This document is a **draft** for input from cluster pre-project steering board members at the 2026-03-04 meeting.

Excellence clusters for groundbreaking technologies - Breakthrough Technologies in Molecular Life Science to Power Precision Medicine and the Future of Healthcare in Sweden

The proposal is a national initiative to drive fast and continuous translation of **breakthrough technologies and AI-powered data analysis from molecular life science towards clinical use** to enable excellent clinical research and efficient, responsible **uptake of precision medicine** innovations into Sweden's healthcare system.

The proposal brings together Sweden's universities and university hospitals while actively integrating Sweden's broader innovation ecosystem spanning industry, SMEs, incubators, investors, and public sector stakeholders, while building on the national capabilities of SciLifeLab in cutting-edge technology and data-driven life science. The cluster will connect technology development, clinical research, and the innovation ecosystem into a continuous translational pipeline to de-risk precision medicine and precision diagnostics approaches, and attract industry-sponsored trials and investments to Sweden.

This document describes the tasks needed to reach the six key objectives that define **what** this initiative aims to achieve, as proposed in the original cluster application. The purpose here is to address each key objective and outline conceptually **how** the objective can be reached. The social sciences and humanities research and communications aspects will be detailed at a later stage.

Key objective 1. Establish complementary molecular medicine units at the seven universities and university hospitals, jointly operated with SciLifeLab

To establish Sweden as a global leader in next-generation healthcare and precision medicine by 2035, the excellence cluster "**Breakthrough Technologies in Molecular Life Science**" will implement a national technology and data infrastructure that bridges the gap between state-of-the-art biotechnology research and clinical care. This infrastructure will provide clinical research with cutting edge, tailored technologies and robust tools for integrating molecular and clinical data, thereby accelerating the transition toward AI-driven, transformative healthcare. Together, these efforts will create a world-class ecosystem that delivers patient benefit, supports nationwide implementation, and drives long-term innovation. Being a specialized testbed for co-creation, the cluster will foster clinical implementation, de-risk technology-based innovations, promote spin-offs, and attract significant global investment into the Swedish life science ecosystem.

Implementation centers on establishing core functional units as early adopter nodes across Sweden, where technology experts and clinicians work side-by-side to drive specific precision medicine moonshots. These moonshots will be disease-specific and include e.g. AI-driven diagnosis and treatment response for cancer, risk stratification for cardiovascular disease, real-time diagnostic data flows for emergency medicine, and multi-omics integration to accelerate diagnosis for rare diseases. Once established, these models for clinical adoption will be shared nationwide, ensuring that all national nodes benefit from these breakthroughs and provide equitable access to transformative care for patients regardless of their geographical location.

Task 1.1. Establish joint molecular medicine units: Create joint molecular medicine units that allow colocation of technology and data experts, diagnostic labs, translational researchers and clinicians to work side-by-side.

Task 1.2. **Capability for advanced sample handling:** Provide the capability for advanced sample handling and pre-analytical processing; establish capabilities typically not found in the healthcare environment, but which are required for successful application of advanced molecular analyses

Task 1.3. Access to developed infrastructure services: Provide the infrastructure services for clinical research projects and large national cohort studies such as SCAPIS, U-CAN etc.

Task 1.4. Structured process for transition from research to diagnostic settings: Provide a structured process for technology transition from research use in academic

setting to diagnostic use within healthcare, including critical aspects such as sample handling and method adaptation, robustness and quality assurance, proof-of-concept studies and clinical implementation studies.

Key objective 2. Develop joint secure data environment to integrate clinical and molecular data at scale

To define the regulatory and technical requirements for a national, federated, and AI-ready data environment that integrates molecular and clinical data at scale, the aim is to ensure AI readiness of the data produced in the infrastructure units (see objective 1), featuring automated de-identification and transformation of sensitive data for trustworthy and integrity-preserving AI model development to empower medical research and future clinical decision making within a secure space without exposing raw sensitive data.

A core component of the data infrastructure will be a comprehensive mapping of the regulatory framework to ensure that all technical solutions are inherently compliant with GDPR, the AI Act, the European Health Data Space (EHDS), and Swedish legislation. This work will also inform policy recommendations to strengthen the national regulatory framework and harmonize its implementation. The resulting regulatory Roadmap will identify concrete measures for legislative modernization, including, for example, a shift from the current "Opt-in" to informed “Opt-out” models for data consent, which is essential to unlock the full potential of real-time clinical data for decision-making. In parallel, the cluster will collaborate closely with the relevant authorities and regional and national stakeholders to promote the development of an integrated national system for clinical data aggregation and reuse. Such a system is critical to enable AI-driven clinical decision support and improve care quality, especially for patients in rural areas and those with rare or complex diseases.

Task 2.1. Requirement Analysis and Architectural Design: Design a federated data infrastructure where data remains at the source (node) while metadata is nationally aggregated and shared for discovery. **Deliverable:** Architectural data infrastructure design, development and testing of a secure processing environment (SPE).

