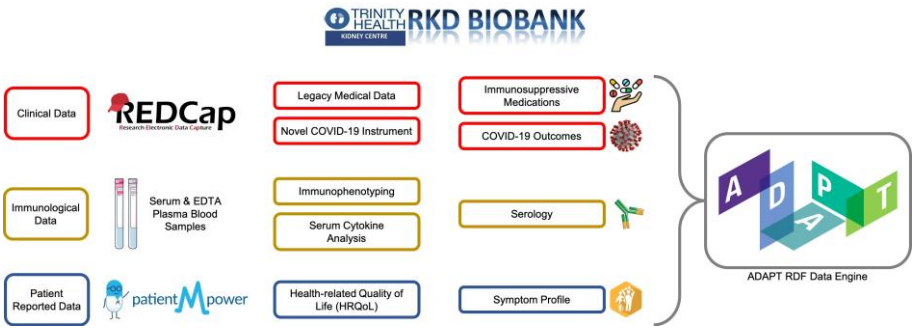

Figure 2 - Overview of Types of Data Collected in the DeCOmPRESS sub-study

D.1.1 Patient Recruitment Log

These logs are maintained on each hospital site in a firewall-protected folder on the hospital server. They are held on excel spreadsheets and include the following information: RKD ID, consent version, date of recruitment and identifiable parameters (name, DOB, MRN, contact details). It is accessible only by local study PI and research nurse.

DeCOmPRESS sub-study subjects are all current recruits of the RKD Biobank. Upon contracting COVID-19 RKD recruits will be recognised by their local medical team and their RKD ID registered with the DeCOmPRESS research group, who will maintain a dedicated log of (pseudonymised) study recruits.

D.1.2 Patient Clinical Data – REDCap

REDCap is a secure electronic data capture (EDC) web platform for building and managing online databases and surveys. Pseudonymised clinical data for all encounters with RKD recruits are recorded in REDCap project “Rare Kidney Disease – RIT Production”. The data dictionary is included in appendix 1. This database operates on multiple-access levels and only the PI and RKD Research Nurse have complete access to the database and permission to modify. Access to patient clinical records is available to the medical team caring for the patient and local study site managers. The RKD registry database is hosted by TCD Research-IT service providers (TCHPC), and its security and access permissions are managed by them. The database is protected behind host and institutional firewalls. This database is backed up daily on an external third-party server located in Dublin.

D.1.3 Experimental data

TCD researchers who generate experimental data deriving from analysis of RKD samples or data store this dedicated TCD SharePoint folders, which is the preferred storage solution of the university. Each researcher has their own access-controlled folder. These data include spreadsheets (excel, CSV, .xlsx), Graphpad Prism files (.pzfx), flow cytometry files (.fcs), word documents, image files (.jpeg, .png, .ndpi), PowerPoint files (.pptx), transcriptomic data files (.cel).

DeCOmPRESS experimental data storage: Sample analysis results from patient samples analysed by CPL will be transferred to the designated DeCOmPRESS OneDrive folder described in **Section G.3.3**. Access to this folder is reserved for the PI, PM, CPL Chief Medical Scientist, and designated CPL Laboratory Technicians. Results will be added as they become available and version control managed by the DeCOmPRESS PM. Coded biological samples are processed and stored temporarily at the CPL Bioresource using industry standard TelePath software. Following batched multiplex analysis, coded serum sample aliquots will be stored in the RKD biobank using standard RKD protocols. Archived RKD Biobank samples and freshly obtained serum will be used for serology analysis.

D.1.4 Biobank sample data

When sample aliquots are archived in the biobank freezer, the provenance data are recorded in the RKD Freezerworks database, which is accessible to the PI, biobank manager and selected delegates. These data include arm to freezer time, sample transport conditions, sample processor identity, aliquot volume, presence/absence of protease inhibitor, freeze-thaw cycles and an audit of sample access. These data are pseudonymised.

D.1.5 Fused experimental/clinical data.

Data integrated into ADAPT's analysis networks will be stored using a Resource Description Framework (RDF) model to facilitate analysis and data sharing. The RDF model stores data in a "triplestore" database. This is a purpose-built database for the storage and retrieval of triples through semantic queries. Semantic triples codify statements about the data in the form of subject–predicate–object expressions. The RDF model facilitates enhanced data analysis and sharing. Examples where this approach is taken include the AVERT study (where RKD clinical data are fused with environmental and app data) and the DeCOmPRESS sub-study (where experimental, clinical and app data are integrated). All such data are coded using the RKD ID.

E. Responsibilities and Resources

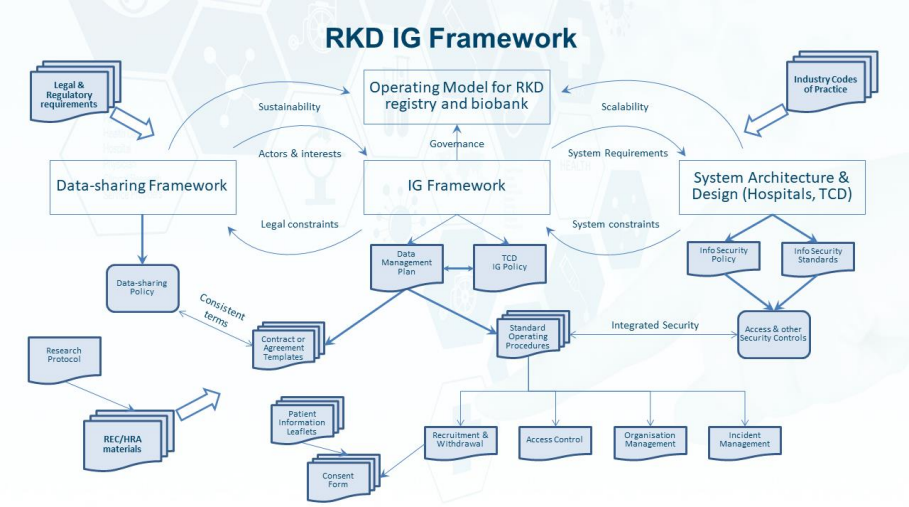

Figure x. Overview of RKD policies and responsibilities

E.1 Data Management

The HRB's "Guidance for health researchers" advises research organisations and researchers on data protection obligations under GDPR, the Data Protection Act 2018 and the new Health Research Regulations 2018. As per these guidelines any project processing personal data for the purposes of health research must assign a data controller and a data processor. There remains both individual and organisational responsibility to comply with these regulations. All members of the study team (and anyone with access to the data) must act responsibly and will be trained in Data Governance principles. Inclusion of patient representatives in the steering committee will ensure that the best interests of patients are adhered to.

A data controller is the individual (or entity) who controls and is responsible for the collection, storage and/or use of personal information, and determines the purposes for which, and the way in which, personal data is processed. GDPR Article 5(2) requires that the data controller be responsible for, and be able to demonstrate, compliance with the principles of data protection. The RKD data controller is TCD, acting through the RKD PI (Prof. Mark Little).

TCD researchers will act as the initial Data Processors and will be responsible for managing access to the relevant data files for the appropriate stakeholders. Additional project members will be assigned Data Processor status as novel analyses are required. A data processor may hold or process personal data on behalf of the data controller but does not exercise responsibility for or control over the personal data. The Data Processors will immediately notify the controller of any data breaches.

If RKD data are shared with third parties, these will then become data controllers of the received data. These interactions will be governed by formal material and data sharing agreements.

