EP PerMed
European Partnership
for Personalised Medicine

EUROPEAN PARTNERSHIP

EP PerMed 3rd Round Table - Summary Report

Challenges and Best Practices in the Implementation of Personalised Medicine Approaches in Nordic Countries – Industry View

18.05.2026, Copenhagen, Denmark

EIT Health

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Table of contents

1 About the European Partnership for Personalised Medicine and its round table series

The vision of the European Partnership for Personalised Medicine (EP PerMed) is to improve health outcomes within sustainable healthcare systems through research, development, innovation and implementation of personalised medicine approaches for the benefit of patients, citizens and society.

EP PerMed is made up of over 60 international partners, mainly ministries and funders dedicated to supporting transnational efforts to foster and accelerate personalised medicine. It is also funded and supported by the European Commission as a co-funded partnership. With a total budget of around 375 million euros and a planned running time of 10 years from 2023 to 2033, its central goal is to support personalised-medicine related research and transfer the accomplished achievements and developments into healthcare across Europe and beyond.

Organised in five work packages led by different partners and covering programme coordination, research-related funding and support, accelerating personalised medicine development, innovation and absorption, implementation of personalised medicine in public healthcare as well as international cooperation, an important component of EP PerMed's activities is identifying needs in personalised medicine throughout Europe in order to better act on them. As part of this effort, EP PerMed is organising a series of annual round table events taking place in different geographical locations with the aim to:

- Increase visibility and awareness of personalised medicine and EP PerMed, especially in a regional context
- Assess readiness of research, innovation and healthcare systems to implement personalised medicine, by identifying general developments, successes as well as drivers and hurdles
- Suggest concrete objectives and actions, to accelerate the development, innovation and implementation of personalised approaches to diagnosis, treatment and monitoring.

The first discussion was held in Brussels, Belgium, in 2024 and focused on "De-risking Innovation in Personalised Medicine" in the Netherlands and Belgium. The second event took place in Valencia, Spain, the following year with participants in attendance from Spain and Portugal.

The third EP PerMed round table was organised in Copenhagen, Denmark on Monday 18th May 2026 and focused on industry in the Nordic countries. Its aim was to gather insights and examples of the status, achievements and challenges ahead for personalised medicine in the region.

2 Participants

2.1 Panellists

- Rasmus Fält, Accelerator Lead, BETA.HEALTH
- Daniel Agren, Personalised Healthcare Lead, Roche
- Marguerite Mensonides, Chief Executive Officer and Founder, Amplio Pharma
- Daniel Mogefors, Chief Executive Officer, Mogefors Consulting
- Peeter Padrik, Chief Executive Officer and Founder, Antegenes
- Richard Rosenquist Brandell, Director, Genomic Medicine Sweden
- Niklas Sandler, Chief Technology Officer and Founder, CurifyLabs

2.2 EP Permed partners

- Wolfgang Ballensiefen, Scientific Officer, The German Aerospace Centre (EP PerMed Coordinator and Round Table Moderator)
- Lisa Bandholtz, Programme Manager, Vinnova
- Ilias El Houari, Policy Adviser to the Flemish Government (EP PerMed Work Package 3 Lead)
- Torstein Kige Rye, The Research Council of Norway (EP Permed Work Package 2 Co-Lead)
- Merike Leego, EP PerMed Senior Manager, EIT Health (EP PerMed partner)

2.3 Additional contributor

- Holti Kellezi, Vice President of Business Development, Dawn Health

3 Summary

In the first part of the round table, participants were invited to present their organisations and activities and discuss their experiences with regard to the implementation of personalised medicine. Their presentations (see Annex) showcased the diversity of possible approaches to precision medicine and brought to light common challenges, lessons learned and best practices in taking research innovation all the way to implementation. The second half of the event opened the floor to a discussion about how innovative approaches could be transferred from academia to routine clinical practice and scaled across countries. Participants contributed with different perspectives on critical success factors ranging from multistakeholder collaboration throughout research, development and implementation, to driving adoption and supporting system transformation. They also put forward concrete recommendations for EP PerMed and other actors within the personalised medicine ecosystem to bring into their future innovation initiatives.

3.1 Part one – Experiences, challenges and best practices in personalised medicine in the Nordic countries

In individual presentations, participants reported on their experiences in the research, development and implementation of personalised medicine approaches, describing key challenges and practical solutions identified along the way.

3.1.1 Learnings from different actors in the personalised medicine ecosystem

Lisa Bandholtz, Programme Manager, Vinnova

An EP PerMed partner, Vinnova is Sweden's innovation agency supporting needs-driven research and innovation for both the public and private sectors, and acting as a partner for system innovation and transformation. In 2025, the organisation invested 3.4 billion Swedish crowns (approx. 317 million euros) into 3,452 innovation projects. Looking back on her own professional trajectory from research on immunostimulatory DNA and DNA vaccines as a PhD student and postdoctoral researcher within the public Karolinska Institute in Stockholm, through startup and large pharmaceutical companies, to the non-profit Swedish Pharmaceutical Society before joining Vinnova, Lisa Bandholtz recounted various challenges and successes in implementing personalised medicine in Sweden.

Working on chronic inflammatory diseases at InDex Pharmaceuticals, which focuses on developing treatments for immunological diseases with high unmet medical need following a precision-oriented strategy, Bandholtz's role was to prove the drug's mode of action in selected patient subgroups with specific disease biology. From her time with the company in its startup days, she recalled the difficulty of trying to conduct extensive

laboratory work on strong time pressure and limited resources. Further challenges included requirements related to the protection of intellectual property and patents, as well as the high risk, uncertainty and time spent chasing investment money inherent to the startup environment. She found that **collaboration, especially between researchers and entrepreneurs, was critical in this early-stage setting**, and saw **a role for EP PerMed in facilitating this collaboration across borders through its matchmaking, mentorship, knowledge-sharing and call activities**.

