Breakthrough Technologies for Health: Innovation Plan

Vision

The convergence of molecular technologies, advanced imaging, and artificial intelligence has created an unprecedented opportunity to transform our understanding of disease and reshape the future of healthcare. For the first time, the molecular mechanisms underlying disease can be decoded across scales, from molecules to organs (see cluster research plan), enabling deeper characterization of the individual patient, earlier diagnosis and personalized treatment. Yet, realizing this potential requires more than technology development and scientific discovery. While breakthrough technologies continue to emerge at an accelerating pace, the pathway for validation, implementation, commercialisation, and large-scale adoption in health care remain fragmented and slow. As a result, scientific discoveries and transformative innovations often take decades to reach patients, limiting societal and economic impact.

The *Breakthrough Technologies for Health* cluster will address this challenge by establishing a nationally coordinated innovation and implementation platform that connects and integrates clinical research infrastructures, healthcare, industry, investors, and public stakeholders to dramatically shorten the pathway from discovery to patient benefit. The cluster will position Sweden as a global leader in precision medicine, health technology innovation, and technology-driven healthcare transformation. This vision will be achieved through three mutually reinforcing strategic measures:

1. The SciLifeLab clinical infrastructure platform. The cluster establishes a next-generation clinical infrastructure platform to translate and scale breakthrough technologies and AI solutions. This new platform builds on Sweden's life science research community and national infrastructures SciLifeLab and MAX IV, in strategic partnership with the Swedish University Hospital Alliance (SUHA) and their precision medicine centers. The platform provides rapid access to emerging technologies in genomics, proteomics, metabolomics, spatial biology, advanced X-ray imaging, and AI-enabled analytics. Simultaneously, the platform delivers federated data and AI environments for secure integration of multimodal molecular and healthcare data. This creates a unique, nationally coordinated environment to rapidly develop, validate, benchmark, and scale technologies in real-world healthcare settings.

2. Healthcare implementation of breakthrough technologies. Our cluster will redesign the process for healthcare implementation of breakthrough technologies and AI provided by the clinical infrastructure. Through strategically selected demonstrator projects, nationally coordinated clinical validation and implementation accelerators, the cluster will establish a new model for introducing breakthrough technologies proactively into healthcare. By integrating implementation planning, regulatory preparedness, health-economic evaluation, and stakeholder engagement from the earliest stages of development and validation, technologies can be adopted much more rapidly and at scale across Sweden, ensuring equitable access.

3. National Innovation framework. A nationally coordinated, clinical-need driven innovation framework for breakthrough technologies will be developed in an integrated partnership between academia,

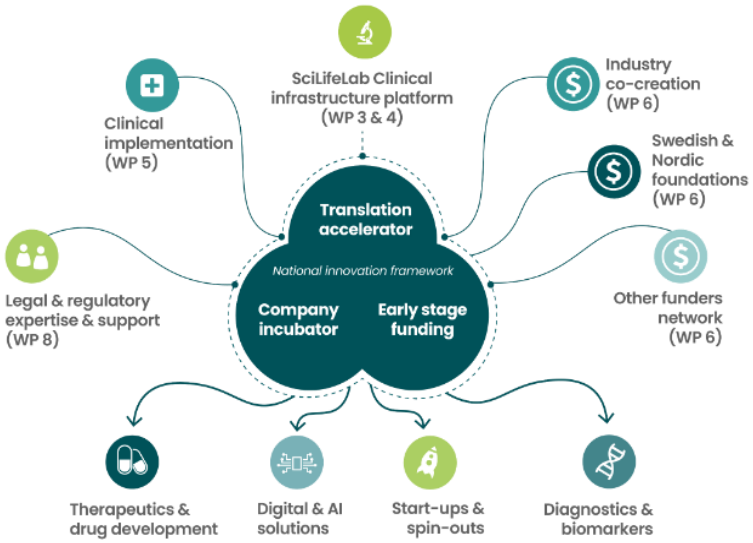

Figure 1. *The core of our innovation strategy is a unified implementation and innovation engine that converts Sweden's research excellence into a coherent, scalable national accelerator for precision medicine.*

healthcare providers, patients, industry, and investors. This framework will ensure that innovation is guided by major unmet clinical needs and business opportunities, and supported by clear and efficient pathways for selection, early stage funding, scaling and economic impact. At its core, the national innovation framework will set up a national innovation fund, clinical infrastructure associated company incubator and translation accelerator (Fig. 1), that provide early-stage funding and rapid validation and investment value building, thus closing critical gaps in the currently fragmented innovation system in Sweden.

Together, these three strategic measures establish a new national model for precision medicine innovations in which breakthrough technologies and AI solutions are developed, validated, implemented in health care, and commercialised, in parallel rather - not sequentially. By uniting world-leading research infrastructures, healthcare systems, AI capabilities and research communities, with industry and national investment capital within a single coordinated framework, the cluster will accelerate the translation of scientific discoveries into patient benefit, and secure Sweden's position as a global leader in precision medicine.

International benchmark

No comparable cluster exists anywhere in the world that combines national research infrastructure at this scale with coordinated, nationwide health-care implementation. Our cluster uniquely integrates SciLifeLab and MAX IV technology power-houses operating across all major Swedish universities with the clinical reach of every Swedish university hospital, creating an unbroken pipeline from fundamental discovery to real-world patient impact. Where international leaders in life science and health innovation have achieved such synergies only between individual institutions, in single-disease contexts, and without systematic public healthcare integration, our cluster will build the national architecture to do this at scale and this is our innovation engine. The cluster will continuously benchmark its performance against leading life science and health innovation environments, *e.g.* the US Boston/Cambridge innovation ecosystem around the Broad Institute, and the UK “Golden Triangle” around the Wellcome Sanger Institute. Table 1, compares the current status of these international ecosystems with the capabilities of the proposed Swedish cluster across the nine strategic innovation dimensions. In addition, we will add a tenth dimension specifically focused on healthcare implementation, a strategic aspect currently missing from the venture capital and innovation-focused dimension, that is critical for this strategic future market. Our cluster will develop its own benchmark based on lessons learned from Sweden’s pioneering role in early adoption of whole genome sequencing as a public health service through the SciLifeLab

Strategic dimensions (KPIs)	Broad Institute (Boston/ Cambridge)	Wellcome Sanger Institute (Golden Triangle)	Current excellence cluster application: Breakthrough Technologies for Health (National)
1. Research base	>1,000 faculty; >$1B annual budget	~900 staff; £170M Wellcome funding	National ecosystem of ~420 group leaders, SciLifeLab & DDLS Fellows and >600 infrastructure experts; 10 national platforms; ~1 BSEK annual funding, MAX IV, the first 4th gen synchrotron light source.
2. Technology infrastructure	High-throughput screening platforms; CRISPR, cell painting	Industrial-scale sequencing infrastructure	Europe's broadest integrated technology portfolio across genomics, proteomics, metabolomics, spatial biology, imaging, structural biology and drug discovery
3. Data & AI capability	World-leading cloud (Terra 80 PB) and elite computational infrastructure.	COSMIC; 90 PB scientific data; DeepMind; Dell AI Factory servers	Federated “code-to-data” clinical data environment enabeling agentic AI training, Berzelius and Arrhenius supercomputers; Mimer AI hub (~240 experts)
4. Clinical integration & testbeds	Physically separated project-based hospital collaborations	NHS-linked genomics-only programmes	Seven university hospitals; Genomic Medicine Sweden; embedded clinical infrastructure and national implementation pathways for multiple technologies
5. Laboratory-to-clinic translation	Strong discovery engine	Strong genomics pipeline	Integrated technology development, validation and implementation within a single national framework
6. Innovation model	Independent nonprofit and venture creation	Dedicated TTO, Startup School, entrepreneur-in-residence	Current gap addressed through National Innovation Coordination Office, Venture Lab and Translation Fund
7. Corporate ecosystem	Kendall Square	Wellcome Genome Campus	Forskaren, Hagastaden, GoCo, Medicon Valley and regional innovation hubs
8. Venture capital & scale-up	Top lobal biotech VC hub, Third Rock, RA Capital	Cambridge Innovation Capital (CIC), IP Group	Current gap addressed through BioInnovation Institute partnership and dedicated Translation Fund
9. Spinout track record	Foundation Medicine, Editas, Beam, Verve, Prime Medicine	Kymab, Genomics plc, Microbiotica and others	Olink, Spatial Transcriptomics, CARTANA, Elypta and others but no structured national tech transfer.
10. Healthcare implementation	Institution-specific implementation pathways	NHS implementation programmes	National implementation through university hospitals, Clinical Genomics, Genomic Medicine Sweden (GMS) and future clinical infrastructure platform

Table 1. *Key dimensions of selected globally competitive innovation clusters used as benchmarks.*

Clinical Genomics platform and Genomics Medicine Sweden (GMS), as well as from leading international genomics health care programs including the UK's NHS Genomic Medicine Service, (1-2) and Singapore's PRECISE strategy (3-4). Biannual benchmarking will allow our excellence cluster to continuously refine its KPIs, activities and track its progress toward establishing Sweden as one of the world's leading innovation environments for precision medicine and health technologies by 2035.

