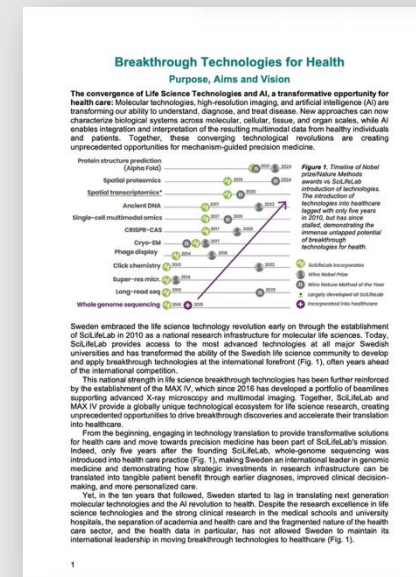


Breakthrough technologies for Health

Clusters of excellence for groundbreaking technology application
figures and tables



Breakthrough technologies for Health – Research plan



Research plan
22 pages

Breakthrough technologies for Health – Research plan Figure 1.

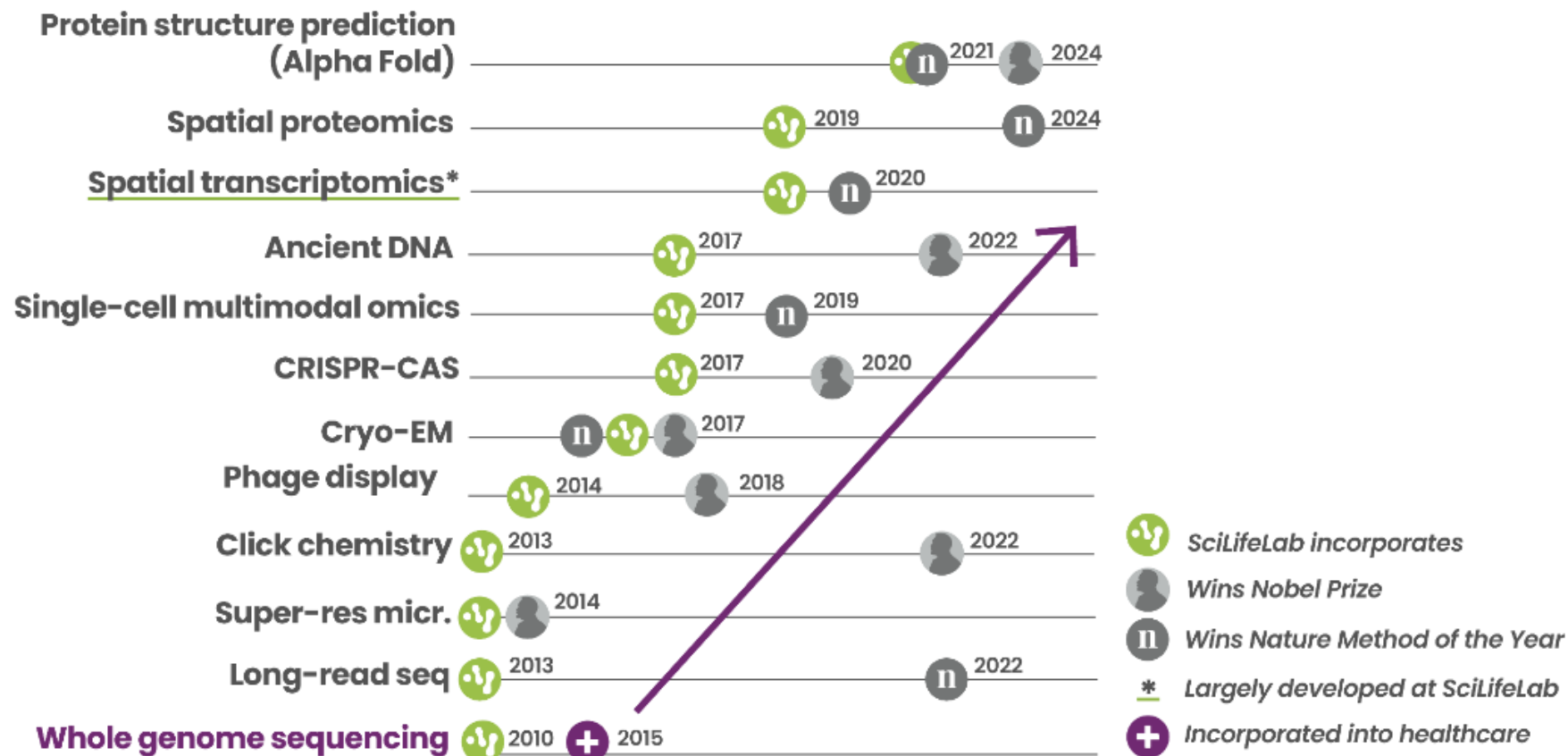


Figure 1. Timeline of Nobel prize/Nature Methods awards vs SciLifeLab introduction of technologies. The introduction of technologies into healthcare lagged with only five years in 2010, but has since stalled, demonstrating the immense untapped potential of breakthrough technologies for health.

Breakthrough technologies for Health – Research plan Figure 2.