Bandholtz later worked for large pharmaceutical companies MSD and Merck, on more mature products closer to routine patient care which confronted her with new challenges related to the innovation pressure to keep these products attractive on the market. There, she worked on personalised drug delivery devices and patient support programmes intended to tailor treatment to individual needs and improve adherence while generating real-world data on compliance with therapy—a core component of personalised medicine, she argued, as even the best treatment will fail if patients do not adhere to it properly. This is particularly true for chronic diseases. She highlighted **the value of registries in this context, which enable patient stratification, long-term follow-up and more individualised care when combined with other data sources.** The Nordic countries have a clear advantage in this area, being internationally recognised for their high-quality health registries. However, Bandholtz pointed out that because these are not set up for commercial use, companies face challenges related to access, governance, standardisation, and alignment with commercial and regulatory needs. She learned from these experiences that **patient engagement is key to precision medicine, as are strong external partnerships for its implementation**.

Having joined the Swedish Pharmaceutical Society, which works with the entire value chain from product research to drugs in routine use, Bandholtz found it was the ideal platform to bring together different stakeholders from various disease areas to develop solutions to complex problems. The personalised medicine initiatives she contributed to included PLATINEA, a Platform for Innovation of Existing Antibiotics aiming to optimise treatment by data-driven precision health and guard against the public health threat of antimicrobial resistance, involving collaboration between 21 different actors. Another was ATMP 2030, a project bringing together multiple stakeholders to drive the successful development and implementation in Sweden of advanced diagnostics and gene and cell therapies. She also had a part in the Society hosting annual conferences on quality registries for research, involving important stakeholders including industry and patient organisations. Lastly, she highlighted the tangible results achieved following the organisation of round table discussions between the six Swedish university hospitals and six major pharmaceutical companies for the implementation of sponsored clinical trials in infectious diseases.

3.1.2 Modernising drug compounding for the personalised medicine era

Niklas Sandler, Chief Technology Officer and Co-Founder, CurifyLabs

Founded in 2021 and headquartered in Helsinki, Finland, with subsidiaries in Germany and the USA, CurifyLabs has set out to modernise the still largely manual process of non-sterile drug compounding. Whenever an individualised dose of an existing drug is prescribed—one of the oldest forms of personalised medicine—pharmacists weigh, mix, dispense and label it by hand to this day. This is a slow, expensive and operator-dependent process that lacks standardisation and quality assurance even though mistakes can have fatal outcomes. From a business perspective, the lab costs of compounding outpace revenue growth and the practice also poses a compliance risk due to lacking digital audit trails. CurifyLabs' solution, a digital compounding platform for pharmacies, includes compliance software designed to standardise the compounding process by translating physicians' prescriptions into adapted drug formulations for specific patients such as children, and robotics inspired by 3D printing to homogenise the manufacturing process with integrated quality control on every dose produced. An audit-ready batch record is then produced automatically.

Validated for the automated compounding of oral paediatric tablets in a 2023 study[1] across 30 European hospital and community pharmacies, the platform is now in routine use in 18 US states and 14 European countries. Sandler noted that **adoption has been much faster in the USA, which already account for half of the company's customer base and revenue although it only began operations there in January 2025. Many of the institutions in which the solution was tested have also become customers** and as of March 2026, 70,000 tablets were being produced each month with this technology.

Most of the drugs compounded are generic medicines, though patented agents can undergo this process too. Formulations are developed at customers' request and then added to a validated product library with quality documentation that becomes available to all other clients. One notable example of the technology's use was made by Tartu University Hospital in Estonia with the production of personalised doses of epalrestat, which is commercialised in a 50-milligram tablet form, for seven paediatric patients in the country affected by a rare congenital disorder known as PMM2-CDG. Doses range from 3 to 35 milligrams in line with the recommended dosage of 1 milligram per kilogram divided into three daily doses. The technology also allows for the dispensing of

[1] Sandler, Topelius et al. Automated Non-Sterile Pharmacy Compounding: A Multi-Site Study in European Hospital and Community Pharmacies with Pediatric Immediate Release Propranolol Hydrochloride Tablets. *Pharmaceutics* 2024, 16(5), 678.

different dosage forms including tablets, troches, suppositories, orally dispersible forms, liquids and capsules.

As Sandler highlighted, **the personalisation of drug dispensing has applications across the fields of women's and men's health, neurology, endocrinology and cardiology in addition to paediatrics, and its potential combination with pharmacogenomics could further expand the possibilities for treatment personalisation in the future**.

3.1.3 Personalising cancer prevention and screening

Peeter Padrik, Chief Executive Officer and Founder, Antegenes

Estonia has a long-established national biobank that currently includes the genotypes of over 210,000 individuals, representing about 20% of the country's population. In the years 2015-2018, the Estonian government commissioned a personalised medicine implementation project which, unlike in some other countries, focused more on disease prevention than treatment, using genetic risk information derived from biobank data and polygenic risk score technology. In the years that followed, several clinical pilot projects for precision prevention of breast cancer and cardiovascular diseases were carried out by a consortium of Estonian hospitals and academic institutions. Parallel to this, the EU In Vitro Diagnostics Regulation adopted in 2017 categorised genetic tests evaluating disease predisposition as in vitro medical devices in Europe.