Strategy and Implementation

The *Breakthrough Technologies for Health* cluster is built on a set of internationally competitive foundations: SciLifeLab and MAX IV deliver world-class research infrastructures; the SUHA and its member hospitals provide the frontline of advanced health care and nationally coordinated clinical reach. The excellence cluster will for the first time unite these national capabilities and coordinate rapid implementation of technology and AI solutions into clinical practice and scaling by commercialisation.

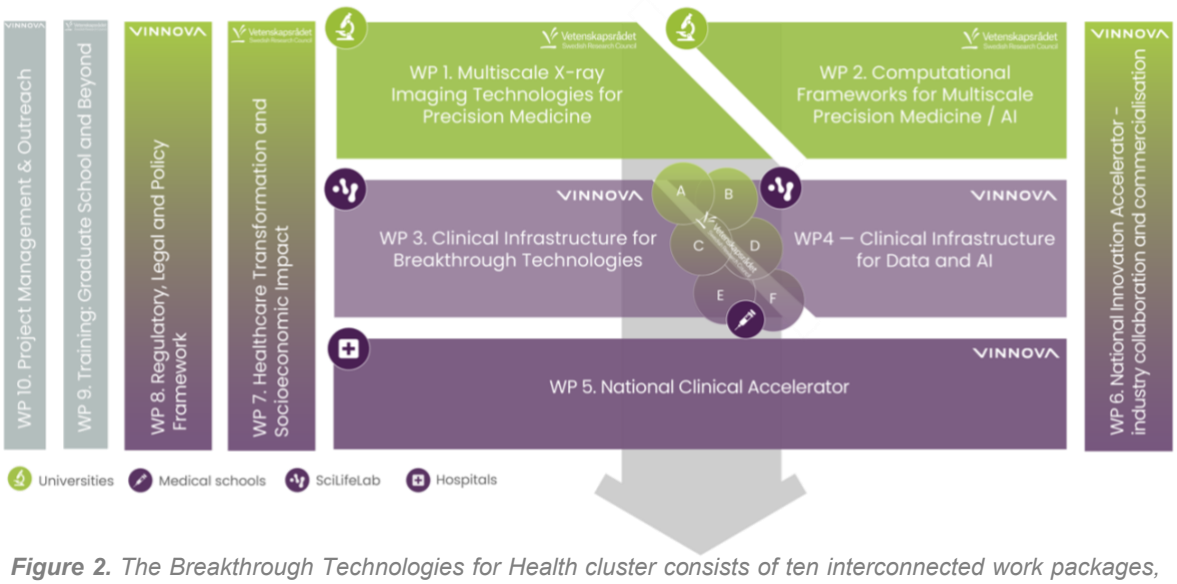

Figure 2. *The Breakthrough Technologies for Health cluster consists of ten interconnected work packages, WP1-WP2 pioneer the technological core, developing multiscale synchrotron imaging and agentic AI for predictive modelling. Implementation is operationalized via WP3/WP4 establishing the SciLifeLab clinical infra-structure platform, clinical acceleration process driven by SUHA, WP5, and WP6's commercialization engine. Strategic sustainability is ensured by WP7 including HTA/legal research, WP8 on regulatory governance-by-design support, and WP9's national graduate school. WP10 provides the governance through a Strategic Steering Board and dual- leadership model (Project Leader/Cluster Manager), supported by an International Advisory Board to ensure global, industrial scaling, project management and communication. With the aim to transform Sweden's scientific excellence into a scalable operating system for precision medicine, the cluster aim to deliver tangible patient benefits and global leadership by 2035.*

This innovation strategy is implemented through a set of interconnected work packages that are closely integrated with the research plan of the cluster as a whole (Fig. 2). A key role is played by the new clinical infrastructure platform set up by WP3/4 embedded within the university hospitals. The platform will continuously make new breakthrough technologies and AI solutions, including those developed in WP1 and 2, available for clinical applications, and set up a federated data infrastructure that enables secure national integration of molecular and clinical data. The clinical infrastructure platform empowers a starting set of six translational research demonstrator projects (A-F) that show how urgent unmet medical needs are addressed by breakthrough technologies and drive the establishment of robust workflows suitable for routine clinical use of cross-scale molecular characterization of patient material in major disease areas. The infrastructure forms the strong bridge connecting fundamental research (WP1/2) to healthcare implementation, which is proactively organized by the National Clinical Accelerator in WP5 in line with Swedish regulatory and health technology assessment frameworks. A second driver of the flow from research to health care is the National Innovation Accelerator (WP6), that capitalizes on the unique testbed the clinical infrastructure provides, to mature technological breakthroughs rapidly into validated, commercial-ready diagnostic and

therapeutic tools and AI decision-support systems. This is further strengthened by cutting edge research in social sciences in WP7-8 that ensure that health economic analysis and regulatory preparedness are integrated from the earliest stages to ensure that the precision medicine transformation of the healthcare system will have a strong positive impact of Sweden's economy and harmonize its legal and regulatory system. This integrated structure, where clinical need continuously feeds back into technology development, ensures a constant innovation flow with effective national coordination, which will make Sweden unique compared to current international initiatives.

The cluster will provide a unique national innovation environment to create start-ups, scale SMEs and attract and anchor international pharma and medtech companies. The cluster will provide a nationally coordinated innovation ecosystem, overcoming its current fragmentation, by setting up the National Innovation Coordination Office, linking university holding companies and incubators in partnership with the Association of Life Science Incubators of Sweden (ALIS) and Swedish Incubators & Science Parks (SISP), university hospital innovation nodes, and connect the 3 major established life science environments Stockholm, Gothenburg and Lund.

Startups and SMEs will profit from the new clinical infrastructure platform, as an ideal testbed, value building and scaling accelerator and unique access point to patient material and data resources. New venture creation will be driven by an integrated national support model that combines the best of the Swedish innovation system, including Navigare and the Knut and Alice Wallenberg launch pad (WALP) with the successful BioInnovation Institute (BII) (5) model from Denmark, that is a cluster partner. Our national venture support model will integrate early-stage funding through setting up a dedicated national innovation fund, provide entrepreneurial expertise from a group of Senior Advisors, and guide companies on the regulatory and governance framework for effective introducing innovations into the Swedish health care market. This will close many gaps in the currently fragmented Swedish innovation ecosystem.

For larger companies, the cluster offers capabilities unavailable at comparable quality and scale elsewhere in Europe, including a federated network of trial-ready patient cohorts across all Swedish university hospitals, precompetitive access to unique data resources, set up with a data governance aligned with EHDS and EU AI Act requirements, and an established and nationally coordinated infrastructure for multi-site clinical validation. Combined with access to the new clinical infrastructure platform, this enables large companies to make use of the unique strengths of the Swedish system for their own R&D programs, run a uniquely powerful quality of clinical studies and trials, and enables software and AI companies to co-develop AI-enabled diagnostics and therapeutics in healthcare settings as new data become available, with a unique depth and national population reach.

AI is central to the cluster’s innovation strategy and will be enabled by its federated national clinical data infrastructure, for the first time allowing using health data at scale in Sweden. Large molecular foundation models and agentic AI analytical workflows will be developed to extract actionable clinical knowledge from complex cross scale and multimodal datasets from patient material. The cluster’s federated code-to-data infrastructure will enable AI models to be trained at the data source, creating patient specific digital twins that allow simulating treatment responses and guiding therapy decisions, empowered by the access to population-scale, longitudinal, multimodal data the cluster will provide in a secure manner.

The inclusive approach our cluster takes, allows its nationally coordinated innovation framework to support also all other, more focused breakthrough technology and AI efforts towards health care in Sweden, for example in the areas of spatial biology or infectious disease. In addition, such initiatives can also make use of the clusters clinical technology and data infrastructure rather than duplicating it for their own more specialized needs. Due to this strategic role our cluster can play for the Swedish breakthrough technology sector in health, our cluster has and will continue to actively seek collaborations with complementary and synergistic Swedish initiatives, and further drive national coordination and integration to overcome fragmentation.

The cluster targets to leverage its public innovation funding from the excellence cluster call several fold by 2035. On the one hand it will put Sweden in a much more competitive position to obtain European Union grants (ERC investigator grants, EIC Pathfinder and Accelerator

grants, EU framework grants for health related missions such as cancer, as well as grants to develop technology for infrastructure and collaborative grants with relevant pan-European infrastructures, including ELIXIR, Euro-BioImaging). Furthermore, industry user and collaboration agreements to use the clinical infrastructure platform and obtain privileged precompetitive access to the federated data resource and AI tools of the cluster will generate significant resources. In addition, the national innovation fund will raise syndicated early-stage investment targeting an initial volume of 500 MSEK, with a mix of public and private national and international investors. Annual benchmarking of fundraising goals and achievements and dedicated fundraising staff in the national innovation office will allow the cluster to strengthen its income year by year.

Overall progress will be monitored through bioannual benchmarking across ten dimensions of innovation reflecting the cluster's commitment to clinical impact alongside commercial performance. For each dimension, key performance indicators (KPIs) will be reviewed by an independent International Advisory Board, and findings will feed directly into operational planning to ensure the cluster continuously gets stronger and moves Sweden into an internationally leading position for technology and AI powered precision medicine.