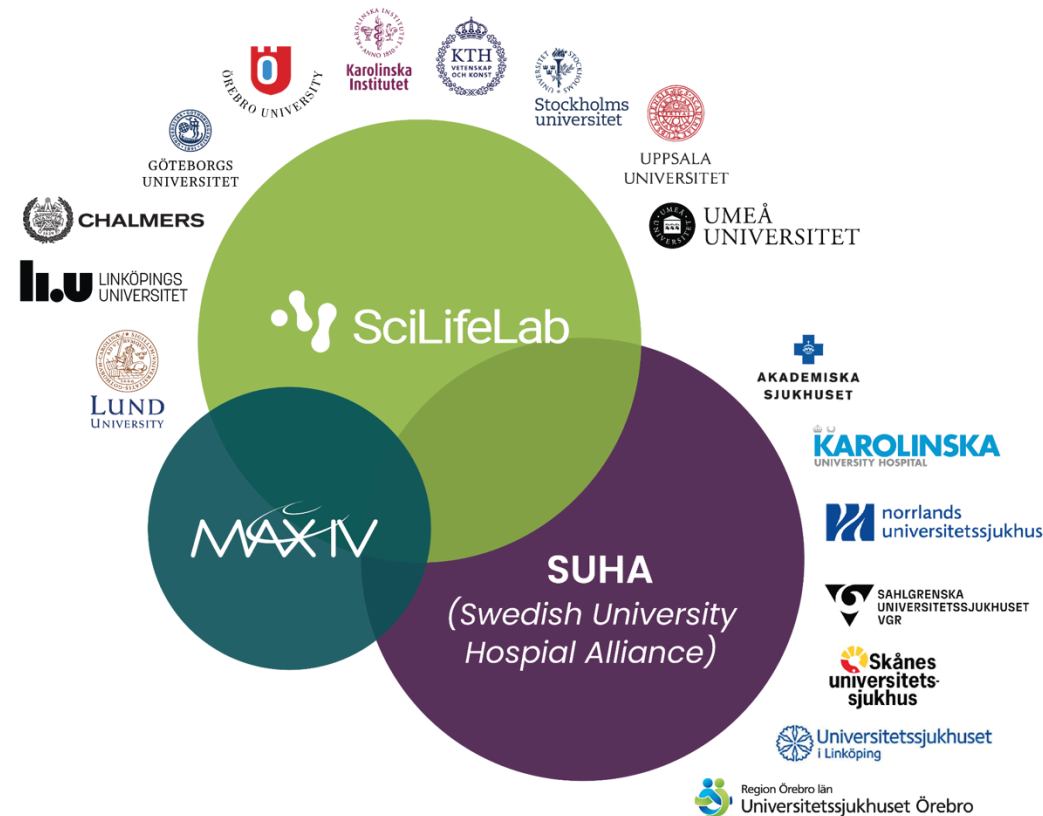


Figure 2. The excellence cluster 'Breakthrough Technologies for Health' joins together SciLifeLab, MAX IV and the medical faculties at the university hospitals with health care through SUHA. The Cluster brings together the excellence from universities with strong regional healthcare to accelerate research, innovation and healthcare implementation.

Breakthrough technologies for Health – Research plan Figure 3.

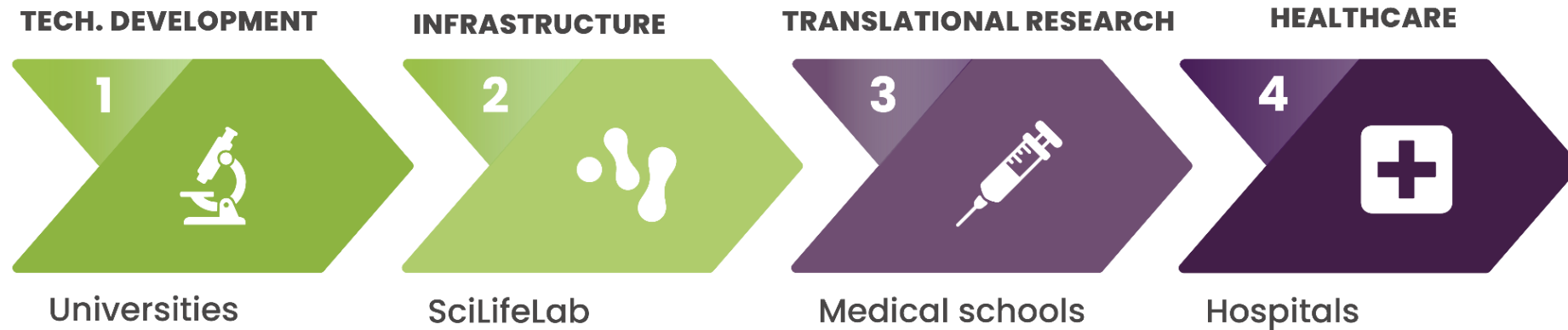


Figure 3. The excellence cluster takes a stepwise approach to ensure efficient translation from discovery to clinically implemented and commercially

Breakthrough technologies for Health – Research plan Figure 4.