E.2 Data Erasure Requests

Patients are free to deny the use of their samples for this project and to withdraw from the study at any stage. In accordance with GDPR legislation, if a participant requests for their data to be erased, this will be managed by the Data Controller (PI). This request may be following direct contact with medical or research teams or the RKD Research Nurse. A log of such requests will be maintained by the Biobank manager. Upon receipt of such a request, all RKD study ID will be deleted from the appropriate files and records. The patient will be removed from the study recruitment log and any linked paper documentation destroyed. This will be undertaken within the time frame stipulated by GDPR. As indicated in the RKD PIL, it will not be possible to erase data that have already been used in a scientific manuscript or collaboration. If desired, the participant will be given a copy of their data on a USB memory stick.

E.3 Data Requests

Chapter 3 of the GDPR details Data Subject Right provisions and calls for mechanisms to be put in place whereby the participant can request a copy of their data. This request may be facilitated following direct contact with medical or research teams or the RKD Research Nurse. Such requests will be noted in the RKD recruitment log. The Biobank manager is responsible for compiling patient data exports and formatting an individualised report. This will be in CSV or PDF format with accompanying metadata and will be transferred to the local research nurse/medical team, who will link to identifiable data and transfer the file to the requester on a USB memory stick. This will be undertaken within the time frame stipulated by GDPR.

E.4 Data Review

The PI will be responsible for managing version control of RKD documents and files and for completing regular QC reviews of data accuracy. Regular audits of access will ensure efficient reporting of results as detailed in the Data Sharing Plan. Where inaccuracies in the data are identified by other RKD study team members this will be amended in the relevant file and recorded in the recruitment log.

F. Ethics and Legal Compliance

All participants have provided consent for research projects deriving from the stored samples and data. The RKD project has oversight by the RKD Steering Committee and sub-studies are approved by the SJH/Tallaght Ethics Committee. For example,

the DeCOmPRESS sub-study has received approval: 2020-04 List 13 – Amendment (22). A log of such approvals is maintained by the RKD PI.

F.1 Informed Consent

All patients enrolled to the RKD Biobank provide informed consent for their data and specimens to be used for research purposes. Full details are provided in the RKD Biobank protocol. Patient information leaflets and RKD protocols are available to download at: **https://www.tcd.ie/medicine/thkc/research/rare.php**.

F.2 Data Linkage

Linkage allows patient-reported data to be linked to clinical data derived from the RKD registry and immunological data from patient sample analysis. The purpose of this is to characterise the immune response to COVID-19 and how AAV treatment regimens affect the disease course. The RKD ID is the primary identifier and unifies data collected from multiple sources. RKD IDs can only be re-identified via the local RKD Biobank recruitment log, to which only the RKD Research Nurse and site PI have access. Study team researchers will have access to the relevant and suitably transformed data with prior approval from the PI. The PI is responsible for ensuring correct data linkage across sources, and the validity and consistency of results and data. In some cases (with complex data streams, such as the AVERT and DeCOmPRESS studies), data linkage is undertaken in the ADAPT RDF triplestore database.

F.3 RKD personnel

Researchers and study team members with access to this data have a responsibility to work with integrity. RKD researchers commit to the highest standards of data security and protection in order to preserve the personal rights and interests of study participants. All RKD personnel who have access to identifiable patient data are required to undergo GCP training and ensure that this training is maintained up to date. They will adhere to the provisions set out in the:

- General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679) as enacted in May 2018, which strengthens and unifies data protection for all individuals within the European Union (EU). It also addresses the export of personal data outside the EU.
- Directive 2006/24/EC of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communication services or of public communications networks.
- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy

in the electronic communications sector (Directive on privacy and electronic communications) and

- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

In addition, data governance will comply with the stipulations of the General Data Protection Regulation legislation enacted in 2018. To ensure the confidentiality, accuracy and security of data, the following measures will be taken:

- eCRFs and other forms needed for the collection of patient data will be unified and exported in appropriate formats for review by the relevant authorities as required.

G. Data Storage and Backup

Data pertaining to the RKD study will be held in hospital and TCD locations as summarised in Figure X. Data held within TCD will be pseudonymised.

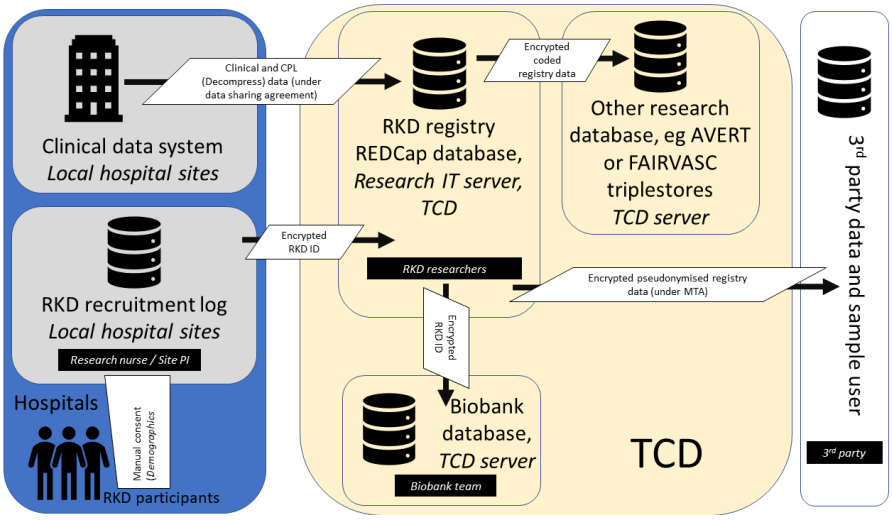

Figure X. Summary of RKD data flows

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G.1 TCD Network Security Statement

I. Information is a critical asset of Trinity College Dublin hereafter referred to as the 'University'. Accurate, timely, relevant, and properly protected information

is essential to the success of the University's academic and administrative activities. The University is committed to ensuring all accesses to, uses of, and processing of University information is performed in a secure manner.

II. Trinity College Dublin is committed to adopting a security model in line with the ISO27001/ISO27002 international best practice standards.

III. Technological Information Systems hereafter referred to as Information Systems' play a major role in supporting the day-to-day activities of the University. These Information Systems include but are not limited to all Infrastructure, networks, hardware, and software, which are used to manipulate, process, transport or store Information owned by the University.

IV. The object of this Information Systems Security Policy and its supporting technical requirements policy is to define the security controls necessary to safeguard University Information Systems and ensure the security confidentiality and integrity of the information held therein.

V. The Policy provides a framework in which security threats to University Information Systems can be identified and managed on a risk basis and establishes terms of reference, which are to ensure uniform implementation of Information security controls throughout the University.

VI. The University recognises that failure to implement adequate Information security controls could potentially lead to:

   i. Financial loss

   ii. Irretrievable loss of Important University Data

   iii. Damage to the reputation of the University

   iv. Legal consequences

VII. Therefore, measures must be in place which will minimise the risk to the College from unauthorised modification, destruction or disclosure of data, whether accidental or deliberate. This can only be achieved if all staff and students observe the highest standards of ethical, personal and professional conduct. Effective security is achieved by working with a proper discipline, in compliance with legislation and University policies, and by adherence to approved University Codes of Practice.

VIII. The Information Systems Security Policy and supporting policies apply to all staff and students of the University and all other users authorised by the University.