WP3 — Clinical Infrastructure for Breakthrough Technologies

The cluster will establish a new national platform, the SciLifeLab Clinical Infrastructure Platform, a hospital-embedded translational environment that connects the technology capabilities of SciLifeLab and MAX IV directly with clinical laboratories and Precision Medicine Centers at the university hospitals across Sweden. The Platform will provide the infrastructure, expertise, and workflows required to accelerate the development, maturation and validation of breakthrough technologies and AI-enabled diagnostics into real-world healthcare settings (Table 2). By close integration with the secure multimodal data environments of the clinical infrastructure for data and AI (WP4), clear health care implementation pathways (WP5), and nationally coordinated innovation support (WP6), the SciLifeLab Clinical Infrastructure Platform creates a coordinated access to emerging breakthrough technologies for clinical use and decision-making, healthcare adoption, and commercial valorisation. Linking the cutting-edge multimodal technology and data/AI technologies to real-world hospital environments will provide new possibilities for co-creation that are currently unmatched in Europe.

Translation of breakthrough technologies follows four defined stages: 1) discovery and technology development; 2) assay maturation and analytical validation; 3) clinical validation and regulatory readiness; 4) routine implementation and scale-up, often through commercial services. While existing SciLifeLab infrastructure platforms are internationally leading in stage 1, the new SciLifeLab Clinical Infrastructure Platform specifically strengthens stages 2 - 4, while advising on stage 1 for clinical needs. Thus, activities will encompass scaling advanced sample handling for emerging technologies, enabling deep phenotyping services, and supporting biomarker-driven clinical trials for evaluation of new diagnostic solutions and treatment prediction in a regulatory-compliant manner. The six demonstrator projects A–F drive immediate platform deployment, serving as concrete test cases across varied technologies and maturation stages to accelerate full-scale translation.

Figure 3. *This cluster creates a new generation of embedded SciLifeLab clinical infrastruture platform to mature and validate breakthrough biotechnologies and AI in response to unmet clinical needs, bringing together patient samples, technologies and data types for increased ability to research, implement and innovate.*

The SciLifeLab Clinical Infrastructure Platform will operate as a federated network of nodes across all seven Swedish university hospital. These complementary nodes are paired with demonstrators based on their technology and AI tool expertise integrated into local clinical workflows, building on strong existing expertise and the partnerships with regional healthcare.

This complementarity is a strength: it enables the Platform to develop and evaluate implementation models for several technologies and disease areas in parallel, identify the most effective approaches, and make solutions found in one location rapidly available nationally, avoiding duplication of effort and providing equitable access as quickly as possible. Our federated national platform design furthermore ensures that innovations can advance beyond validation into widespread clinical adoption (WP5) and commercialisation (WP6), both within and beyond the participating healthcare providers.

Task 3.1 – A federated SciLifeLab Clinical Infrastructure Platform. The objective of WP3 is to connect MAX IVs and SciLifeLab's leading breakthrough technology expertise across all areas of modern life science to a robust clinical infrastructure required to validate multimodal breakthrough technologies in the "real-world" hospital environments. WP3 will expand the so far mainly genomics focused clinical arm of SciLifeLab's infrastructure across all health care relevant technologies, including those provided by MAX IV, and connect to the full breadth of the corresponding receiving functions within the university hospital partners. Investments in new advanced technology platforms, such as clinical proteomics and clinical spatial biology, will be complemented by capacity building in pathology labs, clinical chemistry, and additional hospital-based diagnostic functions, creating a seamless collaborative interface between technology development and clinical adaptation.

The final implementation into clinical routine will be done by regional healthcare in WP5, utilizing the evidence and processes generated by this cluster. To enable an agile and effective translation process, the receiving parties within the diagnostic laboratories will be involved from the beginning in setting up the clinical infrastructure, driven by the initial demonstrator projects paired with respective clinical needs, hospital expertise and workflows. After starting with the initial six projects, additional demonstrators will be selected and included as the cluster starts operating. Importantly, the clinical infrastructure platform will not only accelerate bench-to-bedside transfer but allow for "back-translation" by identifying the most important unmet clinical needs to drive research and technology development. A key mechanism for this will be SciLifeLab's existing regular Technology Development Project (TDP) calls, (6), which push the development of emerging technologies into robust infrastructure services. Continuous horizon scanning is crucial for the new SciLifeLab clinical infrastructure platform, and existing forums such as the Clinical Talks (7) will provide great tools for this. To continuously ensure strategic and internationally competitive priorities, the new clinical platform will participate in infrastructure evaluation through SciLifeLab's International Evaluation Committee (8) and in accreditation processes such as done by the OECI for Comprehensive Cancer Centers (9). This strong feed-back loop from clinical need to technology development will improve the reproducibility and validation of new biomarkers and diagnostic technology solutions that currently frequently fail to progress beyond single-centre studies due to insufficient access to larger patient cohorts, harmonised data, clinical testbeds and clear implementation pathways

Task 3.2 – Advanced Sample Handling Capabilities. Utilization of advanced technologies such as spatial omics, functional testing and phase-contrast X-ray tomography often have different requirements for molecular and structural sample preservation than century old methods, such as paraffin embedding and Hematoxylin and Eosin (H&E) staining. This task will support advanced and real-time sample handling and other pre-analytical processes within healthcare. Here we will leverage learnings from the Precision Medicine Sample Centre, pioneered in 2024 in a strong partnership between Karolinska University Hospital's pathology department and the SciLifeLab Precision Medicine team and Clinical Proteomics infrastructure unit. We will extend this expertise and capability across the other national clinical infrastructure nodes to obtain patient material of high quality that can readily be analysed by the different new breakthrough technologies. This includes; 1) prospective collection workflows, advanced handling and processing of viable tissue, blood, and cellular material to preserve structural integrity and molecular content as much as possible, 2) optimized extraction processes for often minute clinical samples for robust and scalable downstream analysis of DNA, RNA, proteins and metabolite analysis as well as cells and tissue for single cell, spatial, X-ray and functional analysis and 3) standardised sample workflows across sites including sample

provenance. This will enable nation-wide studies linking datasets through use of unique patient sample IDs, consistent sample data provenance to allow for data integration across technology modalities.

Task 3.3 – Deep Phenotyping Service for Patient Stratification. This task will establish integrated services for building on SciLifeLab infrastructure for deep phenotyping combining several breakthrough technologies to enable multimodal characterisation of patient samples and deploy AI to analyze the data together with WP2 and 4. The service will integrate multiple molecular layers to allow integrative analysis of molecular geno- and phenotype, cellular and tissue phenotype as well as clinical and outcome data to allow identification of molecular signatures associated with disease onset, treatment response, resistance, and disease progression, as exemplified by our demonstrator projects. This integrated multimodal service will massively improve the current ability to identify multimolecular biomarker fingerprints and provide essential knowledge for precision prevention and early detection screening studies. The deep phenotyping service will rely on embedded data science and AI competence to harmonize analytical pipelines, meta-data and AI-integration. Together with WP2 and WP4, this task will transform the clinical infrastructure from single-technology data generation into multimodality, which is a key strategic asset to the new national clinical infrastructure platform. Developing this service at a hospital-embedded infrastructure enables continuous joint learning and constant awareness of the full potential of breakthrough technologies to clinicians and increases the attractiveness of the healthcare system for external funding from *i.e*. large pharma companies to carry out multi-technology powered innovative studies and trials.

Task 3.4 – Innovative Biomarker-driven Clinical Studies and Trials. A key use of the novel clinical infrastructure will be in clinical studies and trials, often in close collaboration with industry partners as technology and AI service providers or drug developers, examplified by the national studies described in demonstrators B-D for patient stratification or in demonstrator F needing clinical validation. In this task, the clinical infrastructure platform will support clinical trials units, academic- and industry-driven studies with access to and expertise in multimodal breakthrough technology and data integration and analysis. Lessons from our ongoing VR infrastructure grant (2022-06046) supporting five national precision medicine pilot projects in cancer and cardiovascular disease at SciLifeLab, directly inform this task. Two key findings are incorporated: the necessity of embedding data management and analysis close to the technology infrastructure (task 3.3), and the need for advanced sample handling, scalable unique sample IDs, and data provenance integration (task 3.2). The ability of deep phenotyping will allow a new quality in identifying biomarkers predictive of response prior to treatment, for characterising mechanisms of resistance in non-responders, for enabling adaptive trial designs and for monitoring treatment dynamics longitudinally, including minimal residual disease (demonstrator F) and early relapse detection. Linking national multimodal profiling to agile access to electronic healthcare records (WP4) will be a key deliverable of this cluster.

Task 3.5 – Quality Assurance and Regulatory Compliance. To ensure that the services of the new clinical infrastructure platform meet national and international clinical and industrial standards, WP3 will implement integrated quality, regulatory, and operational processes, contribute to establishing SoPs and national standards for validation and clinical implementation, enabling efficient scale-up and health care adoption. This will include;

1) Accreditation and introduction of robust quality management systems for the participating partners as assays mature in the clinical infrastructure. For example, ISO-certification for the developed analyses, using ISO 17025 at SciLifeLab technology platforms, MAX IV and ISO 15189 for clinical laboratory use.

