Site Profile Services

Providing external partners with early, clear insight into all services facilitated within UMC Utrecht, fostering effective collaboration from the very start

University Medical Center Utrecht

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1. Introduction Site Profile Services

Welcome to UMC Utrecht, where world-leading science meets exceptional patient care. We appreciate your interest in collaborating with us and exploring opportunities within our clinical research ecosystem.

At UMC Utrecht, our mission is clear: together, we shape a future where better health is within reach for everyone. By advancing scientific discovery and translating innovation into clinical practice, we contribute to the healthcare of tomorrow.

Strong partnerships are essential to impactful clinical research. In every collaboration, we aim to combine scientific excellence with efficient, transparent, and predictable study start-up processes.

This *Site Profile Services document* has been developed to provide you with a clear and comprehensive overview of the facilities, capabilities, and services available at UMC Utrecht. It reflects our commitment to working in a structured, transparent, and standardized way, enabling efficient study execution and fostering effective collaboration from the very start.

Why this is important:

- Sponsors receive faster, clear, and uniform information on our services and on the set-up and conduct of studies
- We reduce the burden on internal study teams by limiting the number of questions in feasibility questionnaires, based on frequently asked service-related questions about our hospital
- It makes the feasibility process more efficient, consistent, and practical

We are committed to continuous improvement and close collaboration with our partners. By aligning early and working efficiently together, we aim to accelerate study start-up and strengthen the clinical research ecosystem.

Should you have any questions regarding this document or our services, please do not hesitate to contact us at ResearchQuality@umcutrecht.nl. For study-specific enquiries, we kindly refer you to the local Principal Investigator (PI) or the designated UMC Utrecht study team.

In addition to the *Site Profile: Services at UMC Utrecht*, the *Working Together: Guideline for Sponsors Collaborating with UMC Utrecht as a Study Site* outlines our institution-wide procedures and policies. Both documents complement each other.

We look forward to partnering with you to advance innovative clinical research and improve the lives of patients worldwide.

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2. UMC Utrecht – Contact Information

University Medical Center Utrecht – UMC Utrecht
Heidelberglaan 100, 3584 CX Utrecht
+31 88 755 5555

Site Organization Management Services number (OMS):
ORG-100008351
Type of institution where studies will be performed:
University Hospital

3. Quality Manual Research

UMC Utrecht maintains a quality manual that ensures scientific research is conducted in accordance with applicable laws and regulations (e.g. ICH-GCP) and UMC Utrecht-specific policy.

4. Timelines – Study Start-Up, CDA, CTA, Budget

The expected timeline to obtain full study approval at our site, starting from receipt of the VGO, final protocol and all essential study documents (including draft manuals and guidelines), is approximately 12–15 weeks when the Dutch Clinical Research Foundation (DCRF) procedures are followed. Throughout the review process, the sponsor keeps UMC Utrecht informed of any changes that may affect local feasibility. Otherwise, the process may take longer.

- **CDA**
  We sign the Confidentiality Disclosure Agreement (CDA) after approval of the legal team. Research contracts are first reviewed by our contact person for Legal Affairs. If our template is used, then we can sign quickly. If your template is used, in some cases, it needs to be reviewed by our lawyer, this can take 14 days. In some cases, CDAs can be reviewed more quickly. If you frequently collaborate with UMC Utrecht, please verify whether a Master Confidentiality Disclosure Agreement (Master CDA) is already in place with your organization.

- **Contract and Budget Negotiations**
  To ensure that budget negotiations run smoothly and efficiently, we use a hospital-wide standardized budget tool based on grant plan. This significantly streamlines the process and facilitates alignment between all parties. Budget discussions can proceed in parallel with the regulatory and ethical review process, helping to accelerate overall study start-up timelines. Legal review of the Clinical Trial Agreement (CTA) takes approximately 2 weeks, and signature collection an additional 1–2 weeks. Timelines may also vary depending on the sponsor.
  We require the use of the national CTA template to avoid unnecessary delays. For sponsors outside the EEA, if there is no adequacy decision for the country, and the sponsor is not in the EU-US Data privacy framework, then Standard Contractual Clauses (SCCs) must be included in the CTA.

5. Pathology

Our institution has the capability to ship samples.