IX. The Information Systems Security Policy and supporting policies do not form part of a formal contract of employment with the University, but it is a condition of employment that employees will abide by the regulations and policies made by the University from time to time. Likewise, the policies are an integral part of the Regulations for Students

X. The Information Systems Security Policy and supporting policies relate to use of:

i. All University networks connected to the University Backbone

ii. All University-owned/leased/rented and on-loan facilities.

iii. To all private systems, owned/leased/rented/on-loan, when connected to the University network directly, or indirectly.

iv. To all University-owned/licensed data/programs, on University and on private systems.

v. To all data/programs provided to the University by sponsors or external agencies.

XI. The objectives of the Information Systems Security Policy and supporting policies are to:

i. Ensure that information is created used and maintained in a secure environment.

ii. Ensure that all of the University's computing facilities, programs, data, network and equipment are adequately protected against loss, misuse or abuse.

iii. Ensure that all users are aware of and fully comply with the Policy Statement and the relevant supporting policies and procedures.

iv. Ensure that all users are aware of and fully comply with the relevant Irish and European Community legislation.

v. Create awareness that appropriate security measures must be implemented as part of the effective operation and support of Information Security.

vi. Ensure that all users understand their own responsibilities for protecting the confidentiality and integrity of the data they handle.

vii. Ensure all University owned assets have an identified owner /administrator

XII. The University Board has approved the Information Systems Security Policy and supporting technical policy. The Board has delegated the implementation of the Information Systems Security Policy, to the heads of academic and administrative areas. The Director of IT Services and his/her delegated agents will enforce the Information Systems Security Policy and associated supporting policy.

G.2 Microsoft Office OneDrive/SharePoint

OneDrive/SharePoint is a file hosting and synchronization service operated by Microsoft as part of its web version of Office. OneDrive allows users to sync and share files between computers and mobile devices from anywhere with an internet connection. Document edits are instantly saved online, and can be viewed and edited in real time by anyone with access to the document enabling live collaboration with colleagues. Version and access control of files stored on OneDrive will be the responsibility of the PI. OneDrive data is securely hosted by Microsoft in Europe in compliance with relevant legislation.

G.3 Data Security Statements

G.3.1 RKD Registry

1. Identifiable patient/control data is pseudonymised after recruitment by assigning a study ID; their consent forms with medical record numbers will be stored separately in a secure facility at the local hospital site.
2. Pseudonymised data will be uploaded on the REDCap database which will be mapped to a dedicated password protected computer using IP address. The database will be protected behind host and institutional firewall with access to dedicated personnel only.
3. For further information please refer to Data Protection Impact Assessment.

G.3.2 RKD Biobank samples

1. Coded biological samples are processed and stored centrally at the RKD biobank and archived by the biobank technician using industry standard Freezerworks software; only the biobank technician and Lead study PI have access to the software.
2. This software is maintained on a stand-alone TCD-networked and password-controlled laptop, which is stored in a locked cupboard in the Trinity Translational Medicine Institute. It is not allowed to leave this building.

G.3.3 Experimental Data

1. This data will be stored in password-protected SharePoint/OneDrive folders with strict access control.
    a. OneDrive security is maintained by TCD in accordance with the TCD Network Security Statement
    b. OneDrive data is securely hosted by Microsoft in Europe in compliance with relevant legislation.

G.3.4 RKD ADAPT triplestore database

The ADAPT server is located on the TCD Virtual Machine and Docker cluster.

1. Hardware
    a. 4 Virtual Machine (VM) nodes and 4 storage nodes
2. Software
    a. OS (hosts and storage nodes): Debian 9
    b. VM cluster: OpenNebula 5
    c. Container hosts: Docker
3. Storage: Ceph
    a. This will be backed up daily and stored on a dedicated back-up server.
4. Security Detail
    a. Two firewalls
        i. Between our subnet and the host School of Computer Science and Statistics network that filters connections on some ports
        ii. TCD firewall that blocks all incoming connections and filters some outgoing connections;
    b. For Apache web servers, we use the Nikto tool to scan all the websites hosted in our cluster once per month for known vulnerabilities;
    c. For all webservers, we expose them through our reverse proxy, and the reverse proxy logs every connection and can restrict incoming connections depending on source IP.
5. Access Control
    a. Only the requesting user can login and obtain a shell on the VMs.
    b. Connections to services hosted on the VM can be restricted by source IP as requested by the user.

G.4 Access Management

The PI will be the only study member with full read & write access to all data files in the RKD study. Patient identifying information will only be accessible to local medical teams and not stored in any TCD RKD data files. Historical clinical data for patient group assignment and analysis are stored in the RKD database. This database operates on multiple-access levels and only the lead study PI and Research Nurse will have complete access to the database and permission to modify. Access to relevant documents (and new access requests) will be managed by the Project Manager,

approved by the Lead Study PI, and maintained in an access log. An assessment of all individuals who have accessed each data location, and the nature of all data (e.g. identifiable vs de-identified) will be included in regular study reports report.

H. Data Selection and Preservation

All data collected in the course of the RKD study will be retained in the secure structures as defined above. Data will be stored in accordance with FAIR principles: findability, accessibility, interoperability, and reusability. This will allow results from this work to be interoperable with international data collection initiatives and maximise the impact of the project. Organisation or study groups requesting access to RKD data or samples will be reviewed and approved/rejected by the PI and RKD steering committee as described in the RKD data sharing agreement.

Study data will be held on TCD servers for the duration of the project and beyond for as far as is currently foreseeable. The PI will ultimately be responsible for its management and storage beyond the study duration. Upon completion of specific projects, study datasets and will be deposited in a predetermined, accredited archive, respecting data protection requirements. Linked clinical samples will be stored indefinitely in appropriate storage conditions.

I. Dissemination

A fundamental mission of the RKD study is the timely and open-access dissemination of study results. This is routinely achieved through production of an annual newsletter and publication of study results in open access journals. Audits of data access will be a fundamental part of this reporting procedure. All research outputs will be reported in real time in open access formats and shared with the relevant stakeholders in line with the HRB Joint statement on sharing research data and findings relevant to the novel coronavirus (COVID-19) outbreak. The study protocol will be published on the HRB open research. Detailed processes for data sharing, dissemination and exploitation are described in the data sharing agreement.

Appendix 1: RKD registry data dictionary

Variable / Field Name	Form Name	Section Header	Field Label	Choices, Calculations, OR Slider Labels
record_id	patient		RKD ID	
patient_id	patient		Patient Id	
hospital	patient		Hospital Unit / Site at Diagnosis	
hospital_other	patient			
type_of_patient	patient		Type of Patient	
other_disease_name	patient		Other Disease name	
other_disease_name_other	patient			
self_reported_as_healthy	patient		Self reported as healthy	
urinalysis	patient		Urinalysis	1, Normal | 2, Abnormal | 3, Not Done
de_enrolled	patient		De-enrolled	
date_of_de_enrollment	patient			
reason_for_de_enrollment	patient		Reason for de-enrollment	
enrolled_in_curv	patient		Enrolled in CURV	
curv_enrollment_date	patient			
enrolled_in_critir	patient		Enrolled in CRITIR	
critir_enrollment_date	patient			
enrolled_in_avert	patient		Enrolled in AVERT	
avert_enrollment_date	patient			
pseudonym	patient		Pseudonym	
gender	baseline_characteristics_common		Gender	1, Male | 2, Female | 3, Undetermined
date_of_birth	baseline_characteristics_common		Date of Birth	
year_of_birth	baseline_characteristics_common		Year of birth	
warning_picked_date	baseline_characteristics_common			
ethnicity	baseline_characteristics_common		Ethnicity	
consent_obtained_for_regis	baseline_characteristics_common		Consent obtained for registry/biobank	
consent_version_number	baseline_characteristics_common			