Antegenes was founded with the aim of making polygenic risk score (PRS) tests usable in routine clinical practice to personalise disease prevention and, in particular, increase the number of cancers prevented through current screening programmes, which typically consider only age as a risk factor. As its founder and Chief Executive Officer Peeter Padrik explained, among people diagnosed with cancer, 42% of men and 36% of women still lose their life to the disease, with late diagnosis being a major contributing factor. If cancer screening paradigms do not change, these numbers may rise in proportion to the increasing incidence of cancer in younger adults who have not yet reached the recommended screening age, leading to poor outcomes and suboptimal use of healthcare resources on treating advanced diseases that could have been detected earlier. A particularly telling example is breast cancer, where as many as one in five women diagnosed are younger than the standard screening age of 50 years.

Convinced of the potential to optimise prevention as individual cancer risk is estimated to vary as much as tenfold between same-age individuals, **Antegenes developed PRS tests for common cancer types to evaluate polygenic genetic predisposition to these diseases. To support clinical implementation, Antegenes has also developed principles for translating this information into clinical practice and provides individualised cancer prevention and screening plans based on people's polygenic risk score combined with their family history of the disease**. The tests are offered for the

assessment of breast, prostate, colorectal cancer and melanoma risk, with differentiated guidance for screening and prevention through reduction of modifiable risk factors for each tumour type. Validated with data from the Estonian and United Kingdom Biobanks and CE-marked as in vitro medical devices, Antegenes' tests and services are available to healthcare providers in the European Union and the United Kingdom. Antegenes' solution for personalised breast cancer prevention and screening was awarded the title of Best Practice in Personalised Medicine by EP Permed. In Estonia, the public healthcare system is beginning to implement risk-based breast cancer screening for women from the age of 40.

Padrik envisioned that eventually, **all population screening strategies could be informed by an initial assessment of inherited genetic risk, including both polygenic risk scores and monogenic high-risk variants, to determine individual screening schedules for citizens**, but cautioned that implementation of personalised prevention is likely to take time. Among the major challenges to adoption, he cited the fact that **there are currently no international guideline bodies for prevention or for personalised medicine, analogous to medical societies, who could evaluate new approaches and standardise recommendations**. This would be particularly critical for interventions like Antegenes' based on individual genetic risk, which is not a binary positive-negative result and thus requires defining risk score thresholds for differentiated clinical recommendations. The company therefore develops and publishes its own polygenic risk score-based guidelines to translate test results into actionable clinical pathways for different cancer types. A further difficulty, Padrik explained, is that **the implementation of novel preventive solutions is often slow and fragmented: on the one hand, because academic researchers are usually not responsible for the final implementation of innovations, and on the other, because public healthcare systems have different mechanisms and motivations for implementing new care paradigms compared to private providers**.

Round table participants further noted that when it comes to prevention, open questions regarding who should pay, how to guard against insurance premiums becoming tied to individual risk assessments, and even legal issues related to the use of genetic data would also need to be resolved.

3.1.4 Amplifying the efficacy of existing therapies to benefit more patients

Marguerite Mensonides, Chief Executive Officer and Co-Founder, Amplio Pharma

Showcasing a different approach to precision medicine, rather than developing a drug to target a disease biomarker in a defined subset of patients, Marguerite Mensonides, Karin von Wachenfeldt and Charlott Brunmark were brought together by **the ambition to improve outcomes for larger proportions of patients by extending the efficacy of existing active pharmaceutical ingredients (APIs) that are underperforming in**

the real-world setting. The underlying idea: to understand potential genetic features that make it more difficult for medications to work in some populations because of differences in the rate at which individuals metabolise and/or eliminate the API, thus requiring higher or lower doses. Combining their respective expertise in pharmacy, immunology and pharmacology, the three focused their efforts first on the amplification of methotrexate, originally an anticancer agent, which is the current standard of care for the treatment of autoimmune illnesses such as rheumatoid arthritis, psoriasis, Crohn's and a number of orphan autoimmune diseases. Although as many as 4-5 million patients are thought to be receiving the medicine in Europe alone, it is known to be fully clinically effective on its own in only about one third of the treated population.

Having identified a genetic polymorphism in a protein involved in the elimination of methotrexate, the research team found that its presence in treated patients was highly predictive of better response to the drug by virtue of trapping it within the targeted pro-inflammatory cells. Mensonides and her fellow co-founders searched for **an agent that could mimic the effects of this polymorphism to improve the efficacy of treatment for a greater proportion of patients**—and found it in the antibiotic novobiocin, a small molecule capable of slowing down the elimination of the drug for a number of hours and keeping it inside the targeted cells for longer.

Amplio Pharma was founded and its modified retention technology combining methotrexate with novobiocin received patent protection in 2021, but **was not met with significant interest in Sweden. However, it did succeed in attracting several investors and collaborations with universities in the Netherlands, where its novel clinical candidate drug product, AMP101, is currently undergoing Phase Ib testing in patients with rheumatoid arthritis**. Thanks to the company's collaboration with several Dutch academic institutions, Mensonides expected that more would be learned from studying the patients who start using the new agent and searching for genetic signals predictive of response. The company has also applied for funding from the EIC Accelerator to investigate its product's efficacy in orphan diseases, where data is scarce and no private capital is available to develop medicines for very small patient populations.

Reflecting on why they struggled to find backing in Sweden versus the Netherlands, Mensonides reported different understandings of the data required before moving to clinical trials and—among venture capital providers across Scandinavia—a lack of recognition of the added value of improving old treatments to reduce resource wastage and ensure the sustainability of health systems. **By relocating closer to possible collaborators and to an environment with a higher focus on healthcare system sustainability, Amplio Pharma not only found initial investors, but also an academic research collaboration that unlocked access to institutional and regional funds.** Regarding the business model for this kind of therapeutic innovation, Mensonides ventured that the profit should be expected from the product's buyout by a larger industry player once most of the risk related to research and development (R&D) has been

removed and the pharmaceutical company has good prospects for quickly positioning the medicine on the market as the new standard of care.