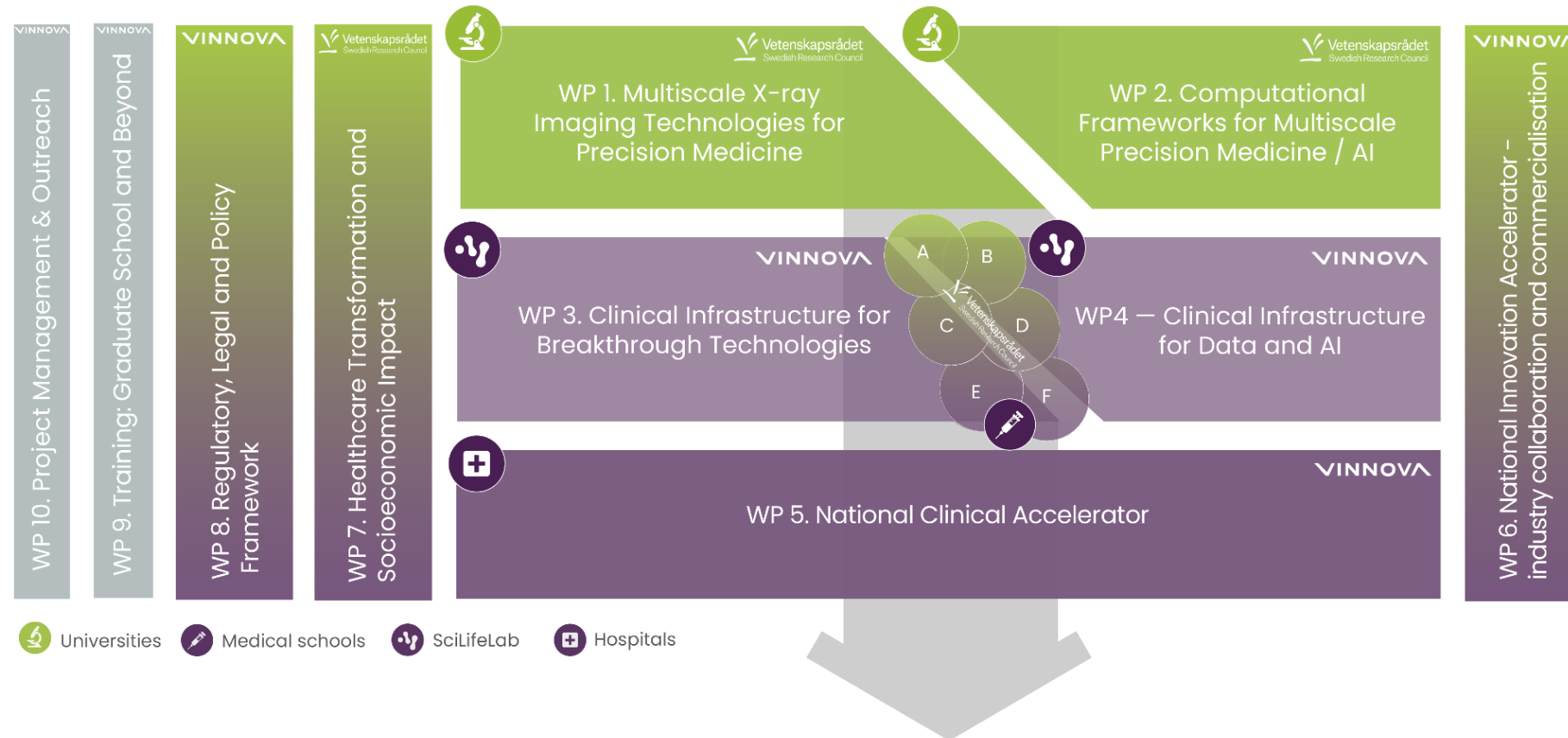
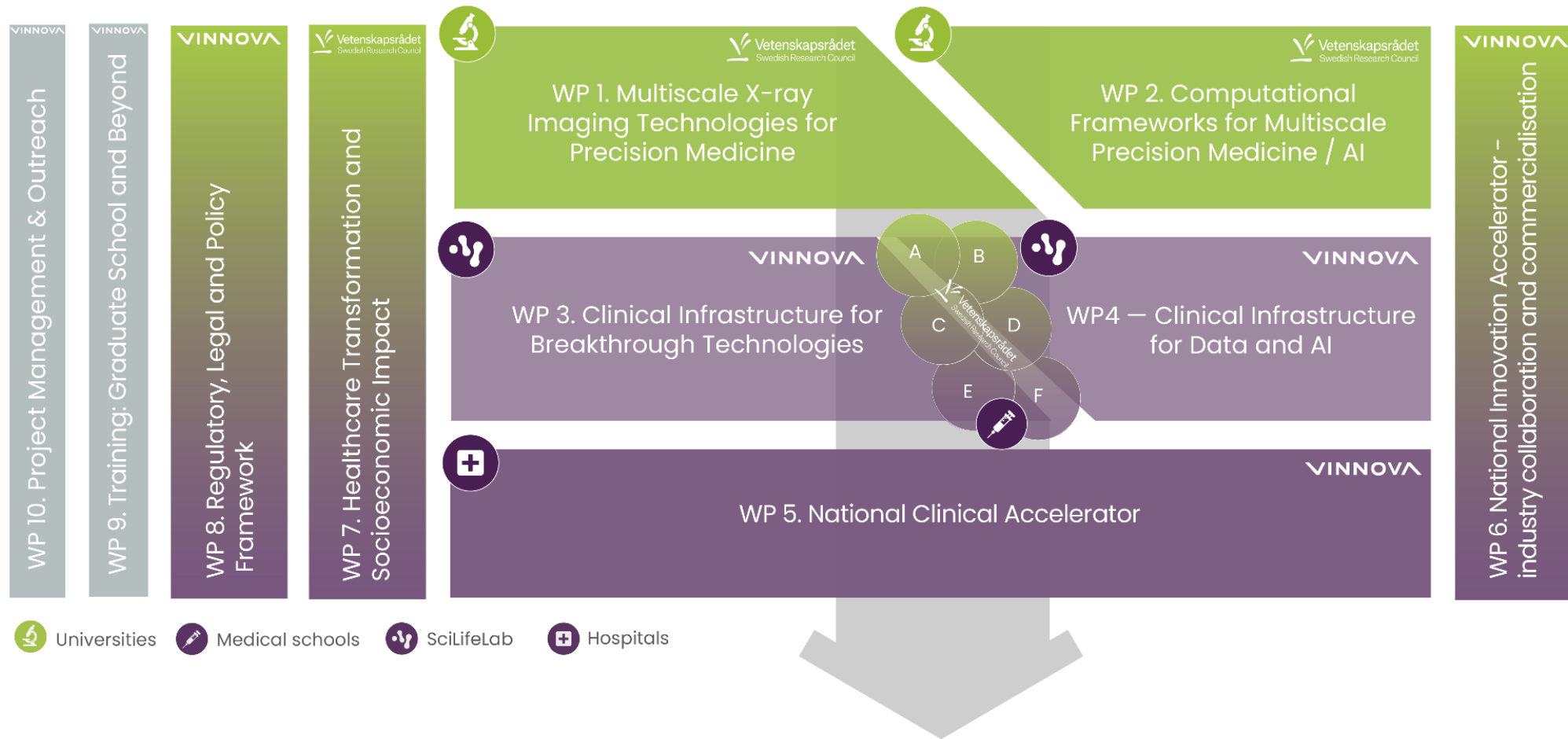


Figure 4. The Breakthrough Technologies for Health cluster consists of ten interconnected work packages, WP1- WP2 pioneer the technological core, developing multiscale synchrotron imaging and agentic AI for predictive modelling. Implementation is operationalized via WP3/WP4 establishing the SciLifeLab clinical infrastructure 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.

Breakthrough technologies for Health – Research plan Figure 4.



Breakthrough technologies for Health – Research plan Figure 5.