date_of_consent	baseline_characteristics_common			
consent_obtained_genetic	baseline_characteristics_common		Has consent been obtained for Genetic studies	
genetic_consent_version_nu	baseline_characteristics_common			
date_of_genetic_consent	baseline_characteristics_common			
education_baseline	baseline_characteristics_common		Education	1, Primary School | 2, High school | 3, University | 4, Unknown or Prefer not to answer
employment_status_at_diagn	baseline_characteristics_common		Employment status at diagnosis	
ethnicity_of_mother	baseline_characteristics_common		Ethnicity of mother	
ethnicity_of_father	baseline_characteristics_common		Ethnicity of father	
country_of_birth	baseline_characteristics_common		Country of birth	
country_of_birth_other	baseline_characteristics_common			
country_residence	baseline_characteristics_common		Country of residence	1, Other | 2, UK | 3, France | 4, Poland | 5, Pakistan | 6, India | 7, New Zealand | 8, Australia | 9, Latvia | 10, Germany | 11, United States | 12, Spain | 13, Ireland
county_residence	baseline_characteristics_common		County of residence	1, Antrim | 2, Armagh | 3, Carlow | 4, Cavan | 5, Clare | 6, Cork | 7, Derry (Londonderry) | 8, Donegal | 9, Down | 10, Dublin | 11, Fermanagh | 12, Galway | 13, Kerry | 14, Kildare | 15, Kilkenny | 16, Laois | 17, Leitrim | 18, Limerick | 19, Longford | 20, Louth | 21, Mayo | 22, Meath | 23, Monaghan | 24, Offaly | 25, Roscommon | 26, Sligo | 27, Tipperary | 28, Tyrone | 29, Waterford | 30, Westmeath | 31, Wexford | 32, Wicklow
date_of_arrival_in_ireland	baseline_characteristics_common			
bcg_vaccination	baseline_characteristics_common		BCG vaccination?	
relationship_to_other_case	baseline_characteristics_common		Relationship to other case	
maternal_or_paternal	baseline_characteristics_common		Maternal or Paternal	
clinical_samples_obtained	baseline_characteristics_common		Clinical samples obtained	
biobank	baseline_characteristics_common		Name of biobank biological sample is stored in	1, RKD Biobank | 2, Other
biobank_other	baseline_characteristics_common		Name of biobank biological sample is stored in - other	
plasma_exchange_collected	baseline_characteristics_common			
plasma_exchange_notes	baseline_characteristics_common			
height	baseline_characteristics_common		Height	
height_cms_known	baseline_characteristics_common			
e_cigarette_or_vape_use	baseline_characteristics_common	Smoking History	E-cigarette or Vape use	1, Yes | 2, No | 3, Unknown

smoking	baseline_characteristics_common		Smoking	
age_of_starting	baseline_characteristics_common		Age of starting	
date_of_stopping	baseline_characteristics_common		Date of stopping	
average_cigarettes_per_day	baseline_characteristics_common			
patient_status	baseline_characteristics_common	Patient Status	Status	
date_of_opt_out	baseline_characteristics_common		Date of opt out	
death	baseline_characteristics_common		Death	
date_of_event	baseline_characteristics_common		Date of event	
cause_of_death	baseline_characteristics_common		Cause of death	
cause_of_death_known	baseline_characteristics_common			
cause_of_death_known_snome	baseline_characteristics_common		Cause of death - known, snomedCT	BIOPORTAL:SNOMEDCT
control_linked	baseline_characteristics_healthy			
relationship_to_recruited	baseline_characteristics_healthy		Relationship to recruited case	
recruited_case_id_number	baseline_characteristics_healthy			
avert_identifier	general_characteristics_vasculitis		AVERT Identifier	
ukvas_identifier	general_characteristics_vasculitis		UKVAS identifier	
anca_if	general_characteristics_vasculitis		At any point ANCA IF pattern	
anca_spec	general_characteristics_vasculitis		At any point ANCA specificity	
anca_spec_other	general_characteristics_vasculitis			
systems_involved	general_characteristics_vasculitis		Systems involved at any point	
systems_involved_other	general_characteristics_vasculitis			
sys_involved_other_icd11	general_characteristics_vasculitis		Systems involved at any point - other, ICD11	
esrd_dialysis	general_characteristics_vasculitis			
date_of_esrd	general_characteristics_vasculitis			
renal_recovery	general_characteristics_vasculitis			
date_of_renal_recovery	general_characteristics_vasculitis			
induction	general_characteristics_vasculitis		Any Induction Treatment	
induction_treatment	general_characteristics_vasculitis		Induction treatment received	

no_of_plasma_exchanges	general_characteristics_vasculitis		
induction_treatment_other	general_characteristics_vasculitis		
maintenance	general_characteristics_vasculitis	Any Maintenance Treatment	
maintenance_treatment	general_characteristics_vasculitis	Maintenance treatment received	
maintenance_other	general_characteristics_vasculitis		
family_history_choice	general_characteristics_vasculitis	Family history (1st degree relatives only)	
required_renal_replacement	renal_replacement_therapy		
renal_recovery_independ	renal_replacement_therapy		
date_of_renal_recovery_2	renal_replacement_therapy		
end_stage_kidney_disease	renal_replacement_therapy	End-stage kidney disease	
date_of_end_stage_kidney	renal_replacement_therapy	Date of end-stage kidney disease (date of commencement on dialysis or transplant, whichever first)	
family_history	family_histories	Family history	
family_member	family_histories	Which family member	
comorbid_note	preexisting_comorbidities		
comorbid_events	preexisting_comorbidities	Comorbid events (present before vasculitis diagnosis)	
comorbid_events_2	preexisting_comorbidities	Comorbid events (present before vasculitis diagnosis)	
comorbid_events_other	preexisting_comorbidities		
comorbid_events_other_snom	preexisting_comorbidities	Comorbid events other, snomedCT	
comorbid_events_detail	preexisting_comorbidities		
date_of_diagnosis	diagnosis_vasculitis	Date of diagnosis	
age_at_diagnosis	diagnosis_vasculitis	Age at diagnosis	rounddown(datediff([date_of_birth],[date_of_diagnosis],"y","dmy",true),0)
date_of_symptons_choice	diagnosis_vasculitis	Date of onset of symptoms - known/unknown	
date_of_symptons	diagnosis_vasculitis	Date of onset of symptons	
age_onset	diagnosis_vasculitis	Age at onset	rounddown(datediff([date_of_birth],[date_of_symptons],"y","dmy",true),0)
small_vessel_vas_anca	diagnosis_vasculitis	Small vessel vasculitis (ANCA associated)	
please_select_up_to_a_maxi	diagnosis_vasculitis		