3.1.5 An industry perspective on challenges and opportunities in personalised medicine

Daniel Agren, Ecosystem Shaping Lead, Roche

Daniel Agren presented pharmaceutical giant Roche's research and development activities as well as the company's perspective on personalised medicine. With annual investments of 13 billion Swiss Francs (approximately 14 billion euros) in 2024, Roche is the pharmaceutical industry's leading R&D investor. These span across its activities from diagnostics to pharmaceuticals and a third category of digital products closely interconnected with the first two, with a focus on priority disease areas including cardiovascular and metabolic diseases, oncology and neurology. Defining precision medicine by the goal to deliver the right treatment to the right patient, at the right time, Agren explained that Roche's vision for the patient journey includes early detection of disease through advanced diagnostics, a personalised care plan based on all relevant data, treatment tailored to individual needs, and follow-up with a feedback loop to optimise the efficacy of therapies and avoid side-effects.

Highlighting some of the challenges associated with each of these components, **Agren called for a mindset shift among healthcare providers and policymakers to address a general lack of investment in diagnostics, even though these are the basis for optimal clinical decision-making and efficient use of medical resources.** The frequent introduction of new diagnostics without dedicated budgets for clinics, he argued, leads to regional inequalities that are further compounded by the lack of centralised frameworks for comprehensive genomic profiling (CGP) and molecular tumour boards.

Similarly, despite digital products being the company's fastest-growing area, Agren reported **difficulties obtaining funding for the digital tools necessary for healthcare to collect and make use of information, a precondition for implementing data-driven care plans and follow-up**. He also underlined that even **effective solutions recognised as beneficial, such as a digital tool for patients to report side-effects that Roche had piloted as part of a collaboration, often fail to reach routine practice because they cannot be implemented in clinical care.**

On the pharmaceutical side, offering more personalised treatments for smaller and smaller patient subpopulations runs up against significant barriers of its own, from the complexity of navigating regulatory pathways to the difficulty of securing funding from public healthcare payers—particularly in Sweden, where dual reimbursement systems (for prescription and hospital drugs) and fragmented pathways for smaller patient groups delay access to precision therapies. According to Agren, **fewer and fewer new**

therapies are becoming available in Europe as a result, thus limiting the reach of personalised medicine and its benefits for patients.

These hurdles notwithstanding, Agren emphasised that collaboration will be key to advancing personalised medicine in a structured way. He saw an example of this in the Vision Zero Cancer innovation hub in Sweden, which brings different stakeholders in cancer care together on flagship initiatives ranging from precision prevention and early detection, to treatment and rehabilitation.

3.1.6 Helping innovation originate in healthcare

Rasmus Fält, Accelerator Lead, BETA.HEALTH

BETA.HEALTH is a Danish innovation platform dedicated to healthcare professionals, on the premise that innovation should start where patients are and that hospitals are not only well-positioned to identify problems in the patient journey, but also ideal test beds for new ideas and key actors in the implementation of novel solutions. The organisation provides funding, expertise and structured support to help innovators take their ideas all the way to successful implementation, and has granted 123 of the close to 700 applications received in the first five years since its creation. As Rasmus Fält reported, 10 solutions out of the 84 accompanied by BETA.HEALTH have already been rolled out and one third (28) have reached patients in the process of development and implementation.

Reporting on the platform's experience with these initial projects, Fält noted that **healthcare professionals often come in with a deep understanding of the problem they want to solve, competencies for developing the technology for their proposed solution, and a clear idea of the requirements for its clinical validation. However, they frequently need support with or are entirely missing capacity for other critical dimensions of innovation like business, strategy, team-building and execution required for real-world adoption**.

BETA.HEALTH therefore works with a defined innovation model including different innovation readiness levels to help clinical teams understand that innovation maturity is broader than clinical validation and technology readiness. A solution also needs user readiness, team readiness, management support, business or value-case maturity, a clear regulatory pathway, a funding logic, and capacity to be implemented and scaled. From this perspective, Fält argued that even **clinical validation should not just be designed to prove to users that a solution is effective and beneficial for patient care, but also to show that it can fit into clinical workflows, to demonstrate its readiness for regulatory approval and to confirm its business case in terms of savings generated for the hospital or for the healthcare system**.

Because the applications it receives are overwhelmingly based on a clinical idea, BETA.HEALTH works closely with technology transfer offices—not only for technologies that can be patented and commercialised, but also for solutions developed internally and taken into use across institutions or healthcare groups.

Another common challenge for innovation coming from healthcare to mature all the way to implementation, according to Fält, is that **it is easier for medical professionals and researchers than for entrepreneurs to shelve a project when the funding runs out**. As BETA.HEALTH typically works with innovators for only six to nine months, an important part of its work is therefore also to help them identify and secure their next funding sources.

Fält reported that the innovations that move through the development and implementation process the fastest tend not to be medical devices or diagnostics, but solutions with simpler regulatory pathways: estimation algorithms for capacity planning in emergency services, for example, which do not require much personal data but save hospitals money by predicting their personnel needs based on environmental information. It was noted in this context that **for medical devices and diagnostic technologies, regulatory approval, though a challenge in its own right, is not the end goal: the real barrier being acceptance and adoption within healthcare systems**.