Tissue slides or blocks

- Ability to handle and process biopsies (biopsies are received from clinical departments and are not performed on-site at the pathology department).

- Ability to perform histopathological evaluation.
- Ability to prepare formalin-fixed, paraffin-embedded (FFPE) tissue blocks from fresh tissue.
- Ability to prepare FFPE tissue sections (slides) from fresh tissue blocks.
- Ability to process flash-frozen tissue samples (availability of a calibrated thermometer for -70°C/-80°C storage).
- Up to 20 slides can be shipped per case.
- If an FFPE block is generated for the trial, the block can be sent. For archival FFPE material, only unstained slides can be provided. The number of available slides depends on the remaining tissue, typically 15–20 slides.
- Turnaround time for retrieval of tissue blocks is usually approximately 5–7 days. If archival material must be retrieved from external hospitals, this timeline may not always be feasible.
- All material is processed and assessed according to standard pathology guidelines.
- Access to pathology reports is available.

6. The UMC Utrecht Laboratory Test Directory

The UMC Utrecht Laboratory Test Directory (Bepalingenwijzer) provides an overview of the laboratory tests covered by our laboratories. Detailed information on individual laboratory tests, including relevant requirements and procedures, can be found in the Laboratory Test Directory. The laboratories included in the Laboratory Test Directory are:

- Central Diagnostic Laboratory
- Genetics – Genomic Diagnostics
- Genetics – Metabolic Diagnostics
- Medical Microbiology

7. Central Biobank UMC Utrecht

Short summary

The Central Biobank was established to collect, process, and store human biological material—such as blood and tissue—for future medical research. This material is essential for understanding the genetic, biochemical, and cellular processes underlying diseases.

Samples may come from diagnostic procedures, treatments, or specific research studies, always with patient consent. By preserving this material, we enable groundbreaking research that would otherwise not be possible.

The Biobank operates under strict ethical and quality standards, including ISO 9001 certification, and follows the UMC Utrecht Biobank Framework Regulations. Material is only distributed after approval by the independent Biobank Review Committee (TCBio).

Researchers can request access through collaboration with UMC Utrecht and via our biobank management system, OpenSpecimen.

Central Biobank

For medical scientific research, patient-derived biological material is essential—such as blood or tissue samples. The aim of this research is to gain deeper insight into the genetic, biochemical, and cellular processes underlying diseases. Without this material, such research would not be possible.

Sometimes, biological material is collected from specific patient groups without knowing in advance which research project it will be used for. Patients always provide consent for this. Material that remains after diagnostic tests or medical treatments can also be highly valuable for future research. This leftover material may be stored for later use in medical scientific studies. Additionally, material remaining from a specific medical research study (subject to WMO regulations) can be preserved for future research if the participant has given consent.

The Central Biobank at UMC Utrecht was established to collect human biological material intended for future scientific research, process it if necessary, store it under controlled conditions, manage it, and make it available for specific medical research projects. Material is only stored and distributed after approval by an independent committee—the Biobank Review Committee (TCBio)—which ensures compliance with the Biobank Framework Regulations set by UMC Utrecht. These regulations specify what patients must be informed about, what consent is required, and the standards future research must meet.

Access for External Researchers
External researchers can request material from the Central Biobank through collaboration with a UMC Utrecht researcher. Responsibility for the material remains with the UMC Utrecht researcher.

ISO 9001 Certification
The Central Biobank (CBB) aims to provide uniform, high-quality storage and integrated management of all collections (sub-biobanks) of human biological material and associated data. To achieve this, the CBB has implemented a quality system describing and enforcing all processes. To demonstrate compliance with state-of-the-art standards, the CBB applied for ISO 9001 certification and has been certified since April 20, 2015.

Setting Up a Sub-Biobank
Before submitting a sub-biobank for review by TCBio or METC, contact the CBB. The CBB will assess the design, logistics, and execution (e.g., use of a Preferred Partner) and verify compliance with the Framework Regulations. If approved, an Agreement Form will be completed and signed by both parties and submitted with the review dossier.

Processing Biological Material
Before storage, material often requires processing. Preferred Partners are strongly recommended for these steps, as they follow CBB protocols and quality standards. Depending on the material type, different Preferred Partners may be involved. Deviations are possible only in consultation with the CBB. Early engagement with a Preferred Partner can save time after committee approval.