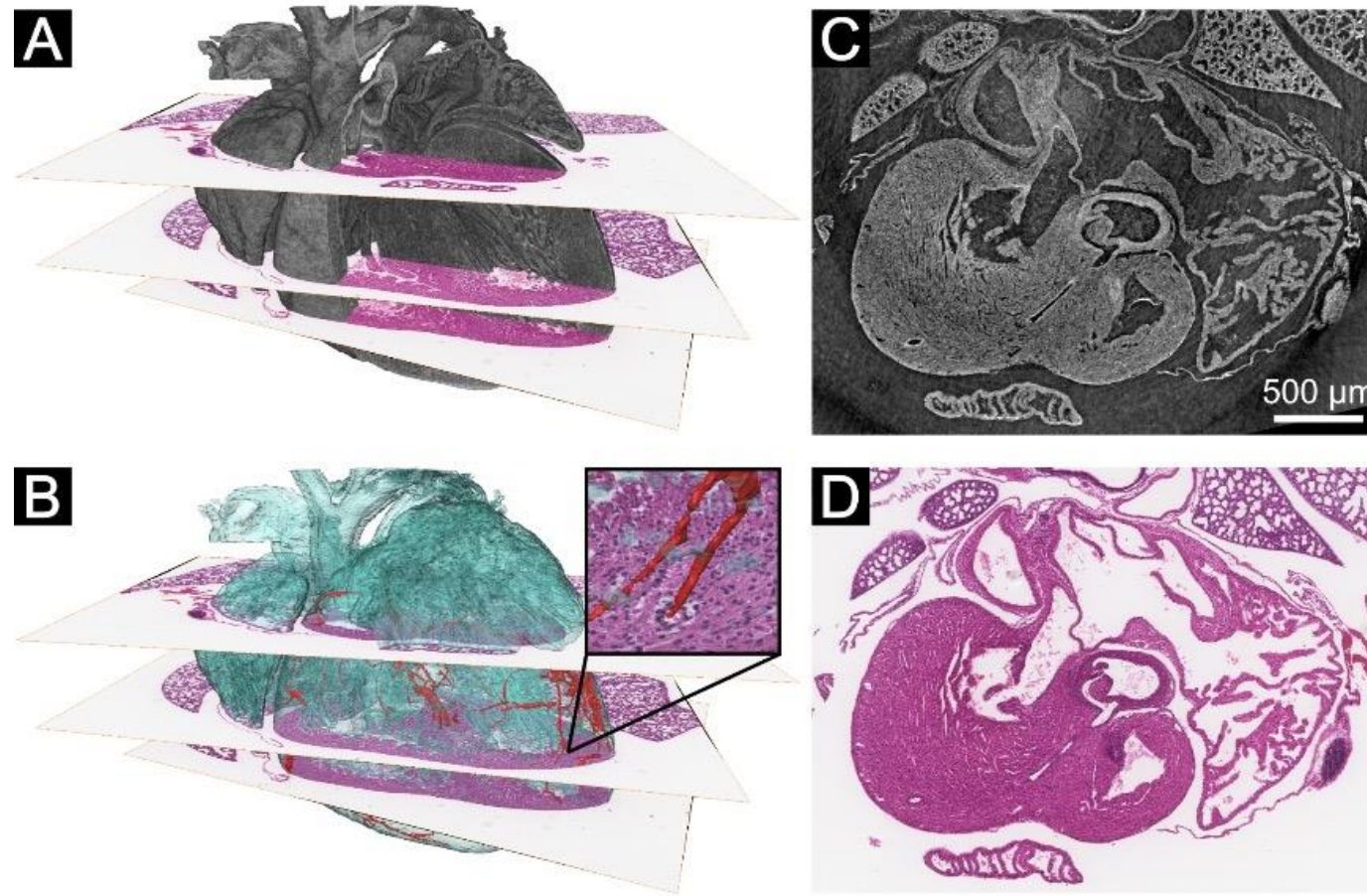


Figure 5. A-B) Integration of standard H&E staining with X-ray phase-contrast micro-tomography of a mouse heart. C-D) examples of sections through the volume matched between X-ray phase-contrast and histology (18).

Breakthrough technologies for Health – Research plan Figure 6.

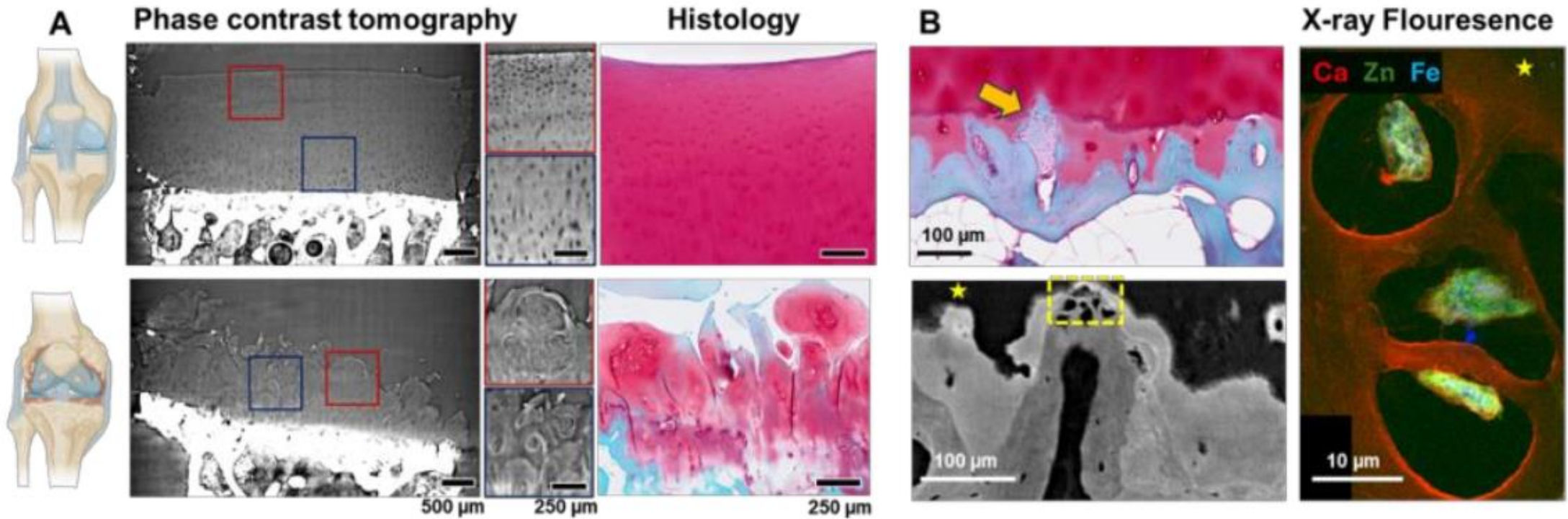


Figure 6. Multimodal and multiscale synchrotron imaging as A) Virtual histology for phenotyping of osteoarthritis (10), B) linking pain, nerve and vessel ingrowth to cell activity.

Breakthrough technologies for Health – Research plan Figure 7.