3.1.7 A study of the factors preventing European start-ups from scaling

Daniel Mogefors, Chief Executive Officer, Mogefors Consulting

Speaking from his experience leading the development of CELSI, Sweden's Centre for Emerging Life Science Innovation, a public-private project focused on how life science start-ups can move toward implementation readiness and scale, Daniel Mogefors provided a perspective on why so many promising solutions in Europe stall before implementation. To underline the extent of the problem, Mogefors drew a comparison with the USA, which tallies approximately the same number of start-ups as are present in Europe but boasts five times more scale-ups. **In spite of its high innovative potential and intellectual output through patents and research then, Europe falls short when it comes to the final stages of scaling up to achieve widespread implementation of novel solutions**. Reporting on the findings of a CELSI pre-study on evidence-driven life science and innovation partly funded by Vinnova alongside other public and private partners, Mogefors laid out ecosystem-level reasons for this paradox and practical lessons for facilitating the implementation of personalised medicine.

While it is common for healthcare innovation to be conceptualised as an orderly succession of logical consecutive steps from research, through clinical validation and market access to integration in clinical workflows and cross-border scaling, Mogefors explained that in most cases, the reality is a much more complex iterative process between different activities. For this reason, **when research, clinical validation and adoption are**

managed as separate journeys, promising solutions tend to lose momentum in the later stages of development which should have been anticipated and prepared for from the start. Indeed, the study found that **evidence brought forward is not clearly linked to adoption decisions**, and that **validation depends more on innovators' relationships with key clinical actors than on clear pathways**. In addition, **capital raised frequently does not match the regulatory evidence burden and causes development milestones to be missed or delayed**, while fragmented, misaligned funding mechanisms heavily reliant on public sources constitute an increased burden on innovators to apply for and maintain multiple grants as well as comply with reporting requirements. Lastly, **the fragmentation of the European market was found to lead to fragmentation and inefficiencies in the process of scaling innovations internationally**.

Mogefors therefore suggested that European start-ups' weakness lies not in the science, but in the connections between their different activity nodes. On the one hand, capital-raising is fragmented and misaligned with evidence timelines, causing delays that are often compounded by the fact that access to clinical and industrial validation is ad hoc rather than systematised. On the other, companies frequently fail to bring on board the expertise needed to support regulatory affairs, reimbursement, intellectual property and commercial functions soon enough in their development and too often neglect to power their leadership teams for scale-up, subsequently struggling to recruit the required profiles to executive and advisory positions.

Translating these findings into practical recommendations, Mogefors suggested three main levers to better align start-ups' different activities around a common set of milestones and prevent their progress from stalling:

1) **Innovators and investors must make it a priority to match resources to the required evidence burden and validation timelines rather than following generic start-up cycles. Cultural differences in financial risk-taking and focus on research versus innovation between the USA and Europe may need to be compensated in different ways.**
2) **Companies should start building scale-up capability with specialised expertise and leadership from the early stages to prevent implementation from eventually failing for lack of production capacity.**
3) **Public health actors must ensure structured access to clinical and industrial validation that is more predictable, milestone-based and less dependent on personal networks.**

3.1.8 A structured path to implementation for advanced diagnostics

Richard Rosenquist Brandell, Director, Genomic Medicine Sweden

Genomic Medicine Sweden (GMS) was founded in 2018 with the aim of translating innovation in genomics into clinical practice and implementing a sustainable infrastructure for precision medicine in Sweden. The organisation has received national funding from the Swedish Innovation Agency, Vinnova, and since 2025, long/term funding from the Swedish government. It is also co-funded by the seven regions with university hospitals and the seven Swedish universities' medical faculties. Bringing together clinicians, researchers, industry and patient organisations, it has built a research-to-implementation pathway for clinical diagnostics spanning across rare or complex diseases, cancer microbiology and pharmacogenomics. In collaboration with the Science for Life Laboratory, Sweden's national infrastructure for high-throughput technologies, it has established twinning units at all Swedish university hospitals to lead the deployment of tests under development. Its **seven genomic medicine centres across the country focus on bringing precision medicine to the clinic with harmonised methods, standards and guidelines as well as shared development for orderly and resource-efficient implementation**. The organisation has also built a national genomics platform for data-sharing, storage and analysis.

Following the identification of promising tests in early development and validation, GMS supports strategic development projects to be implemented nationally with solid regional anchoring, aiming for deployments to reach at least five of its seven sites within one to three years. **All strategic development projects must perform an assessment such as a micro-costing analysis to support reimbursement when solutions are brought into healthcare, and the data from each implementation process must be deposited on the national genomics platform to ensure a learning system**. As GMS Director Richard Rosenquist Brandell reported, next-generation sequencing (NGS) analyses have increased accordingly by 10 to 15 percent annually in Sweden over the last five years, with the total number of tests performed and paid for by the healthcare system (as opposed to research and development) since 2017 passing the 500,000 mark in 2025.

After becoming one of the first best-practice examples cited by the International Consortium for Personalised Medicine (IC PerMed) at its first major conference in Berlin in 2018, GMS was also recognised by EP PerMed for its deployment of whole genome sequencing at diagnosis for childhood cancer. Having demonstrated that clinically relevant genetic alterations could be determined in over 90% of paediatric patients and that one in four children could potentially be matched to a potential targeted therapy,[2] the

[2] Wadensten et al. Diagnostic Yield From a Nationwide Implementation of Precision Medicine for all Children With Cancer. *JCO Precision Oncology* 2023, 7, e2300039.

test became the standard of care across Sweden in 2024. A parallel project to implement a test determining genetic predisposition to childhood cancer similarly became standard of care following the demonstration of its utility for tailoring surveillance and treatment.[3] Around 80% of children now benefit from whole genome sequencing, with no regional differences across Sweden, and a new interactive module developed within the national genomics platform allows the national registry for paediatric cancer to be linked with genomic data, and soon with pathology images, for further research on biomarkers for targeted therapies. Another project, attempting real-time validation of whole genome and transcriptome sequencing for the risk stratification of patients with acute leukaemia, has already become the standard of care for children and is currently ongoing for adults.