Coding of Biological Material
Before processing begins, material is registered in OpenSpecimen under the sub-biobank name. OpenSpecimen generates a unique code (e.g., Q23_123456), which is used throughout processing and linked to a secure key field (usually the patient number). Final products, such as serum tubes, are labeled with this code, material type, and tube number, ensuring that researchers cannot trace samples back to individual patients, in compliance with the Framework Regulations.

Storage
Processed material is stored under CBB management in designated conditions, typically in -80°C freezers or liquid nitrogen tanks. In some cases, temporary storage at a Preferred Partner may be arranged. The CBB ensures proper conditions, monitors compliance, and has emergency procedures in place.

Distribution
Before material can be distributed, researchers must confirm under which approval (METC or TCBio) this is permitted. Three scenarios apply:

1. Sub-biobank material: Requires TCBio approval.

2. Material from a WMO-regulated study used for its original purpose: Covered by the original METC approval; no additional review needed.

3. Leftover material from a WMO-regulated study for other research: Requires TCBio approval.

In exceptional cases, material may be requested for diagnostic purposes when no alternative is available; no additional review is required.

Requests are submitted via OpenSpecimen. Access can be requested via biobank@umcutrecht.nl. A basic account provides read-only access; an extended account is required for material requests.

8. Cleanrooms/immunotherapy

CAR T product can be received from Monday-Friday
Apheresis can take place from Monday-Friday.

The cell therapy facility of the Pharmacy has six class B cleanrooms where ATMPs can be manufactured.

If further information is required regarding feasibility, please contact the trial department of the Pharmacy at kgo-opstartstudie@umcutrecht.nl.

9. ICAT – Shared open innovation lab (PlusUltra Utrecht)

Cell expansion platforms (bioreactors)

- CliniMACS® Prodigy Platform Miltenyi Biotec
- CliniMACS® Electroporator
- Scale-X hydro Univercells Tecnology
- Biostat RM – Wave-Mixed Bioreactor Sartorius
- Osilaris Scinus Cell Expansion

Multi-technology biofabrication platforms

- ExplorerOne (extrusion) Biomotion
- R-GEN 200 (extrusion incl EHD) RegenHU
- Xell (Xolography) Xolo
- X1E Combo printer (FDM technology) Bambu Lab
- Form 4B (SLA technology) FormLabs

Advanced Microscopy

- EVOS M5000 (four-color fluorescence, transmitted-light, and color imaging) Invitrogen
- M205 C (Encoded Stereo Microscopes) Leica
- Axio Imager M2 (Open Microscope System) Zeiss
- Primovert (inverted microscope) Zeiss

Histology

- Embedding station MPS P II Slee Medical
- MTP Carousel tissue processor Slee Medical

- Semi-automatic precision microtome Slee Medical
- Auto-lader cassette printer Slee Medical
- Microscope slide printer Slee Medical

Biomaterial analysis
- Dynamic Mechanical Analyzer DMA850 TA Instruments
- Discovery Hybrid Rheometer HR20 TA Instruments
- OsteoChondral Platform LifeTec Group

Cell analysis (QC equipment)
- FACSLyric BD
- Countess 3 Invitrogen
- Nucleocounter NC-202 Chemometec
- Ella Auotmated ELISA platform Bio-Techne
- Microplate Reader CLARIOstar Plus BMG Labtech
- Digital PCR System QIAcuity Qiagen

General equipment

Cell Culture
- LAF hoods: ML-1 and ML-2
- Autoclave
- Water baths
- Incubators
- Glucose monitor
- Bio-welder / Sealer
- Bright-field microscopes

Other
- -150°C freezer
- -80°C freezers
- -20°C freezers
- Fridges
- Fume hoods
- Cooling centrifuges
- Microcentrifuges
- Analytical balances
- Syringe pumps
- Ice machine
- Milli-Q® water system
- Ovens
- Microwave
- Roller mixer
- (Magnetic) stirrers
- Shakers
- pH meters
- UV-lamps
- Vortex
- Sonication bath
- Lyophilizer (freeze dryer)

10. Innovation Center for Advanced Therapies (ICAT) services

https://www.icat-utrecht.nl/

Shared open innovation labs

- Memberships: we offer a variety of membership plans with pricing tailored to the intended use (General Lab, ML-1 and/or ML-2), including access to flexible desk space in a shared office setting
- Equipment rentals: We offer access to a wide range of laboratory equipment and specialized instruments through hourly rental, with equipment-specific training and user support to ensure safe and efficient use
- Education and networking events

GMP simulation services (contract research and consultancy services) for Advanced Therapy Medicinal Products (ATMPs)

GMPsim closely mimics the GMP environment to enable early identification of challenges, optimization of production workflows, and accelerated clinical translation of ATMPs.