2) Compliant-by design approach for our validation activities including bioinformatic and AI development processes to provide high-quality programmatic code compliant with the regulations (MDR, IVDR, AI-act). Here WP3 will work in close collaboration with WP7 and 8 ensuring early compliance to EU regulations as a competitive advantage. For example, access to test samples and data with documented validation reports is critical for processes relating to MDR/IVDR for the use of in-house exemption for health institutions.

3) A fast-learning healthcare system - by ensuring well documented methods and tools for national dissemination and rapid deployment openly shared across the different nodes. This will be done in close collaboration with the SUHA health care implementation process in WP5 and the health economy research in WP7, to ensure we gather the evidence needed for health technology assessment and reimbursement schemes following the established structures for clinical implementation but in a nationally harmonized fashion.

Table 2. WP3 — Clinical Infrastructure for Breakthrough Technologies | Lead: Valtteri Wirta, SciLifeLab / KI

Task	Expertise & Resources	Key Output
3.1	Clinical infrastructure managers & hospital-embedded laboratory specialists	National network of sustainable clinical infrastructure nodes across all university hospitals
3.2	Pathology & molecular technology experts; demonstrator teams	National capability for advanced sample handling supporting breakthrough technologies
3.3	Technology & infrastructure experts; embedded bioinformaticians	Integrative multimodal datasets enabling clinical studies and trials
3.4	Clinical trial & systems medicine experts	Molecularly defined disease subtypes; data-driven therapy stratification; increased industry trial attractiveness
3.5	Regulatory support & quality managers	Accredited, agile national pipeline for clinical translation and precision medicine implementation

WP4 — Clinical Infrastructure for Data and AI

WP4 establishes a federated ecosystem for the national AI-native digital infrastructure required to bridge the critical bottleneck between high-volume molecular and imaging data obtained by new breakthrough technologies for health and clinical decision-making (Table 3), and it is the digital partner of WP3, and part of the clinical infrastructure platform. The design of WP4 relies on the current transitioning from centralized data repositories to federated “code-to-data” architectures where sensitive patient data remains locally governed while computational workflows and AI models are securely deployed at the data sources. An example along these lines is the well-established DataSHIELD framework (10).This paradigm shift is driven by three converging developments; 1) the rise of federated Secure Processing Environments (SPEs and/or Trusted Research Environments (TREs), 2) automated interoperability pipelines that are replacing manual data handling, enabling transformation of heterogeneous clinical and research data into interoperable standards across data types, and 3) transition to multimodal agentic AI approaches that allow integration of omics, imaging and clinical datasets (WP2).

Sweden has all the essential components required to lead the data and AI revolution in healthcare, but these capabilities remain distributed across institutions, infrastructures, and healthcare systems. Unlocking their full potential requires new forms of coordination, integration, and implementation. On the one hand Sweden has world-leading research infrastructures in SciLifeLab and MAX IV, which will be systematically provided by this cluster to healthcare, and has large population cohorts and longitudinal health data registries. On the other hand, the health care data is currently fragmented by distribution across regions, including the already established SPEs, while the national bioinformatics services by SciLifeLab and high performance compute capacity provided by NAISS is still very difficult to deploy for sensitive patient data. Solutions are therefore typically established by complex local and regional networks for individual translational projects, rather than in a harmonized fashion at the national level. The latter is absolutely essential in order to take full advantage of the AI revolution and put Sweden at the forefront of precision medicine, and as an attractive international host to the next generation of clinical trials.

The regional nodes bring complementary and world-class data infrastructure assets and a few examples of the current system might be instructive as the starting point for WP4. Gothenburg: Sahlgrenska and GU provide the BFR repository (~1.5 billion images) and the 30,000-participant SCAPIS cohort, operationalized via SFM (Kubernetes, GPU-accelerated) and Chalmers E-commons HPC. Linköping: Acts as the computational backbone, hosting NAISS, the Arrhenius supercomputer, Berzelius AI, and Mimer (Swedish AI Factory), clinically integrated through CMIV and the AIDA Data Hub. Lund: Deploys a multimodal data lake via the Skåne AI Competence Centre, connecting to Öresund’s supercomputing and quantum infrastructure. Stockholm: Karolinska provides CDR Catalyst (openEHR/HL7 FHIR standards), Region Stockholm Private Cloud, and validation via TEF-Health and the Center for AI Innovation.Umeå: Leads federated architecture via EUCAIM, Welkin (healthcare-compliant

Kubernetes), and the PREDICT cohort. Örebro: Contributes an evolving openEHR-based longitudinal data lake.

Until now, the absence of a coordinated national capability for federated data management limits integration, scalability, and clinical impact and, maybe above all, the data volume and statistical power needed for training new AI models and extracting clinically relevant knowledge, so that all patients can profit from all data in Sweden. WP4 aims to address this challenge by building an operational layer that allows independently governed regional data infrastructures and secure environments to function as a single network for shared metadata, discovery, and controlled deployment of AI analytical workflows. This architecture ensures that new molecular insights can be translated equitably across regional borders without compromising data sovereignty or security. By federating the existing fragmented environments, the new national clinical data infrastructure will provide the high-performance compute and governance foundation required to transform Swedish healthcare into an AI-ready ecosystem by 2035.

Task 4.1: Federated Three Layer Secure Data Architecture. This task establishes the technical foundation of a national "code-to-data" infrastructure, ensuring sensitive patient records remain locally governed while analytical workflows are securely distributed. We will design and deploy a three-layer privacy-by-design architecture at each node: 1) an Open Innovation Zone for early-stage development and interaction with external large language models; 2) a Secure Research Zone for analysis of sensitive datasets; and 3) a Clinical Production Zone for pre-deployment of validated AI and/or clinical decision tools. The federation network of the nodes allows the independently governed secure environments (SPEs/TREs) to work as one network for shared metadata and discovery, access and audit procedures, approved workflow deployment, and controlled return of outputs. To enable agentic AI workflows developed in close collaboration with WP2, the three-layer architecture will expose standardized interfaces, allowing AI agents to securely launch federated analytical tools, query cohort definitions, and coordinate multi-node tasks within strictly governed boundaries. The infrastructure will be tested using the demonstrator projects included in the research plan of this cluster.

Task 4.2: Interoperability and Automated Multimodal Data Integration Pipelines. This task addresses the critical bottleneck of fragmented health data by implementing semi-automated and quality-controlled pipelines for harmonising and integrating heterogeneous clinical, molecular, and imaging data to ensure FAIR data principles, and to support the development of new AI tools and models in WP2. The pipelines will convert data into global interoperability standards including *i.e*. OMOP CDM for longitudinal health data, HL7 FHIR for real-time exchange, and OME-NGFF and DiCOM for multiscale imaging, molecular technology-specific standards such as Pride for proteomics and Metabolights for metabolomics data, as well as sample data provenance. This will be achieved through development of a national extract-transform-load (ETL) library of reusable, version-controlled data transformation modules — co-developed across the nodes using Swedish clinical terminologies (KVÅ, ICD-10-SE) and validated against the demonstrator datasets — supplemented by AI-assisted mapping tools to accelerate terminology definition and reduce manual data curation. Secure APIs, also enable integration of external data sources such as wearable data and patient-reported outcomes (PROMs) where available, expanding the scope toward real-world and population-level evidence. Wearable and sensor data extend the federated infrastructure beyond the hospital walls, into everyday life where deterioration begins - and exemplify the paradigm shift towards automatic data integration.

Task 4.3: Pre-deployment and Clinical Validation of AI Decision Support Tools. This task translates transformative AI capabilities, both developed within the cluster and internationally, into clinical practice by developing and validating decision-support tools. Spearheaded by the cluster's demonstrators, e.g. cardiovascular risk models (demonstrator B) or AI-assisted Molecular Tumor Boards (demonstrator B, D) and to achieve this, we will deploy the AI tools developed in WP2 into the federated digital testbed, where they are evaluated against ground-

truth patient outcomes using standardized metrics and electronic health records. This ensues both technical robustness and clinical relevance prior to formal validation of a new analytical tool. All tools will undergo rigorous validation using the TEF-Health validation framework and the evidence and regulatory principles provided by WP7 and 8, including “silent trials” in non-interventional modes to monitor for model drift, bias, and robustness in real-world clinical settings before routine deployment of a new analytical tool. Such a “data and AI testbed” will have a strong impact on the innovation system for new data and AI services provided to health care, as described in WP5 and 6.

Task 4.4: National Data Governance Framework for Standards and Joint Infrastructure. To ensure long-term sustainability and equity, this task establishes a 1-1-1 national federated governance model across nodes comprising: 1) a body for technical standards and metadata management; 2) a compliance body to ensure harmonized legal interpretations for data access; and 3) a collaborative data innovation body connecting researchers and industry to the network. Each body will operate through lightweight shared operating procedures co-developed across nodes, with explicit conflict resolution mechanisms to ensure that ongoing harmonization of standards or access modalities do not stall the start-up of first federated operations but are resolved in a solution-oriented manner continuously. This framework furthermore provides a structured roadmap to allow to scale the nodes from the initial seven university hospitals to all 21 Swedish regions in the long term. We will follow a stepwise maturity model where nodes adopt shared secure data blueprints and governance standards at a pace matched to their current infrastructure readiness, ensuring no region is left behind. Alignment with the European Health Data Space will be prioritized throughout with input from WP7 and 8, ensuring that governance decisions taken nationally are interoperable with cross-border data access and promote international collaboration, especially within the Nordics and the European Union.