small_vessel_vas_immune	diagnosis_vasculitis	Small vessel vasculitis (Immune complex)
medium_vessel_vasculitis	diagnosis_vasculitis	Medium vessel vasculitis
large_vessel_vasculitis	diagnosis_vasculitis	Large vessel vasculitis
variable_vessel_vasculitis	diagnosis_vasculitis	Variable vessel vasculitis
single_organ_vasculitis	diagnosis_vasculitis	Single organ vasculitis
secondary_vasculitis	diagnosis_vasculitis	
other	diagnosis_vasculitis	Other
other_details	diagnosis_vasculitis	Other details
unclassified	diagnosis_vasculitis	Unclassified
biopsy_performed	diagnosis_vasculitis	Biopsy performed
histologically_confirmed_d	diagnosis_vasculitis	Histologically confirmed diagnosis
please_open_supporting_pdf	diagnosis_vasculitis	
diagnosis_confidence_init	diagnosis_vasculitis	Diagnosis confidence (initial assessment)
clinical_diagnosis_1	diagnosis_other_disease	Clinical diagnosis 1
clinical_diagnosis_1_snome	diagnosis_other_disease	Clinical diagnosis 1, snomedCT
date_of_diagnosis_1	diagnosis_other_disease	Date of diagnosis1
clinical_diagnosis_2	diagnosis_other_disease	Clinical diagnosis 2
clinical_diagnosis_2_snome	diagnosis_other_disease	Clinical diagnosis 2, snomedCT
date_of_diagnosis_2	diagnosis_other_disease	Date of diagnosis 2
clinical_diagnosis_3	diagnosis_other_disease	Clinical diagnosis 3
clinical_diagnosis_3_snome	diagnosis_other_disease	Clinical diagnosis 3, snomedCT
date_of_diagnosis_3	diagnosis_other_disease	Date of diagnosis 3
drug	treatment_continuing_medications	Drug
drug_selected_choices	treatment_continuing_medications	Drug
drug_atc	treatment_continuing_medications	Drug, ATC
dose	treatment_continuing_medications	Dose
unit_of_doses	treatment_continuing_medications	Unit of Doses
unit_of_doses_other	treatment_continuing_medications	
frequency	treatment_continuing_medications	Frequency

frequency_other	treatment_continuing_medications	Frequency - other
start_date	treatment_continuing_medications	Start Date
on_going	treatment_continuing_medications	On going
stop_date	treatment_continuing_medications	Stop Date
warning_the_selected_stop	treatment_continuing_medications	
iv_therapy	treatment_intermittent_pulse_administrations	IV therapy
iv_therapy_other	treatment_intermittent_pulse_administrations	IV therapy - other
iv_therapy_other_atc	treatment_intermittent_pulse_administrations	IV therapy - other, ATC
date_of_iv_therapy	treatment_intermittent_pulse_administrations	Date of IV therapy
dose_of_iv_therapy	treatment_intermittent_pulse_administrations	Dose of IV therapy
unit_of_dose	treatment_intermittent_pulse_administrations	Unit of dose
unit_of_dose_other	treatment_intermittent_pulse_administrations	Unit of dose - other
date_of_biopsy	biopsies	Date of biopsy
site_of_biopsy	biopsies	Site of biopsy
site_of_biopsy_other	biopsies	
general_findings	biopsies	General findings
size_of_vessel_involved	biopsies	Size of vessel involved
vessel_specific_findings	biopsies	Vessel specific findings
organ_specific_findings	biopsies	Organ specific findings (renal section below)
the_berden_classification	biopsies	
berden_score_renal_biopsy	biopsies	Berden score on renal biopsy
number_glomeruli_active	biopsies	
number_glomeruli_healed	biopsies	
number_normal_glomeruli	biopsies	
number_globally_sclerosed	biopsies	
total_number_glomeruli	biopsies	
acute_tubular_damage	biopsies	Acute tubular damage
tub_interstitial_fib_per	biopsies	
tub_interstitial_fib_est	biopsies	Tubulo-interstitial fibrosis estimation

tubulointerstitial_infiltr	biopsies		Tubulointerstitial infiltrate	
arteritis_arteriolitis	biopsies		Arteritis / arteriolitis	
pauci_immune	biopsies		Pauci-immune	
igg_deposits	biopsies		IgG deposits	
c3_deposits	biopsies		C3 deposits	
c4d_deposits	biopsies		C4d deposits	
date_general_imaging_test	general_imaging_and_other_investigations			
modality	general_imaging_and_other_investigations		Modality	
modality_other	general_imaging_and_other_investigations		Modality - other	
site_investigated_2	general_imaging_and_other_investigations		Site investigated	
general_findings_2	general_imaging_and_other_investigations		General findings	
specific_findings_2	general_imaging_and_other_investigations		Specific findings	
date_vascular_imaging_test	vascular_imaging			
vascular_imaging_modality	vascular_imaging		Vascular imaging modality	
vessels_imaged	vascular_imaging		Vessels imaged	
vessels_imaged_other_arter	vascular_imaging			
vessels_imaged_other_vein	vascular_imaging			
laterality	vascular_imaging		Laterality	
abnormal_findings	vascular_imaging		Abnormal findings	
abnormal_findings_other	vascular_imaging			
date_of_event_comp	complications		Date of event	
warning_complications	complications			
complications_type	complications		Complication type	
additional_ref_for_ctcae	complications			
infection_type	complications	Complications - Infection	Infection Type	
infection_type_snomed_ct	complications		Infection Type, snomed CT	
organism	complications		Organism (if known)	
organism_if_known_ido	complications		Organism (if known), snomedCT	BIOPORTAL:SNOMEDCT
infection_severity	complications		Infection severity	

infection_severity_2	complications		Infection severity, CTCAE	
leukopenia_severity_score	complications	Complications - Leukopenia	Leukopenia severity score	
leukop_severity_score_2	complications		Leukopenia severity score	1, 1 - Nadir WCC = 3.1-4x10^9/L | 2, 2 - Nadir WCC = 2.1-3x10^9/L | 3, 3 - Nadir WCC = 1.1-2x10^9/L | 4, 4 - Nadir WCC = < 1.1x10^9/L
thromboembolic_events_spec	complications	Complications - Thromboembolic events	Thromboembolic events specify	
other_adr_disease_complica	complications	Complications - Other ADR / disease complications	Other ADR / disease complications specify	
other_adr_dis_comp_meddra	complications		Other ADR / disease complications specify, MEDDRA	BIOPORTAL:MEDDRA
other_adverse_event_score	complications		Other adverse event score	
other_adv_event_score_2	complications		Other adverse event score, CTCAE	
steroid_associated_comp	complications	Complications - Steroid associated complication	Steroid associated complication - specify	
steroid_associated_comp_2	complications		Steroid associated complications	
steroid_assoc_comp_other	complications		Steroid associated complication - specify, other, MEDDRA	BIOPORTAL:MEDDRA
corticosteroid_complicatio	complications		Corticosteroid complications severity	
corticosteroid_comp_2	complications		Corticosteroid complications severity, CTCAE	
cardiovas_comp	complications	Complications - Cardiovascular complication	Cardiovascular complication - specify	
cardiovas_comp_other	complications		Cardiovascular complication - specify, other, MEDDRA	BIOPORTAL:MEDDRA
cardiovascular_complicatio	complications		Cardiovascular complications severity	
cardiovascular_comp_2	complications		Cardiovascular complications severity, CTCAE	
type_of_malignancy	complications	Complications - Malignancy	Type of malignancy, MEDDRA	BIOPORTAL:MEDDRA
malignancy_complications_s	complications		Malignancy complications severity	
malignancy_comp_serv_2	complications		Malignancy complications severity, CTCAE	
requiring_ivig	complications	Complications - Hypogammaglobulinaemia	Requiring IVIG	
nadir_igg	complications		Nadir IgG level (g/L)	