In addition to healthcare, **the organisation's partnerships with industry extend the range of supported solutions beyond diagnostic tests to data-sharing and clinical decision support tools**. Opportunities for collaboration include early technology testing and co-development, validation and scale-up of tools, providing access to large datasets, validation of biomarkers and therapeutic targets, conducting feasibility and health economic analyses, proposing translation-ready research frameworks and facilitating the integration of solutions in real-world healthcare. While GMS is prepared to pursue CE marking for in vitro diagnostics, if necessary, it currently operates principally under the regulatory exemption afforded to laboratory-developed tests.

Although he deemed all stakeholders involved to be pulling in the same direction, Rosenquist Brandell nonetheless reported persisting challenges for projects to implement personalised medicine in Sweden. The first of these **hurdles are the legal and contractual aspects, not only of collaborations with companies but also with hospitals**, which he claimed can take as long as a year to resolve. When it comes to convincing large industry players to invest in projects with GMS, Rosenquist Brandell also highlighted the difficulty of positioning a small healthcare ecosystem like Sweden among larger countries' initiatives and infrastructures.

On the side of public funding, Rosenquist Brandell lamented the fact that Sweden's three national strategies for the life sciences, cancer, and the implementation of personalised medicine are not connected to any substantial resources to support their execution. However, he welcomed the **assignment recently given to Sweden's National Board of Health and Welfare for an equitable and coordinated implementation of precision health, which is to include a steering board for national coordination, a five-year implementation programme for equal access to precision diagnostic services, and the proposal of a regulation for long-term state support to GMS**.

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[3] Tesi et al. Diagnostic yield and clinical impact of germline sequencing in children with CNS and extracranial solid tumors – a nationwide, prospective Swedish study. *Lancet Regional Health Europe* 2024, 39, 100881.

3.2 Part II – Round table discussion: How to transfer successful approaches from academia to clinical implementation and scale valuable solutions across countries?

During the open discussion, the attention turned to practical lessons and recommendations for overcoming the challenges to implementing personalised medicine at scale in Europe and transferring innovations from academia to routine clinical care. These were concentrated in the following domains: improving collaboration and communication between stakeholders; creating pathways from innovation to clinical practice; driving adoption in resource-constrained healthcare systems; and rethinking current models of care.

3.2.1 Improving collaboration and communication between stakeholders

There was widespread consensus around the fact that early involvement of all stakeholders in innovation is key to developing solutions that can actually be implemented in real-world healthcare later on. As Rosenquist Brandell suggested, it is not reasonable to expect the output of life sciences labs to simply infuse into healthcare once published: its transfer to clinical practice requires people inside the system to advocate for new solutions. Among the key actors to be brought to the table, comprehensive cancer centres and large industry players were cited alongside venture capital providers and altruistic foundations, but also healthcare professionals as well as healthcare payers, public and private.

The two latter groups, some argued, are too often not represented at conferences and other initiatives around innovation, and new, less academic formats for interaction are needed to help people exchange ideas freely and connect with other stakeholder groups that could be instrumental to their projects. Mensonides called for the involvement of different kinds of payers across Europe to provide their perspectives on different financial models for personalised medicine and the questions it raises when solutions benefit not those paying for it, but a different entity in the system. Also, among the suggestions for improving communication between stakeholders, events and programmes with a focus on implementation were thought to be particularly relevant for pharmaceutical and diagnostic companies in a context where Europe is lagging behind internationally.

The creation of financial incentives was proposed as another way to foster multistakeholder collaboration. From the company perspective, Sandler reported that CurifyLabs succeeded in finding innovators among healthcare professionals in Europe and gaining access to pharmacies and hospitals by offering to pilot their solution for free. In the US, the company worked with the Mayo Clinic on the basis of a reward system for the research groups involved in testing and validation. Similarly, Fält believed that healthcare

professionals' primary motivation for applying to BETA.HEALTH is to obtain funding, while the benefits of the support and relationships they gain from collaborating with the organisation become apparent later on. Rosenquist Brandell confirmed that the co-funding offered by Vinnova in Sweden plays an analogous role in attracting healthcare professionals to innovation projects.

Key recommendations:

→ Ensure better representation of healthcare professionals and payers in innovation conferences and collaboration initiatives

→ Design interaction formats that allow different stakeholders to establish meaningful connections with the right partners for their projects more easily

→ Launch events and programmes dedicated to the topic of implementation

→ Create financial incentives for multistakeholder collaboration

3.2.2 Creating pathways from research innovation to clinical practice

Another point of agreement in the group was that Europe generally tends to be too heavily focused on research and not enough on innovation compared to the USA—in terms of both the funding available and the scientific culture within the health sector. For Padrik, current structural incentives lead the key academic and clinical experts who define the evidence base for innovations to be oriented primarily towards research and less towards the operational task of translating existing science into routine practice. Holti Kellezi, Vice President of Business Development at Dawn Health, Denmark, additionally noted that academic prototypes are rarely built to scale but rather designed as research artefacts without the consumer-product mindset or quality systems required to qualify as Software as a Medical Device. While research is about generating new knowledge, implementation is about bringing existing knowledge into everyday workflows, and each domain has its own specific incentives, required skillsets and timelines. In a thus fragmented ecosystem where it is difficult to bring together the required multidisciplinary expertise to move from research breakthrough to regulatory approval and clinical implementation, a gap therefore persists between what is known and what is operationally deployed—even in fields where the evidence is already strong.

Especially for innovation born in academic settings, which too often remains academic-led with industry and payer involvement arriving later, several participants argued that partnerships with industry and public payers should be built into the project structure from day one. This would allow each stage of implementation to be jointly defined and evaluated, ensuring that evidence is generated for real adoption decisions rather than only for scientific proof-of-concept.