Table 3. WP4 — Clinical Infrastructure for Data and AI | Lead: Päivi Östling, SciLifeLab / KI

Task	Expertise & Resources	Key Output
4.1	IT architects, data engineers & regulatory compliance specialists	National Agent-ready SPE architecture blueprint; federated data-handling guidelines; HPC deployment at NAISS
4.2	Health informaticians, bioinformaticians & data stewards; demonstrator domain experts	Standards-compliant national data interoperability system; reusable mapping packages; secure data gateway
4.3	AI developers, clinical researchers, data scientists & MDR/ IVDR/AI Act specialists (WP8)	Digital testbed for regulatory-compliant AI validation; portfolio of validated decision-support tools ready for clinical deployment
4.4	University/clinical leadership, legal & policy experts; ecosystem coordinators (WP5/6)	Federated data governance model; EHDS compliance roadmap; national scaling pathway from 7 university hospitals to all 21 regions

WP5 — National Clinical Accelerator for Healthcare Implementation

WP5 focuses on implementation science, healthcare integration, and scale-up of clinical translation of emerging technologies (Table 4). The WP supports regulatory pathways (together with WP7 and 8), clinical integration models and healthcare process adaptation of new technologies from the new SciLifeLab clinical infrastructure platform (WP3/4) and coordinated national health care service strategies. WP5 is one of the cluster's key international differentiators by combining breakthrough technology development and their access through clinical infrastructure platforms with coordinated national implementation capabilities embedded directly within healthcare systems (see Table 1). At its core is the development and operationalization of a structured clinical translation and adoption process – a “Clinical Acceleration Process” - designed to facilitate and speed up implementation and clinical integration.

The process builds on the lessons learned from genomics, where Sweden has developed internationally recognized collaborative frameworks between SciLifeLab and university hospitals for genomic medicine and draws on the experience of Genomic Medicine Sweden (GMS), which has supported the collaborative implementation of panel- and whole-genome sequencing to healthcare through national coordination across health regions, shared standards, and promoting integration of clinical-research environments. WP5 will adapt and extend this approach to include the new breakthrough technologies relevant for the health care of the future and take full advantage of the AI revolution to empower mechanism-driven

precision medicine. This will happen stepwise through validation with the clinical infrastructure platform (WP3/4), where the next generation technologies to consider for health care introduction are proteomics, metabolomics, spatial biology, X-ray and advanced imaging, and AI-enabled molecular decision support as outlined by the demonstrator project.

Our Clinical Acceleration Process is a three-step process designed to translate breakthrough technologies and AI into scalable and sustainable clinical implementation. The steps are interconnected, ensuring a continuous translational flow from early validation of clinical relevance to formal healthcare adoption, and our process aligns with the principle of human dignity and equitable access, the basis for health care in Sweden.

Step 1: Clinical guidance and early integration. The first step establishes a systematic and early integration of unmet clinical needs and healthcare priorities into research, innovation, and health technology development, ensuring high clinical relevance and strong implementation potential. This step will be done with WP3/4 through close interaction models between healthcare and the research environments, such as our graduate school training programs, through cluster meetings and future demonstrator projects, enabling early integration of clinical needs and translational perspectives. This includes co-defining clinically relevant research questions, identifying technologies with high translational potential, establishing a constant dialogue between stakeholders, and assessing translational maturity and implementation potential early on, with standardized evidence gathering developed by WP7. For industry actors, the WP establishes interaction models to provide early clinical access and technology validation opportunities, together with WP6. A key supporting activity is technology horizon scanning in WP3, to identify emerging technologies and support decisions on when they should enter subsequent stages as future demonstrator projects.

Step 2: Technology, governance, scalability and adoption preparation. This step prepares technologies for scalable adoption and is initiated proactively at defined milestones of translational maturity, readiness and relevance for clinical integration are reached in step 1. This includes assessing clinical applicability, infrastructure and governance needs, and expected value in terms of patient outcomes and healthcare efficiency, with emphasis on scalability and equitable national adoption. This step will be done in close collaboration with experts in WP7 on health economy and technology assessment research. National implementation roadmaps are developed covering governance, financing, responsibilities, sustainability, and health economic aspects, alongside frameworks for IVDR, MDR, and hospital exemption pathways. To study and strengthen this aspect, we link the SUHA expertise with WP7 and 8 to become compliant-by-design and use national coordination to ensure that rapid implementation is not hindered by differences in interpretation across Swedish University Hospitals. For industry-driven innovation, activities centre on preparing technologies for certification, procurement and national healthcare adoption, including processes related to public procurement (LOU), targeting solutions with clear clinical relevance and feasibility for integration into routine care, strengthening Sweden's home market for start-ups based on breakthrough technologies and AI solutions.

Step 3: Formal evaluation and implementation. The final step constitutes the formal entry into healthcare decision-making and adoption processes, where technologies, prepared through Steps 1 and 2, progress into regional adoption pathways and emerging national frameworks for equitable healthcare implementation currently being developed by the National Board of Health and Welfare, in a government assignment that includes the cluster partners SciLifeLab and GMS. Since the technologies reaching this stage have already matured, been validated, and prepared in Step 1-2, the formal evaluation will proceed much more efficiently than today, reducing uncertainty and fragmentation, supported by systematically collected evidence, thorough implementation plans, economic analyses, and governance structures.

The three-step Clinical Acceleration Process is driven and facilitated through a coordinated process across the cluster. At each university hospital, a dedicated Process Lead, supported by a Process coordinator, is responsible for driving and coordinating the process and ensuring alignment between clinical, research, and other implementation stakeholders. Expert competencies at each university hospital, related to current demonstrator portfolio, are engaged to support the implementation purposes. In the event of a positive implementation

decision, the established regional processes are followed, such as the procurement of relevant infrastructure - funded outside of the WP5 work package budget. The work of these local functions will be supported by Clinical Infrastructure Platform (WP3 and 4) for hand-over, by WP6 for innovation and WP7 and 8 for health- economics, technology assessment and regulatory compliance and governance to bridge the current gaps in the fragmented implementation landscape. The WP will be led by the SUHA Precision Medicine work stream, in close collaboration with this cluster, the Precision Medicine Centres (PMCs) and Genomic Medicine Sweden (GMS).

Task 5.1 – Process design: Clinical Acceleration Process. The Clinical Acceleration Process is designed and agreed between all involved parties, based on the three steps outlined above. The process defines how clinically relevant use cases are identified, how translational maturity, clinical applicability, and implementation potential are assessed, and how technologies with strong potential for healthcare adoption are identified at an early stage. Progression criteria and associated "toll gates" are established to determine when technologies are ready to advance between the different steps of the Clinical Acceleration Process. The task is developed in close alignment with the whole cluster including horizon scanning activities, ensuring that emerging technologies can be systematically identified, assessed, and guided into the appropriate stages of the process.

Task 5.2 – Pilot and validation. The Clinical Acceleration Process is tested on our first set of demonstrator projects, which will allow the evaluation of performance across different levels of maturity. Entry and progression are guided by defined criteria in task 5.1, enabling testing of decision points and identification of when preparation for clinical integration should begin. The process is adapted across project types and levels of readiness, ensuring flexibility while maintaining consistency. Not all demonstrator projects may progress to full healthcare implementation; a key outcome is an improved ability to identify technologies with genuine potential for healthcare adoption as early as possible. Experiences from the pilots are used to refine criteria, decision frameworks, and operational workflows before broader rollout.

Task 5.3 – Implementation and National scale-up. Building on task 5.2 the Clinical Acceleration Process is extended and implemented across the cluster and integrated into regular operations. The incoming demonstrators, and other translation projects are continuously monitored to identify those ready for next steps and trigger coordinated actions. Depending on the complexity of the technology, the implementation can include clinical infrastructures, PMCs, diagnostic hospital laboratories, and new emerging pathways for adoption and funding. For each new technology the key goal is to enable harmonised implementation of equitable access across regions. Still, rollout might occur in a phased and stepwise manner, driven by the maturation of breakthrough technologies and the readiness of the receiving region. The underlying principle is that clinical implementation should be equitable and accessible across the healthcare system, while recognizing that initial implementation may require a certain degree of centralization. Over time, the implementation can then be progressively scaled and disseminated to additional sites in a gradual and structured manner. Early implementation prioritises technologies with the highest readiness and clinical relevance, followed by expansion as additional technologies mature.