patient_id_encounters	encounters		Patient ID	
date_of_visit	encounters		Date Of Visit	
covid_19_related_entry	encounters		COVID-19 related entry?	
c19_relation_warning	encounters			
interval_from_diagnosis	encounters		Interval from diagnosis (months)	
hospital_site	encounters		Hospital Site	1, BEU - Beaumont | 2, SVH - St. Vincents Hospital | 3, SJH - St. James Hospital | 4, TUH - Tallaght | 5, GAL - UCH Galway | 6, CUH - Cork University Hospital | 7, LIM - Mid-West Reg. Hosp. Limerick | 8, MUH - Mater University Hospital | 9, PRA - Prague | 10, Other Hospital
other_hospital	encounters		Other Hospital	
type_of_visit	encounters		Type of Visit	
employment_status	encounters	Disease assessment - common	Employment status	1, Unknown | 2, Not working | 3, Disability benefit | 4, Employed full time | 5, Employed part time | 6, Retired | 7, Student
disease_activity_since_las	encounters		Disease activity since last return	1, Remission | 2, Active | 3, Low disease activity
uninalysis_done	encounters		Uninalysis Done	
uninalysis_protein	encounters		Uninalysis Protein	1, Negative | 2, +1 | 3, +2 | 4, >=+3
uninalysis_blood	encounters		Uninalysis Blood	1, Negative | 2, +1 | 3, +2 | 4, >=+3
esrd	encounters		ESRD (Permanent kidney failure requiring dialysis or transplant)	
dialysis_dependent	encounters		Dialysis dependent	

date_of_dialysis_start	encounters		Date of dialysis start	
date_of_dialysis_stop	encounters		Date of dialysis stop	
weight_kg	encounters		Weight (KG)	
please_fill_in_the_height	encounters			
bmi	encounters		BMI	[weight_kg]/([height_cms_known]*[height_cms_known]*0.0001)
clin_samples_obtained	encounters		Clinical samples obtained	1, EDTA for DNA | 2, EDTA for PBMC | 3, PAX gene tube for RNA | 4, Urine | 5, Serum | 6, Saliva for DNA | 7, Tissue | 8, Plasma exchange fluid | 9, EDTA for plasma | 10, none
patient_first_assessment	encounters	BVAS	Is this the patient's first assessment?	
general_features	encounters		General features	
general_features_yes	encounters		General features - yes	
cutaneous	encounters		Cutaneous	
cutaneous_yes	encounters		Cutaneous - yes	1, Infarct | 2, Purpura | 3, Ulcer | 4, Gangrene | 5, Other skin vasculitis
mucous_membranes_eyes	encounters		Mucous membranes / eyes	
mucous_membranes_eyes_yes	encounters		Mucous membranes / eyes - yes	1, Mouth ulcers | 2, Genital ulcers | 3, Adnexal inflammation | 4, Significant proptosis | 5, Scleritis / Episcleritis | 6, Conjunctivitis / Blepharitis / Keratitis | 7, Blurred vision | 8, Sudden visual loss | 9, Uveitis | 10, Retinal changes (vasculitis /thrombosis / exudate / haemorrhage)
ent	encounters		ENT	
ent_yes	encounters		<span style="background-color:	1, Bloody nasal discharge / crusts / ulcers / granulomata | 2, Paranasal sinus involvement | 3, Subglottic stenosis | 4, Conductive hearing loss | 5, Sensorineural hearing loss

		#ffcc00;">ENT - yes	
chest	encounters	Chest	
chest_yes	encounters	Chest - yes	1, Wheeze | 2, Nodules or cavities | 3, Pleural effusion / pleurisy | 4, Infiltrate | 5, Endobronchial involvement | 6, Massive haemoptysis / alveolar haemorrhage | 7, Respiratory failure
cardiovascular	encounters	Cardiovascular	
cardiovascular_yes	encounters	Cardiovascular - yes	1, Loss of pulses | 2, Valvular heart disease | 3, Pericarditis | 4, Ischaemic cardiac pain | 5, Cardiomyopathy | 6, Congestive cardiac failure
abdominal	encounters	Abdominal	
abdominal_yes	encounters	Abdominal - yes	1, Bloody diarrhoea | 2, Peritonitis | 3, Ischaemic abdominal pain
renal	encounters	Renal	
please_record_only_one_of	encounters		
renal_yes	encounters	Renal - yes	1, Hypertension | 2, Proteinuria >1+ | 3, Haematuria >= 10 RBCs/hpf | 4, Serum creatinine 125-249 >= uM/L | 5, Serum creatinine 250-499 >= uM/L | 6, Serum creatinine >= 500 uM/L | 7, Rise in serum creatinine >30% or fall in creatinine clearance >25%
nervous_system	encounters	Nervous system	
nervous_system_yes	encounters	Nervous system - yes	1, Headache | 2, Meningitis | 3, Organic confusion | 4, Seizures (not hypertensive) | 5, Cerebrovascular accident | 6, Spinal cord lesion | 7, Cranial nerve palsy | 8, Sensory peripheral neuropathy | 9, Mononeuritis multiplex
other_bvas	encounters	Other	
other_1_yes	encounters	Other 1 - yes	
other_2_yes	encounters	Other 2 - yes	
other_3_yes	encounters	Other 3 - yes	

other_4_yes	encounters		Other 4 - yes	
persistent_disease_only	encounters		PERSISTENT DISEASE ONLY: (Tick here if all the abnormalities are due to persistent disease)	1, Yes | 2, No
bvas_description_text	encounters			
bvas_score	encounters		BVAS score	
bvas_score_calculator	encounters		BVAS score (calculator)	
number_of_major_bvas_items	encounters		Number of major BVAS items	
number_of_minor_bvas_items	encounters		Number of minor BVAS items	
vasculitis_relapse	encounters	Disease assessment - Vasculitis	Do you think Vasculitis is relapsing in this encounter	1, High Probability | 2, Possibly | 3, Unknown | 4, No
adj_probability_relapse	encounters		Adjudicated probability of relapse	1, Definite | 2, High Probability | 3, Possible | 4, No
nature_of_confirmed_relaps	encounters		Nature of confirmed relapse	
nature_of_relapse_other	encounters			
diagnostic_biopsy	encounters		Diagnostic biopsy	
immunosup_med_2	encounters		Immunosuppressive status	1, Discontinuation of immunosuppression within 6 months prior to this encounter | 2, Discontinuation of immunosuppression > 6 months prior to this encounter | 3, Currently on immunosuppression | 4, Treatment Naïve
corticosteroids	encounters		Corticosteroids	
corticosteroid_dose	encounters		<span style="background-color:	1, < 5 mg/day | 2, 5 - 10 mg/day | 3, 11 - 20 mg/day | 4, > 20 mg/day

		#ffcc00;">Current corticosteroid dose Corticosteroids in response to this clinical encounter/episode	
corticosteroid_response	encounters		1, Increased | 2, No change | 3, Reduced | 4, Stopped | 5, Unknown
immunosup_med	encounters	Immunosuppressive medication Immunosuppressive medication in response to this encounter	1, Daily oral cyclophosphamide - UATC/LC01AA01 | 2, Mycophenolate mofetil - UATC/L04AA06 | 3, Azathioprine - UATC/L04AX01 | 4, Methotrexate - UATC/L01BA01 | 5, Leflunomide - UATC/L04AA13 | 8, IV Cyclophosphamide - UATC/L01AA01 | 9, Mabthera: Rituximab - UATC/L01XCO2 | 14, Truxima: Rituximab - UATC/L01XCO2 | 10, Ustekinumab - UATC/L04AC05 | 11, Tacrolimus (including Advagraf, Prograf, etc.) - UATC/L04AD02 | 12, Mepolizumab - UATC/R03DX09 | 13, Methotrexate - UATC/L01BA01 | 6, Other (ATC ontology) | 7, No
immunosupp_med_reponse	encounters		1, Immunosuppression increased | 2, No change in Immunosuppression | 3, Immunosuppression reduced | 4, Immunosuppression stopped | 5, Unknown
response_to_increased_immu	encounters	Response to increased immunosuppression	
immunosup_med_3	encounters	Additional Immunosuppressive medication Additional Immunosuppressive medication, other, ATC	1, Daily oral cyclophosphamide - UATC/LC01AA01 | 2, Mycophenolate mofetil - UATC/L04AA06 | 3, Azathioprine - UATC/L04AX01 | 4, Methotrexate - UATC/L01BA01 | 5, Leflunomide - UATC/L04AA13 | 8, IV Cyclophosphamide - UATC/L01AA01 | 9, Mabthera: Rituximab - UATC/L01XCO2 | 14, Truxima: Rituximab - UATC/L01XCO2 | 10, Ustekinumab - UATC/L04AC05 | 11, Tacrolimus (including Advagraf, Prograf, etc.) - UATC/L04AD02 | 12, Mepolizumab - UATC/R03DX09 | 13, Methotrexate - UATC/L01BA01 | 6, Other - ATC ontology | 7, No
immunosup_med_3_other	encounters		BIOPORTAL:ATC
immunosup_med_3_resp	encounters	Additional	