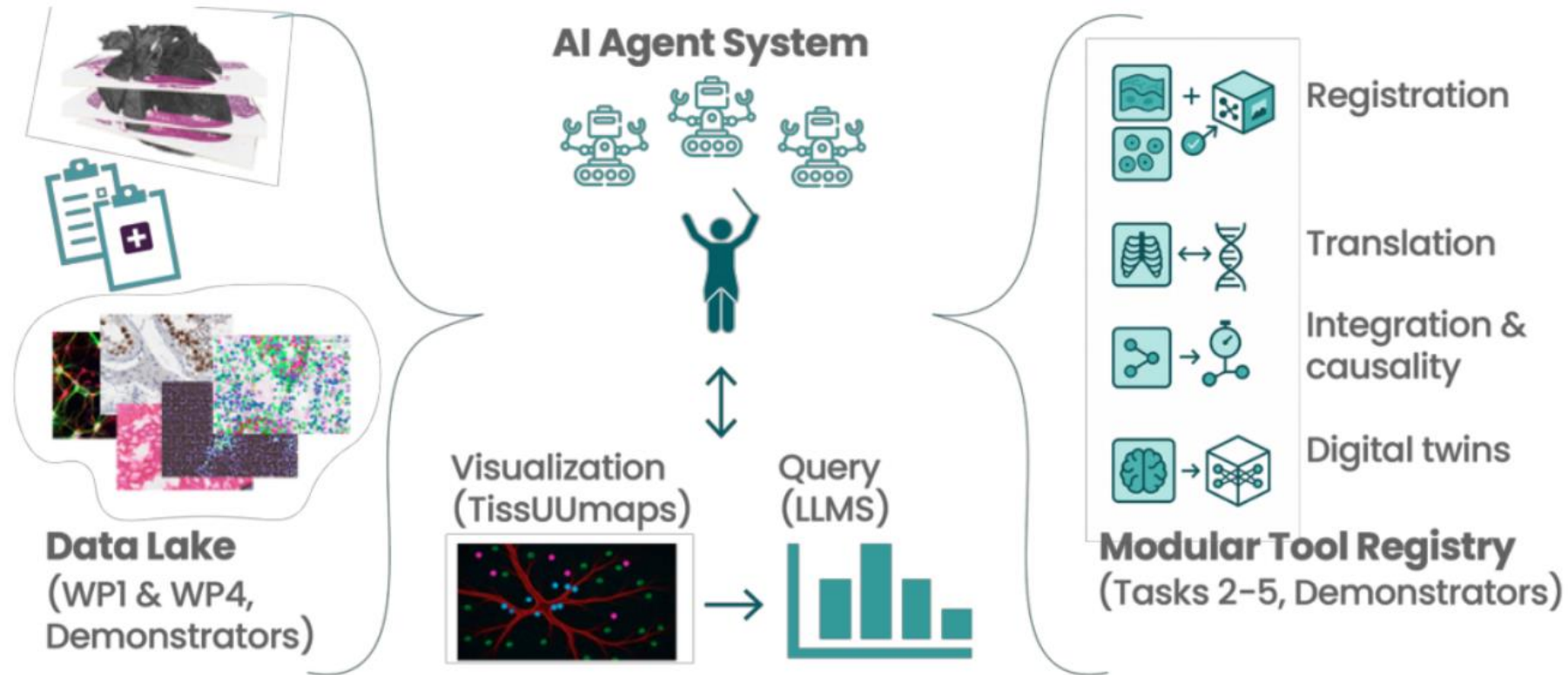


Figure 7. Overview of the computational framework. A multi-agent system acts on query input from the user, e.g., "Delineate the vascular system in this X-ray Computed Tomography (XCT) volume and locate adjacent immune clusters". It acts and reasons using input from Literature, the distributed Data Lake, the set of developed specialized AI tools. The expert can guide and refine the analysis via interactive visualizations in TissUMaps.

Breakthrough technologies for Health – Research plan Figure 8.