Table 4. WP5 — National Clinical Accelerator for Healthcare Implementation | Lead: Charlotta Ljungman, SUHA

Task	Expertise & Resources	Key Output
5.1	Clinical translation & implementation experts across all seven nodes	Agreed clinical guidance process with defined progression criteria, toll gates and stakeholder interaction models
5.2	Clinical Acceleration Process experts	Validated decision criteria; refined workflows; prioritised technologies for national implementation
5.3	Implementation readiness experts across all seven nodes	Cluster-wide phased national implementation model; scalable system for coordinated clinical adoption

WP6 — National Innovation Accelerator: Industry Collaboration and Commercialisation

Despite world-leading biomedical research capabilities, Sweden faces a persistent innovation gap: high-potential health technology discoveries rarely scale into global ventures at the pace and volume that the underlying science warrants. WP6 addresses this by establishing a

nationally coordinated innovation engine, the National Innovation Accelerator, that streamlines the pathway from breakthrough technology development and discovery to clinical deployment and commercial scaling (Table 5). This innovation engine rests on three pillars: 1) expert mentorship and translational support for innovators by senior innovation advisors (see Innovation CVs); 2) structured acceleration from discovery to market by testing and incubation close to the clinical infrastructure; and 3) a National Innovation and Translation Fund to support early stage funding (Figure 1). Our innovation model relies on nationally integrating the best aspects of Sweden's currently fragmented innovation sytem and incorporating the successful process of the BioInnovation Institute (BII) from Denmark. As a result, we will integrate translational support, talent attraction, and fast track capital access for the best ventures, a concept that has demonstrably increased both the rate and quality of venture creation from publicly funded life science research internationally.

The Accelerator connects the strategic cluster partners, the universities, research infrastructures and university hospitals, with holding companies (*via* FUHS, LoI), incubators (*via* ALIS, SISP, LoI´s), investors, and industry partners within a single national framework, formally coordinating actors that currently operate individually without shared governance, a major change to overcome the fragmentation of the Swedish innovation landscape. By co-locating innovation support and spin-out incubation options with the SciLifeLab Clinical Infrastructure Platform (WP3/4), especially at sites embedded with Swedish innovation hubs in Hagastaden (Stockholm), GoCo (Gothenburg), and Medicon Village (Lund), the cluster replaces a fragmented, region-by-region model with a nationally coordinated effort that can deploy the strongest expertise and capital where it has the most impact. WP6 will develop a sustainable membership and consortium model for the National Innovation Accelerator, learning from successful Nordic models (e.g. Oslo Cancer Cluster; KTH Cybercampus) and provide industry partners with clearly structured, pre-competitive access to the cluster technology infrastructure, data environments, and co-development and industry user opportunities on a continuous basis.

The cluster will generate a new class of technology and data based innovation assets, study-ready cohorts, novel IP, and clinical data services that cannot be replicated outside this integrated infrastructure. The six initial demonstrator projects, provide concrete illustration for this strong innovation potential. For example, demonstrator D creates a prospective, molecularly characterised prostate cancer cohort, SPRINTR, covering more than 90% of newly diagnosed patients across all Swedish university hospitals, with broad data reuse and AI training consent, making it a directly investable asset for pharmaceutical and diagnostics companies, which is second to none in Europe. Demonstrator B, BioBladder, has generated patent-protected spatially resolved companion diagnostic IP (isPLA/mIF) embedded in a national observational platform for urothelial cancer, strategically positioned for direct co-development across other solid tumour indications. Demonstrator A integrates synchrotron-based 3D tissue imaging at MAX IV with spatial transcriptomics to produce mechanistic tissue resolution unavailable in any existing clinical pathology workflow, extensible as a fee-for-service co-development platform for drug discovery, a facility with no equivalent clinical integration elsewhere in Europe or to the best of our knowledge world-wide.

By linking these unique breakthrough technology and data assets with a nationally coordinated innovation and commercialisation framework, WP6 positions the cluster to capture a substantial share of the projected €61 billion EU digital health market, make major contributions to the €252 billion in estimated net cost avoidance from technology-driven healthcare, and establish Sweden as a global reference for AI- and technology-driven life science innovation through 2035 and beyond.

Task 6.1: The National Innovation Coordination Office (NICO). NICO will be the operational hub of the National Innovation Accelerator, providing the coordination layer that integrates the cluster's research, clinical, and commercial activities into a coherent national innovation system. It connects the pentagon of academia, healthcare, industry, regulatory authorities, and patient organisations, and aligns the currently fragmented network of university holding companies, incubators, and SUHA regional innovation nodes around shared priorities. Core

functions include standard and rapid agreements for national industry co-development opportunities, spin-out incubation and industry access to the clinical infrastructure platform, rapid clinical validation pathways through WP3/WP4, regulatory navigation through WP7 and WP8, and proactive readiness for healthcare implementation through WP5. NICO also manages the National Innovation Accelerator's membership structure, ensuring that industry partners have structured and pre-competitive access to cluster capabilities and data assets on an ongoing basis.

Task 6.2: National Venture Acceleration Programme. Coordinating the Swedish innovation system and combining it with BII's internationally validated approach, this task establishes a structured national venture acceleration programme that integrates commercial support with the cluster's clinical and technological infrastructure, a combination that standard accelerator and incubator models cannot offer. Systematic scouting across the Swedish research community, the clusters WP1–2 technology outputs, demonstrator projects, and MAX IV's and SciLifeLab's Infrastructure generates a continuous pipeline of investment-grade opportunities in multimodal molecular profiling, spatial biology, X-ray and advanced imaging, AI-enabled diagnostics, and precision medicine. Selected projects will enter a tailored fast track co-developed programme covering scientific, clinical, and commercial due diligence; IP strategy; regulatory and reimbursement planning; and health care implementation and investment readiness, structured using Investment Readiness Levels (IRL). A defining feature is that accelerating ventures gain direct access to clinical infrastructure testbeds, federated health data environments, and a translational validation infrastructure and health care implementation process jointly operated by SciLifeLab, MAX IV, and SUHA enabling generation of regulatory-grade clinical and health-economic evidence in real-world settings. This substantially accelerates breakthrough technology and data/AI based ventures in building value and de-risk their assets for investors. The programme supports commercialisation pathways along the innovation chain, including startup formation, SME growth support, licensing, public-private partnerships, and international scale-up. Further, it builds sustained entrepreneurial capacity through structured mentoring by the experienced founders, clinicians, investors, and industry leaders from the cluster partner network and our dedicated senior innovation advisor group.

Task 6.3: National Innovation and Translation Fund. In addition to the Venture Acceleration Programme, the cluster's National Innovation and Translation Fund directly addresses the pre-seed and seed capital gap that prevents high-quality health technology discoveries from rapidly building value and reaching the stage where standard institutional and international venture capital can engage. The fund targets an initial volume of 500 MSEK, and provides pre-seed allocations (~1 MSEK) for rapid "fail or fly" start-up and seed funding (~10 MSEK) for high-potential projects to enter the full acceleration programme. The fund will draw on syndicated capital from public, private, and philanthropic sources, and align with synergistic pre-seed initiatives such as the Wallenberg launch pad (WALP) and second-stage co-investment through BII's Catalyst Fund for Swedish startups. Beyond providing capital, that the fund will replenish by taking a modest equity in seed-funded ventures, the fund operates as a national venture-building mechanism: strategically important assets whose originating researchers do not pursue commercialisation themselves, so-called orphan discoveries, are matched with experienced entrepreneurs, venture builders, and financing from the cluster network through a digital matchmaking platform, ensuring that high-value innovations are not lost due to lack of a designated commercial driver. This creates a continuously replenishing pipeline of investment-ready ventures and materially strengthens the cluster's attractiveness to global health technology investors and pharmaceutical partners.

Task 6.4: Compliant-by-Design and Tailored Innovation Pathways. Precision medicine and AI innovations face structural regulatory barriers under MDR, IVDR, and the EU AI Act that, when addressed late in development, significantly increase cost and delay market entry. Task 6.3 embeds regulatory and reimbursement expertise from the earliest stages of the innovation cycle, operationalising a Compliant-by-Design approach in close coordination with WP7 and WP8. WP6 will develop tailored, nationally aligned innovation pathways for the

principal asset classes the cluster generates such as companion diagnostics, AI-enabled clinical decision support, and multimodal data services utilising the SciLifeLab Clinical Infrastructure Platform and the TEF-Health framework for validation and beta-testing. Established hospital exemption pathways will enable rapid clinical piloting of early-stage technologies ahead of formal regulatory submission, shortening the timeline from validated prototype to first clinical use.

Table 5. WP6 — National Innovation Accelerator: Industry Collaboration & Commercialisation | Lead: Per Lek		
Task	**Expertise & Resources**	**Key Output**
6.1	Cluster coordinators, business developers, legal/regulatory specialists & senior entrepreneurship advisors	National innovation management structure; industry agreements; asset registry; long-term partnership membership model
6.2	NICO, BII, Navigare Ventures, venture investors & serial entrepreneurs	Investment-ready health technology portfolio; national mentor network; validated technologies positioned for commercial deployment
6.3	Fund managers, venture builders & Nordic/European VC syndicate partners	Sustainable 15-year financing mechanism; national venture-building supporting 5 high-potential projects annually; BII Catalyst Fund syndicate
6.4	Regulatory (WP8), health economics (WP7) & clinical implementation experts (WP3/4/5)	National innovation pathways; regulatory toolkits by asset class; hospital exemption pathways for rapid clinical piloting

WP8 — Regulatory, Legal and Policy Frameworks

WP8 ensures that the cluster's scientific ambitions are matched by governance frameworks that are legally robust, ethically sound, and practically implementable (Table 6). Operating at the intersection of health law, regulatory science, and responsible innovation, WP8 fulfils two interconnected roles: a coordination function, enabling the lawful and compliant operation of the federated clinical infrastructure across the cluster; and a research function, generating the new legal and governance knowledge required to govern emerging precision medicine technologies. WP8 has four overarching objectives: (1) to establish a harmonised regulatory and governance framework for the federated clinical infrastructure (WP3–6); (2) to develop scalable legal and contractual models for multimodal health-data sharing, AI development, and public-private collaboration within secure federated environments; (3) to support the lawful, ethical, and clinically safe deployment of AI-enabled diagnostics and decision-support systems, and to provide structured monitoring of operational ELSI, ethical, legal, and social issues arising across the cluster's lifetime that fall outside the SSH research scope of WP7; and (4) to generate policy recommendations and governance blueprints aligned with EHDS and the AI Act, while actively championing legislative modernisation, in particular, the transition from opt-in to digital opt-out informed consent under Patient data act (Patientdatalagen) essential for unlocking the full potential of real-time clinical data for precision medicine.