			Immunosuppressive medication in response to this encounter	
immunosup_med_4	encounters		Additional Immunosuppressive medication	1, Daily oral cyclophosphamide - UATC/LC01AA01 | 2, Mycophenolate mofetil - UATC/L04AA06 | 3, Azathioprine - UATC/L04AX01 | 4, Methotrexate - UATC/L01BA01 | 5, Leflunomide - UATC/L04AA13 | 8, IV Cyclophosphamide - UATC/L01AA01 | 9, Mabthera: Rituximab - UATC/L01XCO2 | 14, Truxima: Rituximab - UATC/L01XCO2 | 10, Ustekinumab - UATC/L04AC05 | 11, Tacrolimus (including Advagraf, Prograf, etc.) - UATC/L04AD02 | 12, Mepolizumab - UATC/R03DX09 | 13, Methotrexate - UATC/L01BA01 | 6, Other - ATC ontology | 7, No
immunosup_med_4_other	encounters		Additional Immunosuppressive medication, other, ATC	BIOPORTAL:ATC
immunosup_med_4_resp	encounters		Additional Immunosuppressive medication in response to this encounter	
immunosup_med_other	encounters			
immunosup_med_other_atc	encounters		Immunosuppressive medication - other, ATC	BIOPORTAL:ATC
treatment_naive	encounters			
prophylaxis	encounters		Prophylaxis	
anca_titre	encounters	Investigations summary in the context of a potential AAV relapse event	ANCA titre	
suggestive_bloods_or_urine	encounters		Suggestive bloods OR urine tests (excluding ANCA)	
suggestive_imaging	encounters		Suggestive imaging	
biochemistry	encounters	Investigations - Common	Biochemistry	
crp	encounters		CRP	
crp_relation_to_lab	encounters		CRP - relation to laboratory reference range?	
creatinine	encounters		Creatinine	

creatinine_relation_to_lab	encounters	Creatinine - relation to laboratory reference range?
egfr	encounters	eGFR if([creatinine] = "","",round(141 * (min([creatinine]*0.01131222*if([gender]='1',(1/0.9),(1/0.7)),1))^(if([gender]='1',-0.411,-0.329)) * (max([creatinine]*0.01131222*if([gender]='1',(1/0.9),(1/0.7)),1))^(-1.209) * (0.993)^(rounddown(datediff([date_of_birth],[date_of_visit],"y","mdy",true),0)) * if([gender]='2',1.018,1) * if([ethnicity]='5',1.159,1) * if([ethnicity]='6',1.159,1) * if([ethnicity]='7',1.159,1),0))
egfr_calculated	encounters	eGFR (calculated)
egfr_relation_to_lab	encounters	eGFR - relation to laboratory reference range?
urine_pcr_acr	encounters	Urine PCR / ACR mg/mmol
urine_pcr_acr_relation	encounters	Urine PCR / ACR - relation to laboratory reference range?
urine_creatinine	encounters	
hla_type	encounters	HLA type
ana	encounters	ANA
esr	encounters	ESR
esr_relation_to_lab	encounters	ESR - relation to laboratory reference range?
full_blood_count	encounters	
hb	encounters	Hb
hb_relation_to_lab	encounters	Hb - relation to laboratory reference range?
total_white_cell_count	encounters	Total white cell count x10^9/L
total_white_cell_count_lab	encounters	Total white cell count - relation to laboratory reference range?
neutrophil_count	encounters	Neutrophil count x10^9/L
neutrophil_count_lab	encounters	Neutrophil count - relation to laboratory reference range?
lymphocyte_count	encounters	Lymphocyte count x10^9/L
lymphocyte_count_lab	encounters	Lymphocyte count - relation to laboratory reference range?

neutrophil_lympho_ratio	encounters		Neutrophil / Lymphocyte ratio	[neutrophil_count]/[lymphocyte_count]
monocyte_count	encounters			
monocyte_count_lab	encounters		Monocyte count - relation to laboratory reference range?	
eosinophil_count	encounters			
eosinophil_lab	encounters		Eosinophil - relation to laboratory reference range?	
platelet_count	encounters		Platelet count x10^9/L	
platelet_count_lab	encounters		Platelet count - relation to laboratory reference range?	
absolute_cd19_count	encounters			
ast	encounters		AST	
ast_lab	encounters		AST - relation to laboratory reference range?	
haemoglobin_g_dl	encounters		Haemoglobin (g/dL)	
total_cholesterol	encounters			
total_cholesterol_lab	encounters		Total cholesterol - relation to laboratory reference range?	
anca_if_2	encounters	Investigations - Vasculitis	ANCA IF	1, Atypical | 2, C | 3, P | 4, Negative | 5, Not tested | 6, Pending
anti_pr3_level	encounters		Anti-PR3 level	
anti_pr3_level_lab	encounters		Anti-PR3 level - relation to laboratory reference range?	
anti_mpo_level	encounters		Anti-MPO level	
anti_mpo_level_lab	encounters		Anti-MPO level - relation to laboratory reference range?	
immunology	encounters		IMMUNOLOGY	
anti_gbm_antibody	encounters		Anti-GBM antibody	

anti_gbm_level	encounters		Anti-GBM Level
anti_gbm_method	encounters		Anti-GBM Method
anti_gbm_level_lab	encounters		Anti-GBM level - relation to laboratory reference range
igg	encounters		IgG g/dL
igg_lab	encounters		IgG - relation to laboratory reference range ?
iga	encounters		IgA g/dL
iga_lab	encounters		IgA - relation to laboratory reference range?
igm	encounters		IgM g/dL
igm_lab	encounters		IgM - relation to laboratory reference range?
complement_c3	encounters		Complement (C3)
complement_c3_lab	encounters		Complement (C3) - relation to laboratory reference range?
complement_c4	encounters		Complement (C4)
complement_c4_lab	encounters		Complement (C4) - relation to laboratory reference range
rheumatoid_factor	encounters		Rheumatoid factor
rheumatoid_factor_lab	encounters		Rheumatoid factor - relation to laboratory reference range?
hepatitis_b	encounters		Hepatitis B
hepatitis_c	encounters		Hepatitis C
eq_5d_level_used	encounters	EQ5D Results	EQ-5D Level Used
eq5d_exp	encounters		
mobility_level	encounters		5L Mobility Level
selfcare_level	encounters		5L Selfcare Level
usual_activities_level	encounters		
pain_discomfort_level	encounters		
anxiety_depression_level	encounters		
eq3d_exp	encounters		
mobility_level_2	encounters		3L Mobility Level
selfcare_level_2	encounters		3L Selfcare Level