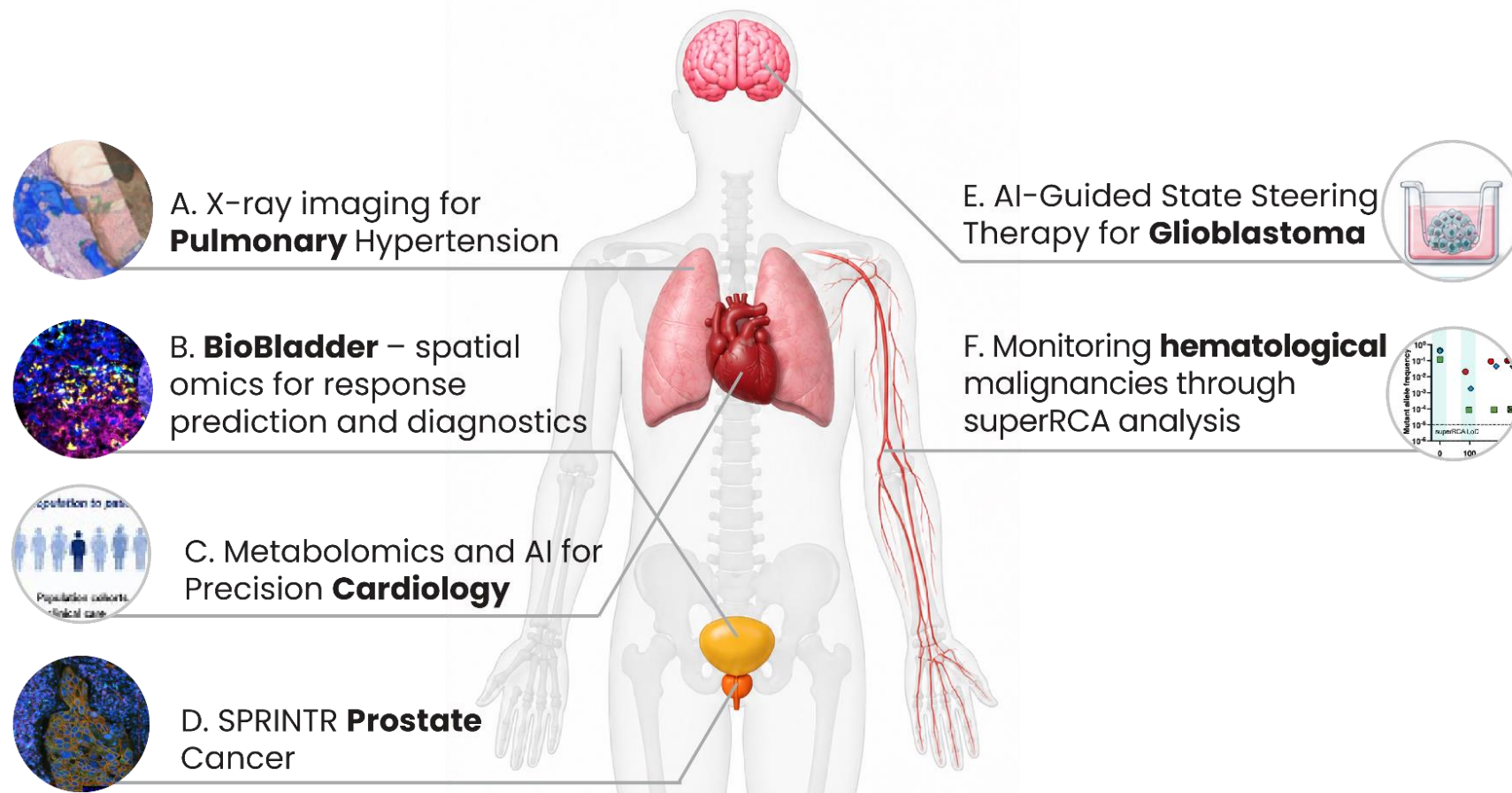


Figure 8. The six selected demonstrator projects representing different levels of maturation toward clinical implementation, and that will function as the clusters initial co-creation testbeds to refine the activities described in our work packages.

Breakthrough technologies for Health – Research plan Table 1.

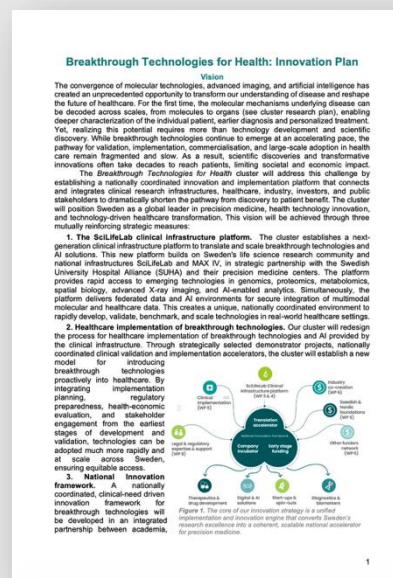


Phase	Theme I Sector-Specific Public Law	Theme II Private & Civil Law (Competition & IP)	Key deliverables (Arts.)
Yrs 1–2 Entry & capital formation	TI-A Regulatory Classification: classifying AI-enabled IVDs, companion diagnostics and digital therapeutics at the MDR/ IVDR/AI Act interface; a framework able to accommodate continuously-learning AI diagnostics.	TII-A Financing Framework: early-stage R&D finance, SAFEs, convertible instruments, blended public–private finance, adapted to university and spin-out settings; seeds the de lege ferenda basis for the Research Data Royalty Certificate (RDRC).	Classification framework; map of precision-medicine financing; RDRC concept and lex lata obstacles. (4)
Yrs 3–4 Development & scale-up	TI-B Manufacturing & Scale-Up: obligations on the research-to-commercial manufacturing transition (incl. structurally derived drug targets); GMP compliance tools for research facilities (MAX IV) entering the pipeline.	TII-B R&D Collaboration, Co-Development & Standardisation: model co-development and patent/ data-pooling structures, while providing a structural standardisation policy benefitting competitiveness; AI Act/IVDR harmonised standardisation.	Model co-development agreements; AI Act/ IVDR dual harmonised-standards solution; GMP toolkit. (3)
Yrs 5–6 Data & evidence	TI-C Real-World Data & Secondary Use: structuring the EHDS, GDPR and AI Act to enable precision-medicine research and AI training while protecting individual rights; data-sharing models for federated architectures of WP4.	TII-C Data Governance & RDRC Architecture: governance and value-allocation of health-data ecosystems; develops the RDRC, allocating value compatible with public-interest healthcare while preserving innovation incentives .	Complete RDRC legal architecture; federated data-governance models; mid-term conference. (3)
Yrs 7–10 Deploy-ment, account-ability & market access	TI-D/E Individual Protection, Accountability & Liability: revised informed-consent frameworks and clinician professional-liability guidance; liability allocation across the multi-actor chain under the revised PLD, the AI Act and Swedish tort law.	TII-D/E Patent Protection, Innovation Markets, Pricing & Reimbursement: patents, SPCs, data exclusivity and thicket risks; pricing and reimbursement of AI-driven precision medicine as a continuously-updatable clinical service.	IP reform proposals; pricing/reimbursement frameworks; liability framework; final anthology + practitioner database. (5+)

Table 1. Project outline: Years 6–10 consolidate and extend the foundational work of years 1–5 into reform proposals and practical instruments, culminating in an edited volume. Successive postdoctoral and PhD appointments are matched to project expertise; Frantzeska Papadopolou (PI WP8) supervises PhD Project under D/E under Theme II (years 7–10), integrating WP8, with the two PIs providing methodological continuity throughout.



Breakthrough technologies for Health – Innovation plan



Innovation plan
20 pages

Breakthrough technologies for Health – Innovation plan Figure 1.