SciLifeLab is a national research infrastructure and collaboration platform rather than a separate legal entity. To mitigate any governance, contracting, and liability risks associated with this structure, the cluster will operate through a clearly defined federated governance model in which all legal commitments, funding agreements, procurement activities, employment arrangements, and intellectual property transactions are undertaken by participating legal entities. A central unit will provide strategic coordination and stakeholder engagement, while formal responsibilities will remain with designated partner institutions under consortium agreements and established governance procedures. Harmonised regulatory, data governance, and operational frameworks developed within the cluster will ensure transparent decision-making, accountability, and legal certainty across all participating nodes. This approach builds on SciLifeLab's proven national operating model and enables effective coordination at scale without requiring the creation of a separate legal entity.

Task 8.1 – Regulatory Mapping and Legal Interoperability. This task analyses how existing and emerging European and Swedish legal frameworks apply to the federated clinical infrastructures and AI-enabled healthcare environments of WP3 and WP4. Special attention is given to regulatory frictions at the intersection of research infrastructures and healthcare operations, where responsibilities are distributed across institutions and regions. The task produces a regulatory interoperability framework for federated precision medicine; legal gap analyses; implementation guidance; governance recommendations for cross-node collaboration; and trusted AI deployment pathways.

Task 8.2 – Contractual Governance and Data-Sharing Models. Federated AI-driven infrastructures require new legal coordination between universities, healthcare providers, infrastructure operators, industry actors, and public authorities. This task develops standardised contractual templates; governance models for Secure Processing Environments (SPEs); data-access governance structures; intellectual property and licensing frameworks; models for responsible AI development partnerships; and governance mechanisms for cross-border and cross-sectoral data access. This work focuses on building legally sustainable structures to balance openness, innovation, patient protection, and industrial collaboration within the European health-data ecosystem.

Task 8.3 – Governance of Clinical AI Translation and ELSI Monitoring. The transition from experimental AI systems to clinically deployable decision-support tools raises fundamental questions of validation, explainability, human oversight, model drift, clinical accountability, and post-deployment monitoring. WP8 develops governance frameworks for AI validation and deployment in collaboration with TEF-Health; supports compliance pathways under MDR, IVDR, and the AI Act; and analyses human-in-the-loop governance models for continuous learning systems in healthcare settings. In parallel, WP8 fulfils a dedicated operational ELSI monitoring function for the cluster, providing structured oversight of ethical, legal, and social issues — including those arising from individual demonstrator projects — that require active management across the cluster's lifetime. Each demonstrator will be subject to annual ELSI review, aligned with the project's yearly reporting cycle, ensuring that responsible conduct remains integral to the cluster's operations rather than one-time compliance exercises.

Task 8.4 – Policy Development, Legislative Modernisation, and International Positioning. Research findings from WP8 are translated into strategic policy recommendations for Sweden and the European precision medicine ecosystem. A specific priority is the modernisation of national legislation: the cluster will actively advocate for a transition from the current opt-in to a digital opt-out informed consent model under Patientdatalagen, a reform that is essential for realising the full value of real-time clinical data in research, AI development, and patient benefit, and in which Sweden has the opportunity to lead internationally. More broadly, WP8 produces national and European policy briefs; recommendations for health-data governance; proposals for regulatory sandboxes and innovation governance; strategic guidance for national authorities; and frameworks for trusted cross-border collaboration and ethical AI governance. Alongside its technological and clinical achievements, the cluster thereby contributes governance leadership at the European level.

Table 6. WP8 — Regulatory, Legal and Policy Frameworks | Lead: Frantzeska Papadopoulou, Stockholm University

Task	Expertise & Resources	Key Output
8.1	Legal scholars (Stockholm Univ.) & compliance officers (KI and partner universities)	Regulatory interoperability framework; governance recommendations for federated cross-node collaboration
8.2	IP & data governance specialists; industry & healthcare representatives	Standardised contracts; SPE governance models; IP/licensing frameworks for cross-sectoral collaboration
8.3	Legal/ELSI experts, regulatory specialists & clinical leads (WP5); TEF-Health partners	AI governance frameworks; MDR/IVDR & AI Act compliance pathways; annual ELSI monitoring structure
8.4	Legal scholars, policy experts & European health regulation advisors	Policy briefs; Patientdatalagen reform recommendations; regulatory sandbox proposals; cross-border governance frameworks

Cluster Potential

The cluster is positioned to generate substantial and quantifiable economic, industrial, and societal value by converting Sweden's research excellence into a nationally coordinated pipeline of breakthrough technology and AI driven innovations for the health market. The projected KPI trajectory (Table 1) is grounded in the operational logic of the best practice Nordic example, the Danish BII model, adapted to the scale and infrastructure of the Swedish cluster. By year three, the cluster is projected to have supported 15 proof-of-concept projects and produced 6 seeded spin-outs, raising over 500 MSEK in external funding against just over 70 MSEK of internal fund deployment — a leverage ratio of approximately 7:1 that reflects the capital-efficiency of the cluster's approach during its build phase. By year ten, over 40 spin-outs are projected, over 10 new products on the market, around 20 clinical trials initiated, and roughly 400 jobs created, with external funding reaching 3,8 BSEK against 500 MSEK

deployed from the National Innovation and Translation Fund — a sustained leverage ratio of more than 7:1 (Table 7). These projections are conservative relative to the capital deployed: they assume a graduation rate and exit timeline consistent with comparable deep-tech life science ventures in the Nordic region. However, our unique National Venture Acceleration programme (WP6) at the new SciLifeLab clinical infrastructure platform (WP3/4) will significantly shorten the innovation and exit timelines and very likely lead to a higher leverage ratio as the clusters starts operating.

The commercial opportunity is structured around four spinout types (Table 7), each with distinct capital requirements, development timelines, and validated international exit comparables. The most capital-efficient near-term opportunity lies in AI Clinical Decision Support Tools and Multi-Omics Molecular Profiling ventures — both reachable within two to five years and directly analogous to exits including Olink Proteomics ($3.1B, acquired by Thermo Fisher) and Congenica (£70M+, acquired by SeqOne). These asset types are well matched to the clusters venture support model and can be bootstrapped with grant and innovation fund capital before requiring institutional VC. The Federated Clinical Data Platform category carries moderate capital intensity and a governance precondition that WP8 will resolve, making it a mid-term opportunity comparable to Owkin's $1B+ valuation trajectory. AI Therapeutics with Privileged Data Access is the highest-capital and longest-horizon category but also the highest-value, with comparable exits at BioAge Labs and Verve Therapeutics exceeding $1.3B; the cluster's nationally unique data and cohort assets provide the differentiated foundation this category requires.

The broader market context supports this ambition. The EU digital health market is projected at €61 billion, and technology-driven healthcare has an estimated €252 billion potential in net cost avoidance across the EU, figure the cluster's WP7 health economic research will help translate into Sweden-specific impact estimates. Societally, the cluster's value extends beyond company creation: by accelerating the adoption of mechanism-guided diagnostics and treatments, it directly reduces the clinical and economic burden of high-prevalence diseases including cancer and cardiovascular disease, with strong relevance for an ageing population. The feasibility of these outcomes rests on three factors that distinguish this cluster from prior Swedish efforts: the national reach of the SciLifeLab Clinical Infrastructure Platform for breakthrough technologies and Data/AI, providing real-world validation environments that de-risk assets for investors; the structured 500 MSEK national innovation fund providing capital at the stage where VC does not yet engage; and the formal coordination of university holding companies, incubators, and SUHA nodes through the NICO, ensuring that promising discoveries do not stall for want of commercialization.

Spinout Type	Capital Intensity	Time to Fundable Milestone	Closest Global Exit	Fit for Bio-Innovation Institute Model
AI Clinical Decision Support Tools	Low to moderate	2–3 years	Congenica (£70M+, acquired by SeqOne)	High — venture lab co-development model
Multi-Omics Molecular Profiling	Low	3–5 years	Olink Proteomics ($3.1B, acquired by Thermo Fisher)	High — capital-light, grant-bootstrappable
Federated Clinical Data Platform	Moderate	3–4 years	Owkin ($1B+ valuation, unicorn)	Medium — requires governance preconditions
AI Therapeutics with Privileged Data Access	High	5–8 years	BioAge Labs ($285M+), Verve Therapeutics ($1.3B, acquired by Lilly)	Medium — right thesis, longer capital horizon

Metric	Year 3	Year 5	Year 10
PoC projects (1MSEK)	15	25	50
Spin-outs/seed (10MSEK)	6	16	42
External funding raised (MSEK)	539	1,438	3,775
Internal fund deployed (MSEK)	77	193	500
Jobs created	55	148	387
Clinical trials initiated	2	6	19
Products on market	2	4	12

Table 7. Left: *An overview map of spinout types.* ***Right****: The expected key metric outputs.*

Organisation and management

The organisation of the excellence cluster *Breakthrough Technologies for Health*, will combine comprehensive national representation in its strategic governance (Board), strong leadership and competence at the executive level (Management Group), with an agile and highly professional implementation support and coordination team (Operations Office).