- Process and QC development, optimization and validation
- GMP Gap analysis and risk assessment
- CMC dossier: A regulatory document that provides detailed information on a drug's chemistry, manufacturing process, quality controls, and stability
- Target Product Profile (TPP)
- Quality Target Product Profile (QTPP)
- Clinical trial dossier: IMPD, IB, clinical protocol
- Contact with regulatory bodies (CBG, EMA)
- Health Technology Assessment (HTA): supports the evaluation of the clinical and economic value of ATMPs, helping developers generate evidence for reimbursement, market access, and adoption. Through ICAT, HTA expertise for ATMPs is provided in collaboration with the Department of Epidemiology & Health Economics at the Julius Center (UMC Utrecht)

Viral vector development

- ICAT offers services for viral vector development, covering both upstream processing (USP) and downstream processing (DSP) for ex vivo and in vivo applications

GMP production (Cell Therapy Facility of Pharmacy)

- ATMP manufacturing in academia

11. Pharmacy

The Clinical Trial Department of the Pharmacy at UMC Utrecht can support various clinical trials:

- All 4 phases of drug research: Phase 1 to 4 clinical trials
- Studies with small molecule drugs, as well as monoclonal antibodies and ATMPs (gene and cell therapy).
- Labeling operations of investigational medicinal products (IMP's) (GMP manufacturing license)
- Preparation for administration (VTGM: voor toediening gereed maken) of IMPs
- Production of ATMPs (GMP manufacturing license)
- Development and production of IMPs in collaboration with Apotheek A15

The Clinical Trial Department of the Pharmacy has allocated storage space for storing IMPs at room temperature, 2-8°C, -20°C and -80°C, and liquid nitrogen and in the Cell Therapy Facility (CTF) in biostats.
The production department of the pharmacy can prepare investigational medicinal products for administration. Preparation can be performed using aseptic technique in class B cleanrooms under laminar flow hoods of biosafety cabinet (class A background environment).
The CTF is also part of the Pharmacy. In the ML-II manufacturing unit of the CTF, ATMPs (e.g. cell-based products, GMOs) are produced and prepared for administration. In addition, the development and production of ATMPs can also take place here.

If further information is required regarding feasibility, please contact the trial department of the Pharmacy at kgo-opstartstudie@umcutrecht.nl.

12. Radio pharmacy

The Radio pharmacy Department of UMC Utrecht supports various clinical trials and research activities involving radiopharmaceuticals and radioactive samples, including:

- Facilitating radioactive drug studies (phase I-IV)
- Preparation for administration (VTGM) of radiopharmaceuticals
- Production of Tc-99m-, Gallium-68 and Lutetium-177 based tracers
- Storage of radioactive samples at room temperature, 2–8°C, -20°C and -80°C
- Radioactive blood and urine PK sample counting using a gamma counter

The department provides facilities and expertise for the safe handling, preparation, storage and analysis of radioactive compounds and biological samples in compliance with applicable safety and quality standards.
Further information regarding feasibility and service can be obtained by contacting the trial office of the Radiopharmacy Department at rna-trial@umcutrecht.nl.

13. Cardiology

Available facilities and capabilities

- Holter device can be used, also for multiple days
- ECGs can be performed, pseudonymized and printed
- Calibrated 12-lead ECG machine available
- Fully equipped emergency trolley available
- Crash cart including oxygen and defibrillator available
- CPET
- Cardiac MRI
- TTE (echo) with and without strain, and MUGA

There are a few things we are unable to perform or calculate

- Triplicate ECGs with rest periods in between.
- QTcF for cardiac function, although sometimes investigators do this themselves.
- Standard Operating Procedures (SOPs) for ECGs are implemented within the Cardiology Diagnostics Department, and study-specific requirements that deviate from these SOPs cannot be accommodated.