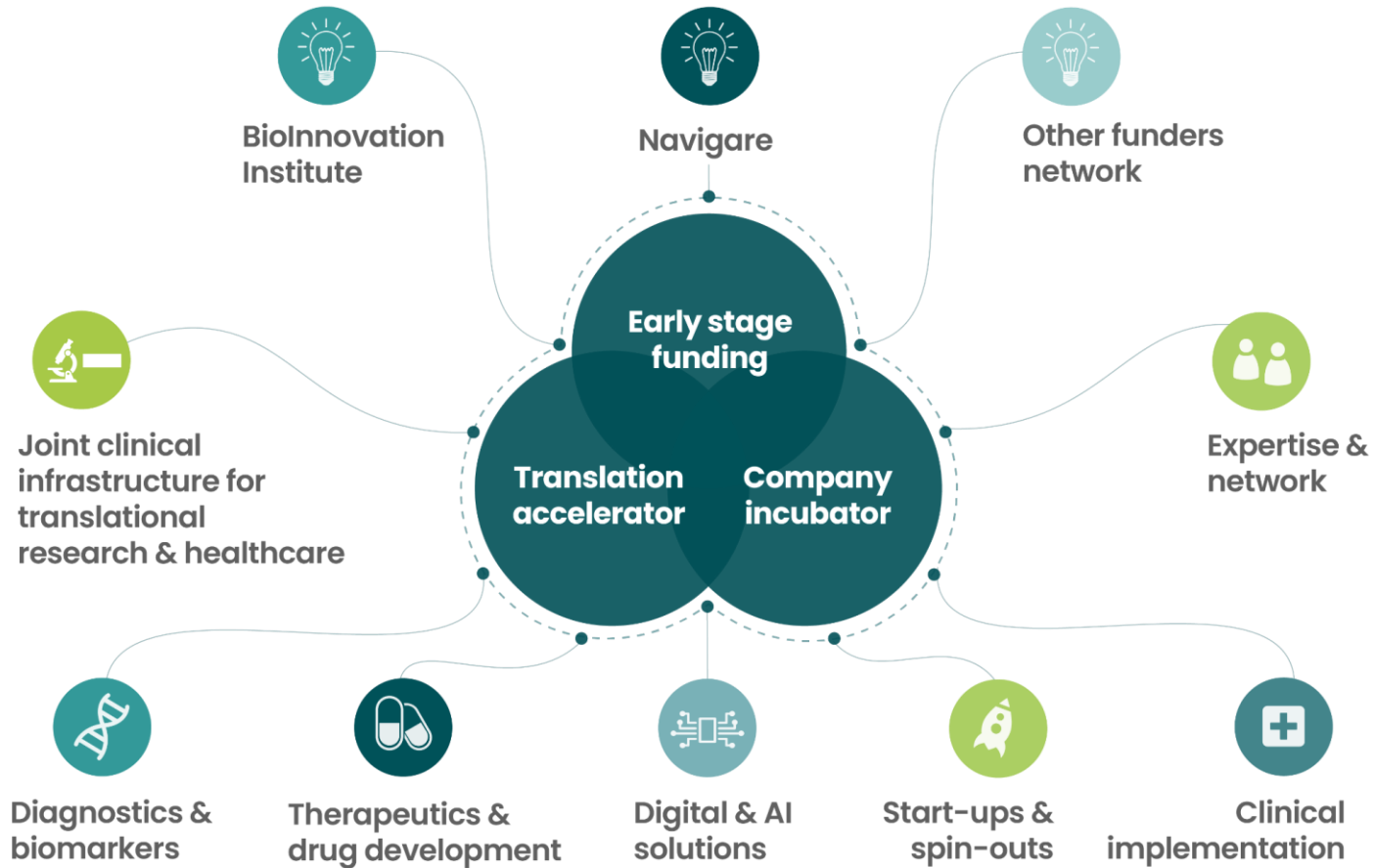


Figure 1. The core of our innovation strategy is a unified implementation and innovation engine that converts Sweden's research excellence into a coherent, scalable national accelerator for precision medicine.

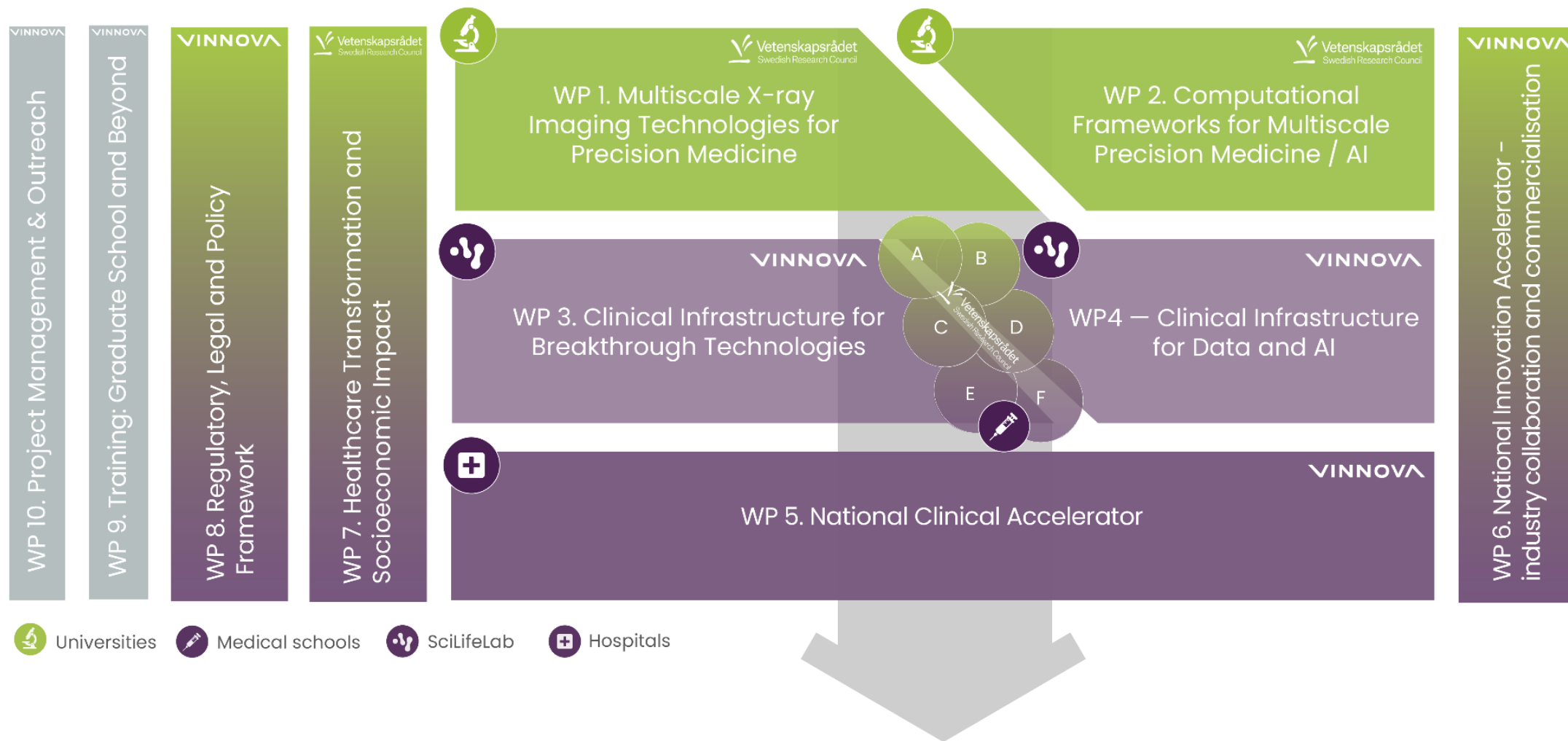
Breakthrough technologies for Health – Innovation plan Table 1.