Strategic oversight will be provided by the interim Steering Board, that was already constituted in December 2025, following the positive phase I funding decision of this cluster,

and oversaw the preparation of this phase II proposal. The Board brings together senior representatives from all major Swedish universities and university hospitals, as well as the director/chair of their national organizations for life science and health, SciLifeLab and the Swedish University Hospital Alliance, SUHA. Key additional partner organisations, such as MAX IV, Genomic Medicine Sweden (GMS), and an industry representative are also already members (Fig. 4). The Board members have confirmed their roles and can take office immediately following the funding decision. The Board will be responsible for overall strategy, approve the cluster's annual strategic plans, its corresponding budget framework, decide on new cluster members and international partnerships and prepare its long-term sustainability. The Board ensures strong and inclusive national anchoring and coordination. It assembles the strategic insights and responsibility needed to realise the cluster's ambitious vision to make Sweden a leading nation in technology and AI driven precision medicine.

Operational leadership will be provided by an executive Management Group, co-chaired by the Project Leader (and Interim Cluster Manager), the Research Manager, and the Cluster Innovation Manager that will be appointed as soon as the cluster obtains innovation funding. The Management Group furthermore comprises all ten work package leads that lead carrying out the cluster activities (Fig. 4). The Management Group will coordinate the operational activities across the cluster's research, clinical infrastructure, innovation and health care implementation flow, prepare strategic plans and resource allocations as well as proposals for adding new partners for the Steering Board. The Management Group will ensure delivery of the cluster's objectives by providing the roadmap for the national Operations Office to coordinate and support implementation.

Nationally coordinated support of the implementation of the cluster's activities will be carried out by an agile, highly professional and nationally coordinated Operations Office. This team will be composed of highly professional cluster project manager, coordinators, economists and area specialists with relevant technical and scientific background. It will include the National Innovation Coordination Office (NICO) to provide specific support for all innovation activities, included coordinated management of intellectual assets. It will coordinate national implementation of the cluster roadmap prepared by the Management Group and approved by the Board, carry out financial controlling and reporting to the funders and oversee external and internal communication and marketing of the cluster.

To gather input from key stakeholder throughout its operation, the cluster has set up three complementary advisory committees. The first is the patient and public authority authority advisory committee, which will ensure the cluster is always guided by human dignity and patient needs and aligns its activities closely with the political and regulatory framework of Sweden and its health care system. Patient representatives and government authorities have already expressed their interest to participate. It is expected that this group elects a representative member to the cluster Board. The second is the industry advisory committee, which will represent the Swedish, European and international companies that are key partners to deliver the cluster objectives (see industry LoI overview, Fig. 5). This group has already elected a representative (Astra Zeneca) to the cluster Board. The third, is an innovation advisory committee, consisting of senior innovation leaders, serial entrepreneurs, investors, and additional innovation ecosystem actors. This group will provide advice on all innovation activities, including start-up mentoring and venture acceleration as well as support innovation

fundraising. Explanation of Project Leader and Cluster Manager. During the establishment phase, Jan Ellenberg will serve as the Project Leader and Interim Cluster Manager. Beyond his international leadership as a scientist in breakthrough technology driven life science, Jan Ellenberg, has extensive experience in leading large-scale European research consortia and infrastructures. Since becoming director of SciLifeLab, Jan Ellenberg has engaged in building national partnerships in breakthrough technologies for health across research infrastructures, healthcare, academia and industry. He is mandated to take the dual role in leading this cluster at the startup phase by the SciLifeLab board representing all major Swedish universities including the SciLifeLab founding university Karolinska Institutet, through which this application is submitted, that both see it fully in line with his role and mandate as director of SciLifeLab. A key task during the establishment phase as soon as the cluster obtains innovation funding, will

be the recruitment of a full time Cluster Manager, with strong innovation expertise, complementing the profile of the Project Leader. Once funded, the cluster will be in a very strong position to attract the strongest innovation professionals to this role.

Figure 4. *Organogram of the projects organization and management*

Participating parties

The cluster brings together a unique national partnership spanning research infrastructures, healthcare, academia, industry, investors, and the innovation ecosystem. Core partners include SciLifeLab, MAX IV, the Swedish university hospitals through SUHA, Genomic Medicine Sweden (GMS), medical faculties, industry partners, and national innovation actors. Together, they provide complementary expertise in breakthrough technologies, AI, precision medicine, clinical implementation and innovation, and commercialization.
The participating organizations share a common ambition to accelerate the translation of breakthrough technologies into excellent research, patient benefit, societal impact, and industrial growth. SciLifeLab and MAX IV contribute world-leading technology platforms, data capabilities, and expert communities. SUHA, GMS, and the university hospitals provide clinical environments, patient access, and implementation pathways, while industry partners contribute co-development opportunities, regulatory expertise, and routes to market.
A particular strength is the engagement of innovation actors across the entire value chain, including university holding companies, incubators, science parks, industry networks, entrepreneurs, and investors such as Navigare Ventures and the BioInnovation Institute (BII). Together, they provide expertise in venture creation, validation, commercialization, and growth financing, enabling rapid translation of innovations emerging from the cluster.
The combined competencies create a nationally coordinated environment for technology development, clinical validation, healthcare implementation, and commercialization. During the programme period, additional capacity will be developed in regulatory science, AI-enabled innovation, implementation science, and growth financing. New companies, investors, patient organizations, public agencies, healthcare providers, and international collaborators will be engaged through demonstrator projects, competitive calls, and strategic partnerships, ensuring continuous renewal and strong end-user involvement.

Overview of the project plan and innovation budget

The proposed budget for the innovation plan is designed to deliver the cluster's core objective: accelerating the translation of breakthrough technologies for health into clinically implemented and commercially viable solutions at national and in the longer-term international scale. It is structured into six of the clusters overall ten work packages, of which some are solely funded by the innovation budget (WP 5, 6, and 8), while others also receive additional funding from the research budgets (WP 3, 4 and 10 as well as demonstrator projects) due to the closely integrated nature of research and innovation in our cluster concept.

The largest investments are directed toward the clinical infrastructures for breakthrough technologies (WP3), as well as data and AI (WP4), and healthcare implementation activities (WP5), which together establish the integrated translational platform described in the innovation plan (tot. 52,5 MSEK for WP3-5). These work packages provide the technical, regulatory, data, and healthcare capacities required to adapt, validate, deploy, and scale new technologies across Sweden's university hospitals and internationally. The funding is sought for central functions such as bioinformaticians, regulatory specialist, data architects, data stewards, system developers, clinical experts and process leads. A federated structure with several roles represented at all seven university hospitals ensures clinical implementation across all SUHA sites as the gateway through which the clinical infrastructure platform technologies and AI tools reach patients. Continuous compliance readiness, from technology maturation through clinical validation, is provided by the dedicated regulatory specialists, in close collaboration with legal expertise in WP8. The core data governance roles ensure the data & AI infrastructure is designed for health care production-grade federated operation and fully prepared to deliver EHDS and EU AI Act compliance.

WP6, the Innovation Accelerator, provides the dedicated innovation, partnership, and proof-of-concept resources needed to bridge the gap between scientific discovery and commercialisation. This National Innovation Coordination Office (NICO) includes a national venture acceleration program coordinator, a national innovation and translation fund manager ad well as a clinical infrastructure incubator manager. Funding is sought at 10,5 MSEK for the innovation pipeline-building phase and will be expanded by leveraging substantial external co-development capital from industry and European programmes.

WP8 with and ELSI lead and patient engagement coordinator ensures that ethics, legal, and social science expertise underpins the cluster's responsible innovation mandate. It provides the ELSI foundation for WP4 data governance, WP5 patient engagement, and WP6 innovation legitimacy. Equitable access frameworks, regulatory alignment, and public trust are prerequisites for clinical adoption at national scale.

The dedicated cluster management (WP10) provides the coordination capacity necessary to integrate activities across all work packages and stakeholders of the entire cluster, with applied funding from both research and innovation budgets. The Cluster Manager and dedicated operational leadership across all WPs ensure focus on innovation delivery and external stakeholder engagement, freeing the Scientific Leader for scientific strategy.

Finally, the demonstrator project budget (composed of 8,5 MSEK funding from the innovation budget, complemented by the majority of funding from the research budget) enables competitive investment in the most promising technologies and clinical applications as they mature, maximizing impact and flexibility over the programme period.

Overall, the budget is calibrated to create a sustainable national innovation ecosystem that combines world-leading research infrastructures, healthcare implementation capacity, AI-enabled secure data environments, and innovation support into a coherent platform for precision medicine and health technology innovation.

Reference list of the Innovation plan

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