One proposed solution was to fund implementation projects with explicit practice-change objectives, where every project should have measurable practice-change milestones tied to its funding agreement, not only publication outcomes. As Mogefors highlighted, the key is to design the translation pathway early and avoid treating commercialisation as something that happens after the research is complete. Successful transfer requires a clear clinical need, an evidence plan, regulatory and reimbursement logic, experienced commercial support and committed validation partners. For scaling across countries, innovators also need adaptable evidence models, trusted European networks, and partners who understand differences in healthcare systems, procurement, reimbursement and implementation.

The latter were deemed to be especially critical for personalised medicine approaches, the implementation of which can be further complicated by legal and regulatory standards: from the rules governing the use of public funding for innovation, through national legislations protecting personal health and genetic data, to the lengthy, costly and sometimes inconsistent process medical devices undergo from submitting their technical file to receiving formal approval in Europe. As Kellezi explained, personalised medicine increasingly involves the development of regulated digital companion products that personalise the patient experience around specific therapies and for which evidence generation is a challenge, because they address diverse patient groups and outcomes that are difficult to evaluate through traditional trial designs. A promising path forward has been pioneered by the US Food and Drug Administration with its Prescription Drug Use-Related Software (PDURS) framework, which allows software with demonstrated clinical benefit to be treated as a single therapeutic product with the drug it supports and added directly to its label. Kellezi highlighted that although a new generation of drug-software combination products is being built on this foundation, Europe has no equivalent framework to date, recommending that EP PerMed should draw inspiration from the US to unlock new opportunities and channels for bringing personalised medicine to market.

Another useful development would be the adoption of trial designs that evaluate clinical efficacy and implementation outcomes in parallel rather than sequentially to compress the timeline between evidence generation and operational deployment, with initial testing and validation conducted at one or two specialised centres before wider rollout. Standardised workflows, robust real-world evidence and close collaboration with healthcare providers were considered essential in this context. Agren cited Roche's Quadruple Helix collaboration with the clinical community to demonstrate the value of tumour-agnostic therapies and their diagnostic landscape as a successful example of this type of approach. The initiative was instrumental to the approval and implementation of the first NTRK treatments for cancer, ensuring that both pharmaceuticals and diagnostics could be integrated into sustainable clinical workflows.

Lastly, several participants drew attention to the need to bridge funding gaps that exist in the final stages of companies' development trajectories. In Sweden, for example, even if funding for a solution is obtained from the healthcare system, the pre-implementation phase is usually not covered by the public payer and tends to require using substantial research funds. In Denmark, the altruistic funding received by BETA.HEALTH prohibits the organisation from using its budgets for business promotion, meaning that the innovators it assists need to look for support elsewhere in that regard. It was concluded that more diverse funding pools should be developed and clearly signposted to support innovation at different stages and for different needs.

Key recommendations:

→ Design innovation projects as partnerships co-led by academia, industry and healthcare payers from the start to ensure evidence generation and development support future implementation decisions

→ Tie funding for innovation to implementation milestones supported by multidisciplinary expertise rather than just to publication outcomes

→ Create a regulatory framework to facilitate the evaluation and approval of hybrid and combination products for personalised medicine

→ Implement clinical trial designs that evaluate efficacy and implementation outcomes in parallel rather than sequentially, working closely with healthcare professionals to ensure standardised workflows that facilitate operational deployment

→ Develop and signpost diverse funding pools to cover the different needs and stages of innovation before it reaches maturity for healthcare coverage

3.2.3 Driving adoption in resource-constrained healthcare systems

Even once all legal and regulatory hurdles have been cleared and an innovation has proven its readiness for routine practice, manufacturers still need to draw attention to their solutions in already busy healthcare environments and actively drive adoption based on clinical validation, integration into or transformation of existing healthcare workflows, as well as developing a solid business case for the relevant sector. Healthcare systems and medical professionals tend to be highly conservative, meaning that any changes take time to be accepted, funded and implemented. This is due partly to the fact that multiple stakeholders are involved in the relevant decision-making processes, and partly to the time and difficulty involved in changing existing workflows—even when a solution's clinical value or potential to improve quality of care is recognised. As Fält highlighted, the wide variability of both workflows and funding mechanisms across European countries makes it particularly challenging for solutions to be adopted on a

large scale. In the absence of clear opportunities to obtain funding at European level, Ballensiefen suggested it would be useful to analyse why given solutions meet with more or less interest in different countries.

A specific difficulty for personalised medicine in this regard is the fact that, as Padrik explained, adoption of innovations in routine patient care requires changes to clinical practice guidelines, which are currently issued by disease-specific societies. Personalised medicine being structurally interdisciplinary, there is no clearly defined body even in Europe to lead the conversation, convene the right experts and issue authoritative practice-change recommendations to turn novel approaches into new international standards. A first solution could therefore be to build this missing layer, relying where necessary on existing professional societies to create permanent interdisciplinary working groups for personalised medicine and collaborate with groups in adjacent specialities. In parallel, public payers and national health systems could take it upon themselves to commission practice changes directly when the guideline pathway is too slow, with these subsequently feeding back into international guideline development.

Once again, there was agreement that the most effective approaches to fostering adoption begin as early as the technology development and evidence generation stages, which therefore need to be designed and planned accordingly. For example, Rosenquist Brandell argued that in addition to the pivotal trials necessary for clinical validation and regulatory approval, retrospective and prospective observational studies powered to generate robust real-world evidence can support adoption and reimbursement decisions. In the piloting phases, Sandler reported that collaborating early on with pharmacies and end users, not only on finetuning the core technology but also its ease of use and integration into workflows, was decisive in positioning CurifyLabs' solution on the market. He highlighted the importance of building trust through automation, traceability, continuous quality improvement and compliance processes, as well as supporting customers with return-on-investment calculations, implementation planning and operational impact assessments. Accordingly, a key recommendation for transferring innovations from academia was to start preparing for adoption much earlier by answering questions such as who will use the solution, what evidence is needed beyond publication, who will own it after the research project ends, and what needs to be adapted for it to work in another hospital, region or country.