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 enabling 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.

Breakthrough technologies for Health – Innovation plan Figure 2.



Breakthrough technologies for Health – Innovation plan Figure 3.



Figure 3. This cluster creates a new generation of embedded SciLifeLab clinical infrastructure 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.

Breakthrough technologies for Health – Innovation plan Table 4, 5.



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

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

Breakthrough technologies for Health – Innovation plan Table 6, 7.



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

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.

Breakthrough technologies for Health – Innovation plan Figure 4.



Figure 4. Organogram of the projects organization and management



Figure 4. Organogram of the project's organization and management.



Breakthrough technologies for Health – Doctoral program

WP9. National Graduate School and Beyond: A Cross-Disciplinary Training Platform for Breakthrough Technologies for Health

Program Description

The graduate school of the Breakthrough Technologies for Health excellence cluster represents a fundamentally new model for doctoral and professional training in life science and precision medicine. Rather than functioning as a traditional, discipline-bound PhD program, it is conceived as a cross-disciplinary training platform whose ambition is to form a vibrant, integrated community of researchers, clinicians, innovators, and technology developers around the shared mission of accelerating breakthrough technologies into patient benefit. Realizing this mission demands a new generation of professionals who are fluent across disciplinary, sector, and national boundaries: scientists who understand both molecular mechanisms and clinical workflows, data analysts who grasp regulatory pathways, and clinician-researchers who can harness AI-enabled tools critically. No single university or research group can provide this breadth. The graduate school does, through a nationally coordinated, infrastructure-anchored program that is unique in Europe.

Overall Vision and Three-Pillar Architecture

The training platform is organized around three mutually reinforcing pillars that together constitute a coherent ecosystem of education:

- 1. Doctoral excellence in breakthrough technologies.** A rigorous, interdisciplinary PhD-level curriculum that trains the next generation of researchers at the interface of synchrotron-based X-ray imaging, spatial multi-omics, AI-driven data science, and clinical translation. Doctoral students conduct research in internationally leading environments at host universities of SciLifeLab and MAX IV, undertake cross-sector secondments, and are exposed to the full translational value chain from technique development through clinical validation to healthcare implementation.
- 2. Technology and AI literacy for clinical researchers.** A dedicated educational track providing clinical researchers, healthcare professionals, and research engineers with practical competence in breakthrough molecular technologies, advanced imaging, and AI/ML-based analytics. As precision medicine technologies enter clinical workflows at accelerating pace, Sweden's capacity for adoption and equitable implementation depends critically on a clinically trained workforce that understands both the potential and the limitations of these tools. Intensive short courses, workshops, and a structured expert lecture series will serve this audience on an ongoing basis.
- 3. Innovation and translation education for all.** A suite of training activities focused on entrepreneurship, intellectual property strategy, regulatory science, health technology assessment, and implementation research. These offerings are open to PhD students, postdoctoral researchers, clinical investigators, and industry partners linked to the cluster, reflecting the conviction that translation is a team sport requiring shared language and shared competences across all participants. This pillar directly embeds the Innovation Plan's ambition to transform Sweden's fragmented discovery pipeline into a nationally coordinated, parallel-track innovation ecosystem.

The three pillars are united by a commitment to open access: all courses, summer schools, and lecture series developed within the program will be made available to participants beyond the formally enrolled doctoral students, extending the cluster's educational impact across the Swedish and Nordic research and healthcare communities. This community of learners, extending from enrolled PhD students to postdoctoral researchers, clinical investigators, research engineers, and industry scientists, constitutes the vibrant professional network that the graduate school is designed to cultivate.

Planned Educational Activities

The program's educational activities span five interconnected formats, each designed to address distinct learning objectives (Table 1).

Doctoral program
9 pages

Breakthrough technologies for Health – Doctoral program Table 1, 2.



Educational Activity	Format	Obligatory?	Open to Non-PhD Participants
Annual Cluster Meeting	yearly, 2–3 days	Yes, all students	Postdocs, industry
PhD Summer School (min. 3)	34x program, 5–7 days	Yes, (min 3) doctoral students	Postdocs, clinical researchers
Overview Courses (min. 3)	Block weeks, ~5 ECTS each	Yes (min. 3 courses)	All registered participants
Specialized Courses (min. 4)	Modules, 2–3 ECTS each	Yes (min. 6 ECTS)	All registered participants
Innovation Courses (min. 2)	Modules, 2–3 ECTS each	Yes (min. 4 ECTS)	All: industry, clinicians, postdocs
Expert Lecture Series	Rolling, ≥10 per year	Yes (10 lectures)	Open access, remote
Secondment	Min. 2 weeks, partner org.	Yes (1 minimum)	Postdocs (encouraged)
Peer Mentoring Program	Ongoing, yr 3–4 as mentors	Encouraged	N/A

Table 1. Educational activities of the Breakthrough Technologies for Health Graduate School.

University	Key Competencies Contributed to Graduate School
Lund University (host, MAX IV)	Synchrotron X-ray imaging, structural biology, materials characterisation, course coordination infrastructure, PRISMAS network, LINXS thematic initiatives
Karolinska Institutet	Clinical and translational medicine, precision oncology, spatial biology, AI in clinical diagnostics, regulatory medicine
Uppsala University	Structural biology, drug development and discovery, genomics, SciLifeLab platform expertise, bioinformatics, DDLS program host
Stockholm University	Computational biology, bioinformatics, data-driven life science, structural biochemistry
Royal Institute of Technology (KTH)	Data science, AI/ML engineering, computational imaging, digital health systems, signal processing
Chalmers University of Technology	Bioinformatics, AI for image analysis, imaging physics, health technology assessment, biomedical engineering
University of Gothenburg	Clinical research, health economics, implementation science, biomarker validation, SUHA partnership
Linköping University	Medical imaging, AI in diagnostics, clinical decision support, biomedical engineering, spatial biology
Umeå University	Epidemiology, clinical genomics, population health, data governance, infection and cancer biology
Örebro University	Clinical microbiology, translational infection research, hospital-based and implementation research

Table 2. Partner universities and key competencies contributed to the graduate school.