Open questions

- Will own Holter devices and/or ECG be used or those provided by the sponsor?

14. Lung function

- Pulmonary Function Test (PFT)
- Pulse oximeter
- Spirometry
- Flow-volume measurement
- Diffusion capacity (DLCO)
- Body plethysmography

15. Available medical equipment

There are potential uses for medical equipment, such as:

- Calibrated weight measurement device (scale)
- Height measurement device (stadiometer)
- Calibrated thermometer for body temperature
- Calibrated manometer and adult blood pressure cuff
- Calibrated infusion pump
- Overnight stay/admission facilities

Note: Compatibility of the IP with common infusion materials is under review; this can be further discussed during the selection interview.

16. Maintenance medical electrical equipment

Maintenance of study specific medical electrical equipment can be arranged through the department of Medical Technology and Clinical Physics (MTKF) on a case-by-case basis. Either by training of UMC Utrecht personnel, or the manufacturer's personnel can be granted access to our facilities. either way with the proper contracts must be established. This can be identified through the Introduction Procedure.

17. Local introduction equipment and medical devices

All equipment and medical devices used in clinical investigations within the UMC Utrecht must be introduced into the hospital following the "introduction procedure" for research. This includes activities such as regulatory status check, risk assessment, local implementation and maintenance needs, and technical inspection. Consider that this process will take six to eight weeks to complete. The local investigator must initiate this with their division's quality coordinator (*kwaliteitscoordinator*) and is responsible for its completion.

18. Imaging

- Magnetic Resonance Imaging scanner (MRI)
    - magnetic resonance angiography (MRA)
    - magnetic resonance spectroscopy (MRS)
    - Cardiac MRI
- Computed Tomography scanner (CT)

    - HRCT
    - CTA
- PET CT
- SPECT CT / moleculair imaging
    - MUGA
    - Bone scan
- X-Ray (rontgen)
- Mammogram
- DXA
- Ultrasound
- Interventional angiography
    - Radio embolization
    - Imaging guided biopsies (ultrasound or CT guided)

eUploading scans: Site is capable of uploading scans to sponsor designated central imaging centers where all scans are being collected.

19. Ophthalmologist assessments

An ophthalmologist may be contacted at baseline and as needed to perform the following eye assessments:

- Best Corrected Visual Acuity (BCVA) testing
- Slit lamp examination
- Dilated funduscopic examination
- Spectral-Domain Optical Coherence Tomography (SD-OCT)
- Optic nerve and macula imaging, and wide-field retinal imaging

Withdrawal follow-up is possible, provided that consent is obtained.

20. Source documentation

Paper and electronic. Our site is capable of using Electronic Data Capture (EDC) systems.
The Electronic Health Records (EHR) system has controlled and restricted access.
CRA and auditor be granted access to the EHR to perform source data verification.

EMR system

- Restricted access to the system for non-employees/ Protection from unauthorized access
- Unique username & password for site staff with edit access
- Audit Trail (when & who did the change, the action done, the old & new data values
- Data backup & recovery process in place
- Written procedure for the use of the EHR system
- The system meets the necessary standards for data integrity, traceability, and security. The eSRA document and accompanying statement can be requested. Monitor read-only access to the system with unique username & password and restricted to study subjects

Additional Electronic Systems for Clinical Trial Conduct

We have the capability to work with clinical trial conduct:

- Electronic diaries
- ePRO (Electronic Patient Reported Outcome)
- IWRS (Interactive Web Response System)
- Site has previous experience with studies utilizing ePRO devices

Considerations e-consent
Electronic informed consent (e-consent) is legally permitted in the Netherlands.

When you want to implement e-consent:

- Follow the CCMO's guidelines on electronic consent (only available in Dutch)
- Inform local study team during the site suitablity fase (VGO). They consult with the privacy officer at an early stage to determine whether the proposed tool and procedure are in line with UMC Utrecht's privacy policy.

Other notes
No restrictions at site that prevent the use of portals or web-based applications (e.g., Central Lab Vendor – Lab data queries, acknowledgement and receipt of Investigator safety notifications).