usual_activities_level_2	encounters		
pain_discomfort_level_2	encounters		
anxiety_depression_level_2	encounters		
visual_analogue_health_sca	encounters		
urine_creatinine_2	encounters	Biomarkers	
scd163_serum_ng_ml	encounters		
urine_scd163_pg_ml_duoset	encounters		
urine_scd163_ng_mmmol_duos	encounters		
urine_scd163_ng_ml_duoset	encounters		
urine_scd163_ng_ml_euroimm	encounters		
urine_scd163_ng_mmmol_euro	encounters		
serum_il1_pg_ml	encounters		
urinary_calprotectin	encounters		
plasma_cd146_pg_ml	encounters		
urine_betaine_results	encounters		Urine Betaine Results
urine_betaine_normalised	encounters		Urine Betaine normalised
urine_citric_acid_results	encounters		
urine_citric_acid_normalis	encounters		
urine_creatinine_metabolom	encounters		Urine Creatinine (metabolomic)
urine_creatinine_normalise	encounters		Urine Creatinine normalised (metabolomic)
urine_dimethylglycine_resu	encounters		Urine Dimethylglycine Results
urine_dimethylglycine_norm	encounters		Urine Dimethylglycine normalised
urine_glutaric_acid_result	encounters		Urine Glutaric acid Results
urine_glutaric_acid_normal	encounters		Urine Glutaric acid normalised
urine_glycolic_acid_result	encounters		Urine Glycolic acid Results
urine_glycolic_acid_normal	encounters		Urine Glycolic acid normalised
urine_maltose_results	encounters		Urine Maltose Results
urine_maltose_normalised	encounters		Urine Maltose normalised
urine_myoinositol_results	encounters		

urine_myoinositol_normalis	encounters		
urine_n_phenylacetylglycin	encounters		Urine N-Phenylacetylglycine Results
urine_n_phenylacetylglycin_norm	encounters		Urine N-Phenylacetylglycine normalised
urine_oxoglutaric_acid_res	encounters		Urine Oxoglutaric acid Results
urine_oxoglutaric_acid_nor	encounters		Urine Oxoglutaric acid normalised
urine_succinate_results	encounters		
urine_succinate_normalised	encounters		
urine_tmao_results	encounters		Urine TMAO Results
urine_tmao_normalised	encounters		
serum_mpo_dna_elisa_value	encounters		
donor_type	renal_transplantations		Donor type
date_of_transplant	renal_transplantations		Date of transplant
maintenance_i_s	renal_transplantations		Maintenance I/S
maintenance_i_s_2	renal_transplantations		Maintenance I/S 2
rejection_episode	renal_transplantations		Rejection episode
date_of_rejection_episode	renal_transplantations		
graft_failure	renal_transplantations		Graft failure
date_of_graft_failure	renal_transplantations		Date of graft failure
reason_for_graft_failure	renal_transplantations		Reason for graft failure
reason_graft_failure_other	renal_transplantations		
name_of_physician	covid19	Reporter information	
name_of_centre	covid19		Name of centre providing care
name_of_centre_other	covid19		
completion_date	covid19		
c19_completion_date	covid19		
all_databases_shared	covid19		Please select all databases this form has been shared with
country_of_residence	covid19	Patient information (Part 1)	Country of residence
county_of_residence	covid19		County of residence

education	covid19		Education
e_cigarette_or_vape	covid19		E-cigarette or Vape use
eskd_covid	covid19	'Encounters' Data: Vasculitis/Disease status at time of C-19 diagnosis BVAS Medication (partial)	
date_of_end_stage_kidney_d	covid19		
vdi_score	covid19		VDI Score
type_of_renal_replacement	covid19		Type of Renal Replacement Therapy (RRT)
ace_i	covid19	Medication	Angiotensin-converting-enzyme inhibitor at C19 diagnosis (ACE-i)
arb	covid19		Angiotensin II receptor blocker at C19 diagnosis (ARB)
nsaid	covid19		Non-steroidal anti-inflammatory drug at C19 diagnosis (NSAID)
summary_table_encounters	covid19		
date_of_c_19_symptom_onset	covid19	COVID-19 Questions	
date_of_c_19_diagnosis	covid19		
interval_days_covid	covid19		Interval (days) between symptom onset and diagnosis
age_at_c_19_diagnosis_year	covid19		Age at C-19 diagnosis (years)
location_c_19_diagnosis	covid19		Location at which C-19 diagnosis was made
location_c_19_diag_other	covid19		
method_of_c_19_testing	covid19		Method of C-19 testing (select the most objective option)
method_of_c_19_testing_oth	covid19		
level_of_sars_cov_2_covid	covid19		
sars_cov_2_covid_19_igm	covid19		
sars_cov_2_covid_19_igg	covid19		
admission_to_hospital_requ	covid19		Admission to hospital required

date_of_admission	covid19		Date of admission	
admission_to_icu	covid19		Admission to Intensive Care Unit	
date_of_admission_icu	covid19			
interval_months_from_aav_d	covid19		Interval (months) from AAV diagnosis to C-19 diagnosis	
patient_symptoms_resolved	covid19		Have patient's symptoms resolved at time of this report?	
date_of_symptom_resolution	covid19		Date of symptom resolution (if known)	
interval_symptons_current	covid19		Interval (days) between symptom onset and symptom resolution OR current date (if symptoms persist)	
date_of_hospital_discharge	covid19			
length_of_stay_days	covid19		Length of stay (days)	
infection_acquisition	covid19		Infection Acquisition	
clinical_features_at_outse	covid19		Clinical features at outset (check all that apply)	
clinical_feat_out_other	covid19		Clinical features at outset, other (MEDDRA)	BIOPORTAL:MEDDRA
body_temperature	covid19			
creatinine_kinase	covid19	Lab values (Please enter the highest/peak recorded lab value for each field)		
d_dimer	covid19		D-dimer (mg/L)	
ferritin	covid19		Ferritin	
lactate	covid19		Lactate (mg/dL)	
prothrombin_time	covid19			
lactate_dehydrogenase	covid19			
troponin	covid19		Troponin	
troponin_unit	covid19		Troponin Unit	
radiological_evidence	covid19		Findings on chest imaging	
were_antibiotics_administe	covid19		Were antibiotics administered?	

treatment_admin_for_covid	covid19	Was treatment administered for C-19 infection (other than best supportive care)?	
treat_admin_covid_other	covid19	Was treatment administered for C-19 infection (other than best supportive care)? - other, ATC	BIOPORTAL:ATC
complications_covid	covid19	Complications / Disease Course (check all that apply)	
aki_selected	covid19		
complications_covid_other	covid19	Complications / Disease Course - other, MEDDRA	BIOPORTAL:MEDDRA
type_of_infection_in_addit	covid19	Secondary infection selected. Please indicate the type of infection	
type_of_infection_other	covid19	Type of Infection - other, snomedCT	
concom_respiratory_patho	covid19	Concomitant respiratory pathogens detected (select all that apply)	
organism_if_known	covid19	With regards to the secondary infection (if known), snomedCT	
c_19_outcome	covid19	C-19 Outcome (Select the highest level of support the patient received)	
date_of_death_covid	covid19	Date of death	
cause_of_death_covid	covid19	Cause of death, snomedCT	BIOPORTAL:SNOMEDCT
may_we_contact_you_to_get	covid19		
lessons_aspects	covid19		