Perhaps the most critical success factor for personalised medicine, some argued, is the business case for the healthcare system. Even when a solution improves patient care, it must also make sense and be viable in a pressured healthcare system. Does it reduce unnecessary activity, free up staff time, improve patient flow, prevent complications, shift care to a lower-cost setting or create better outcomes without adding unsustainable workload? If the value is not clear, adoption becomes difficult. It was noted that health economics are becoming increasingly important in this context, especially in the Nordic countries where healthcare payers tend to work with fixed budgets and thus to

be particularly sensitive to budget impact. Although personalised medicine's core technologies like genetic sequencing and advanced data analytics are becoming more affordable, that is not the case for the personnel involved in performing the analyses. For many recent innovations, Rosenquist Brandell therefore argued that longer-term studies will be needed to demonstrate that the upfront costs are later offset by more efficient use of therapeutic resources.

Key recommendations:

→ Support the creation of an international benchmarking body for personalised medicine, fostering collaboration between disease-specific medical societies in the interim

→ In the absence of clear international guidelines, empower public payers and national health authorities to commission practice changes when innovative personalised medicine approaches arrive on the market

→ Take into account the requirements for large-scale adoption from the earliest stages of technology development and evidence generation planning

→ Support customers and end users throughout the implementation process, continuously optimising usability and quality assurance and assisting with workflow integration, return-on-investment calculations and operational impact assessments

→ Leverage health economic analyses to demonstrate solutions' value to payers, planning longitudinal studies to clarify how upfront costs can be offset by system savings

3.2.4 Rethinking current models of care

Although personalised medicine is a broad concept that includes applications as diverse as those presented during the first part of the round table event and more, each facing its own challenges to find a place within healthcare, participants observed that in general, public health systems are not currently built for individual care optimisation, but rather for public offers and services. In particular, the shift away from disease management to health promotion and prevention, made possible by personalised medicine, is one that public healthcare payers are often not ready for.

In the Nordics, Agren reported that Roche is moving into a private market in this area because citizens' demand and willingness to pay for preventive solutions is outpacing that of public payers. Padrik added that with public healthcare resources becoming increasingly insufficient, companies are also stepping into the void with insurance packages for employees. These developments carry the risk that personalised medicine will ultimately benefit only the wealthier segments of the population, who tend to show the greatest interest in prevention, leaving minorities and lower socioeconomic groups behind. Paradoxically, an increased burden on healthcare systems and poor patient

outcomes due to overdiagnosis could also be a risk in an environment where interventions are adopted by individual initiative rather than based on medical prescription and public health initiatives.

Some participants predicted that artificial intelligence (AI) would revolutionise medicine and, indeed, allow the personalisation of almost every healthcare service in the medium term thanks to all the data it will become possible to collect, process and interpret—again, with the risk of bringing healthcare systems under pressure as people present with AI-generated results obtained from more loosely regulated players outside of Europe. Others were more reserved, agreeing that AI would be used more and more ubiquitously as a complementary tool but cautioning that in most countries, data infrastructures including electronic health record systems would first need to be comprehensively modernised to support the development of the relevant models. Ballensiefen emphasised the importance in this context of keeping European actors competitive in the AI space to ensure that the models that prevail in the future are both functional and aligned with European values and ethics.

To help Europe's healthcare systems adapt to these transformations while protecting the principles of universal health coverage and equitable access to care, it was suggested that traditional health economics models, which tend to evaluate direct costs, should undergo a paradigm shift to broaden their picture of cost and value to societal dimensions. New models of funding and reimbursement for healthcare services, such as outcome-based pricing instead of fee-for-service, were also deemed necessary for a sustainable implementation of personalised medicine in which the cost of innovation is aligned with its real-world clinical value.

A pragmatic approach was proposed to start with, whereby public health systems should define personalised medicine more precisely and prioritise relevant disease areas, oncology being the most obvious, determining for each application the level of information needed for tailored approaches. Women's health was cited as an important area of opportunity, with a real need for medicines tailored to female physiology and illnesses. With increasing numbers of drugs being approved with a personalised medicine component, it was argued that this way of proceeding could ensure healthcare resources are channelled efficiently towards the innovations most susceptible to yield high benefits within a given system.

An alternative strategy would be to place the emphasis on optimising patient care, following not only an economic but also an ethical rationale. This principle could then guide initiatives to personalise prevention, treatment and monitoring to different population subgroups and perhaps, eventually, to individuals across the entire healthcare landscape. The introduction of pharmacological consultations with elderly patients was cited as a prime example where an effort to improve patient care and safety simultaneously allowed system savings through significant reductions in the number of drugs dispensed to each individual.

Voters were identified as key actors capable of accelerating the required changes to current models of care by putting pressure on the system. Ballensiefen reported that in Romania, for instance, a new law now guarantees people's right to receive personalised treatment for their health conditions when one is available. Informing citizens about the opportunities of personalised medicine was therefore considered critical to ensure societies reap its full benefits in the future.

Key recommendations:

→ Fund and support European-led innovation in the field of AI

→ Integrate societal dimensions in health economic analyses of cost and value for personalised medicine

→ Align funding and reimbursement models for personalised medicine approaches with outcomes achieved rather than services provided

→ Develop educational material and information on personalised medicine and its opportunities for the general public