Task 2.2. Technical Pipeline Specifications: for data standardization through automated ETL (Extract, Transform, Load) pipelines to convert clinical data into machine-readable standards including OMOP CDM and OpenEHR. We will also aim to enable the automatic and secure integration of patient-generated data (wearables/PROMs) into the clinical decision flow where useful. **Deliverable:** Technical specification and development of tools for de-identification and data transformation as well as data gateway API specification.

Task 2.3. Regulatory & Legislative Roadmap: Define a legal path for integrating EHR data with molecular data, including proposals for national metadata aggregation and "Opt-out" legislation. Our aim is to create a draft of a coordinated legal interpretation to resolve conflicting regional interpretations of the relevant legislation. This as a basis to establish a national function (task 2.4). **Deliverable**: Legal compliance and legislative roadmap and change report.

Task 2.4. Federated Infrastructure Strategy: A federated governance model establishes the rules for who can access what data, how permits are granted, and how data standards and interoperability are maintained across the network. This is established through the Health Data Access Body (HDAB) in the European Health Data Space regulation. Here we aim, together with the relevant authorities, to define a clear 1-1-1 national model with 1) national body responsible for technical standards, metadata repository and ensures nodes produce harmonized datasets 2) the authorization body that provides permits for access and ensures legal interpretation are consistent across healthcare regions and 3) a collaborative body that connects researchers, clinicians and industry to the data nodes **Deliverable:** Federated data governance model.

Key objective 3. Develop AI-driven data analysis and provide decision support tools to use molecular insights in clinical practice

To develop the data infrastructure required to support AI-driven multimodal data analysis and clinical decision support (CDS) tools, the SPE blueprint of task 2.1 must support high-volume emergent data types including for example spatial biology, proteomics, and high-resolution imaging. To leap-frog development, we will initially define specific clinical use cases, aligned with the complementary precision medicine moonshots of the molecular medicine units in objective 1. Examples could be 1) Cancer to support Molecular Tumor Boards (MTB) by enable future AI-driven diagnosis and treatment response predictions 2) Cardiovascular Disease (CVD) to utilize existing datasets like SCAPIS for future AI-based risk stratification and 3) Emergency Medicine to support developing real-time data flows for rapid diagnostic support in acute settings. 4) Rare Disease to enable AI-assisted integration of genomic, proteomic and clinical phenotyping data to accelerate diagnosis and guide personalised treatment decisions for patients with rare and complex conditions.The use cases will ensure clinically relevant expert-oriented development of breakthrough tools for the AI era.

Task 3.1. AI Tool Gap Analysis: Perform an inventory of existing tools and define the technical and data quality requirements for multimodal AI applications for the defined use cases. **Deliverable:** AI infrastructure gap analysis report.

Task 3.2. Clinical Decision Support **Prototyping:** Develop the secure compute environment required for AI-assisted clinical decision-making of the future . **Deliverable:** Prototype design for AI-assisted clinical decision support tool(s).

Task 3.3. Multimodal Data Linkage: Define and FAIR-aligned data provenance standards to ensure traceable linkage between patient samples and longitudinal clinical outcomes. **Deliverable**: Roadmap for multimodal data integration.

Task 3.4. Validation Framework (TEF-Health): Define criteria for testing AI tools in an environment ensuring trustworthiness. **Deliverable:** Pilot validation and clinical implementation protocol.

Key objective 4. Scale technology innovation through co-creation with industry, support and enable creation of spin-offs and commercial partnerships

A central pillar is to establish a co-creation environment with industry designed to align the “healthcare pull” with the "technology push" from research. Within this environment, the cluster implements a structured process to select, test, and de-risk high-potential technologies and provide a test bed for industry and healthcare to evaluate new technologies and drive early clinical adaptation. Together with existing innovation systems and collaboration models, the cluster promotes new business models for co-creation in a healthcare setting. Each node will serve as an entry point for cross-sector collaboration, national matchmaking, key opinion leaders and innovation funders. The approach enables academic spin-offs and start-ups, reduces investor risk and provides competitiveness through generation of unique data, thereby attracting both capital and global industry partners, which will benefit the entire Swedish healthcare system.

Task 4.1 Structured collaboration models for co-creation: This multi-partner cluster including the national established innovation systems will establish frameworks for multi-stakeholder collaborations for industry-universities-university hospitals. Diverse collaboration models will be adapted for the different industry stakeholders *e.g.* spinouts, SME, pharma or infrastructure technology providers and adapted to the breakthrough technology at hand. The collaboration models will address agreements, rules of engagement, costs sharing models, ownership, cost of developed goods, business model for co-creation and co-funding and leveraging EU-funded initiatives. A sub-task will be to define some initial areas for collaboration of common interest for industry – academia – healthcare. **Deliverable**: A strategy framework and report for industry collaborations.

Task 4.2. Process for strategic selection: With the basis in clinical needs, a stepwise process for strategic selection of co-creation activities will be established. Criteria will include e.g. scientific evidence, clinical need (pull) and potential application(s), maturity (technology-readiness levels 5-9). **Deliverable**: Transparent and clear governance structure for strategic selection of co-creation activities.

Task 4.3. Create structured paths with innovation support along the translational journey: The units will form strong connections and synergize with existing national innovation support stakeholders in the academic, healthcare and private sector. **Deliverable**: Roadmap for innovations support strongly connected with established stakeholders.

Task 4.4. Regulatory support expert function: In order to test and scale methods and support innovations emerging from the units, regulatory competence (e.g. IVDR, MDR, AI Act) and legislation expertise (university-hospital-external stakeholder) will be needed. We will build on and leverage experience from the cluster partners and authorities such as the Swedish Medicinal Products Agency. **Deliverable**: Established expert function within the cluster. Key persons identified.

Key objective 5. Create new technology-based precision medicine infrastructure for **clinical trials** to improve patient stratification and provide new explorative endpoints

The cluster will establish a next-generation, technology-enabled infrastructure for clinical studies and trials and provide a comprehensive toolbox for integrating multi-omics and advanced data analytics. The full spectrum of clinical studies will be supported, from exploratory academic trials to industry-sponsored and registration-enabling clinical trials, enabling a continuous translation pipeline from discovery to clinical implementation.

By facilitating early access to emerging technologies and generating high-quality data, the cluster will accelerate biomarker discovery, disease stratification, and exploratory endpoints. By integrating unique patient datasets and creating strong synergies across the seven nodes, Sweden's capacity to attract, conduct, and lead clinical trials will be significantly strengthened.

The cluster will enable systematic de-risking of new biomarkers and technologies while strengthening Sweden's attractiveness for industry-sponsored precision medicine trials. Building on and complementing existing clinical trial infrastructures, the cluster will develop solutions that are readily implementable in diagnostic laboratory settings, ensuring regulatory compliance and facilitating seamless clinical translation.

Ultimately, this integrated framework will enable more precise patient stratification, more efficient clinical trial design, and improved clinical decision-making.

Task 5.1 National sample handling and ID and meta data logistics: By unifying sample handling, ID, and meta data standards, the offering for clinical trials is strengthened, ensuring quality, interoperability, and scalability required for multi-site and industry-sponsored clinical studies. Legal and ethical aspects need to be considered in the process. Connects with Objective 2 (Task 2.4) & 3 (Task 3.3) relating to data standards. **Deliverable**: System for national sample and data handling for both academic and healthcare.

Task 5.2 Process- and business-models for multi-omics in clinical trials/studies: How to collect and integrate multi-omics data for explorative endpoints in a systematic and defined manner to provide enhanced patient profiles and disease trajectories. This includes “FOCU•SE explore” and similar processes beyond drug repurposing and genomics, applicable in both exploratory academic studies and early-phase industry-sponsored clinical trials. **Deliverable**: Establish defined academic and industry pathways and costs for exploratory multi-omics biomarkers processes.

Task 5.3. Facilitate access to national patient cohorts: Before, during and after. Connect with patient registries to leverage the value of data even further. Requires collaboration between multiple stakeholders. Could enable patient stratification, right treatment to right patient, data for patient recruitment for clinical trials. The unit will act as a facilitator and establish processes for strengthening clinical trials. **Deliverable**: Establish a process for access to national cohort data.

Key objective 6. Provide an environment to attract additional investments

The core of Breakthrough technologies is designed to create a world-leading environment that systematically attracts private capital, international investments, and large-scale funding by risk-reduction, a main causative factor for the translational gap. By integrating SciLifeLab’s national technology infrastructure directly with Sweden’s university hospitals, the cluster provides a testbed for validating new technologies and methods maturing them to de-risked ventures driven by clinical needs. By integrating molecular and clinical data with AI a unique environment for validating data-driven diagnostic products and novel therapies is accessible to industry. The cluster transforms the innovation ecosystem from a plethora of early stage, unvalidated ventures into a pipeline of stronger, scalable, and sustainable enterprises.

Implementing Objective 1-5 will ensure the success of the cluster.

Task 6.1. Attract additional funding/investments: Multiple pathways for attracting additional funding will be needed to enable start-ups to take advantage of the joint units. One way is through co-applications of grants with other stakeholders (matchmaking) but also direct contacts with venture capital will be established.

In addition, clear service offerings for companies (service/infrastructure, knowledge) needs to be established. Attracting funding connects Task 4.1 (collaborations models). **Deliverable**: Strategy for the cluster in attracting funding supporting the overall goal.

Task 6.2 Communication plan and execution: Develop a clear pitch of the cluster offering and include a dissemination plan that reaches beyond Sweden. Define what arenas/conferences, companies should be targeted. Have Breakthrough technology ambassadors demonstrating validated success cases. Important to not build parallel functions to already existing “marketing” initiatives/organisations: e.g. Business Sweden, SwedenBio, Lif as well as the academic innovation support system. Collaborate and leverage with ongoing initiatives and organisations. **Deliverable**: Communication and execution plan.