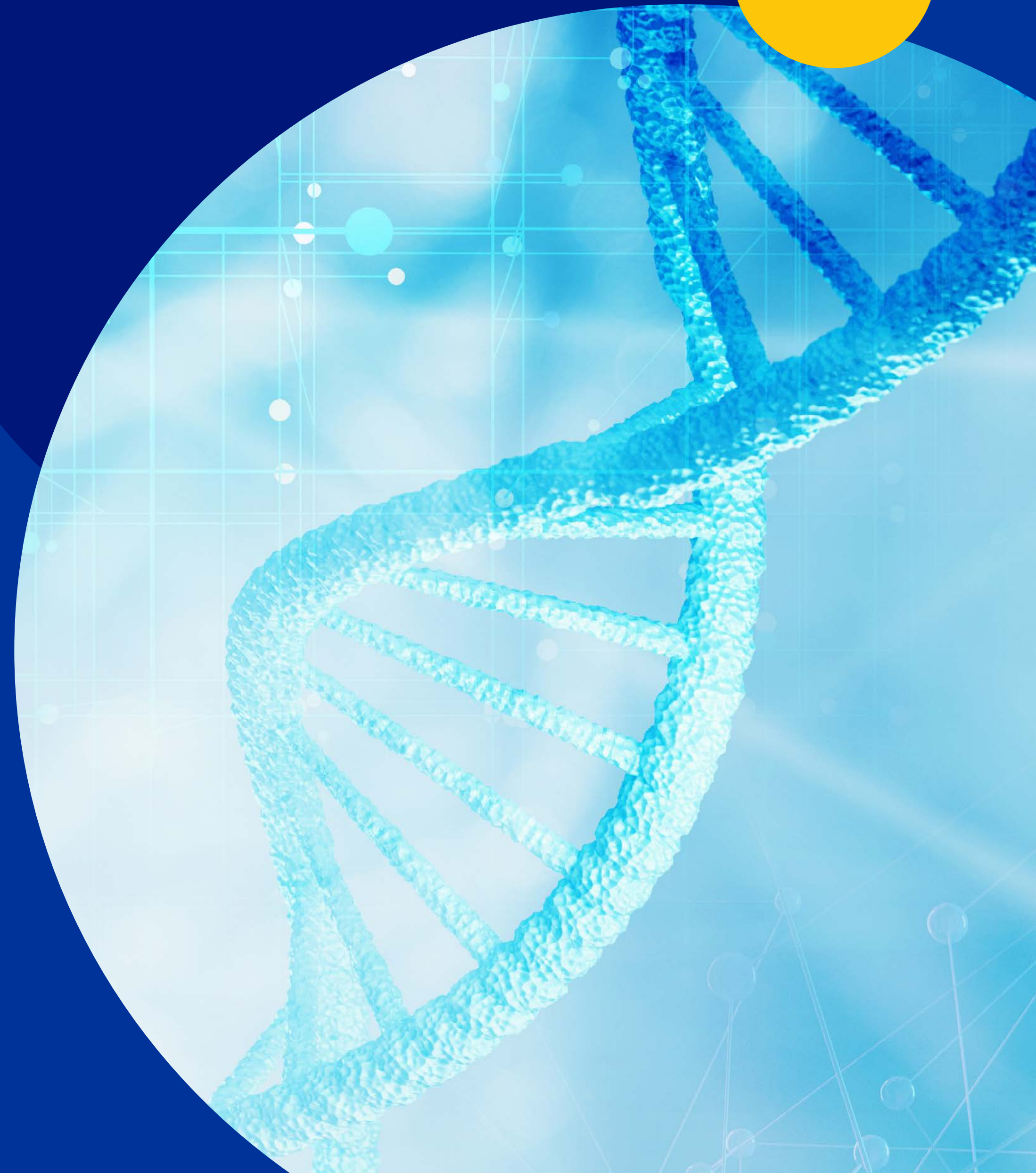


Codex4SMEs Companion **Diagnostics** expedited for SMEs

Fostering the development of companion
diagnostics for personalised healthcare



Introduction

With the mission of "the right drug, at the right dose, at the right time, to the right patient", the Interreg North-West Europe Codex4SMEs project funded the development of innovative companion diagnostics (CDx) and diagnostics (Dx) in general for improved personalised medicine (PM) in Europe.

Launched in 2017, Codex4SMEs has supported more than 400 small and medium-sized enterprises (SMEs) in the life sciences and medical technology sectors engaged in the development of CDx & Dx to expedite their innovations through a comprehensive support programme.

The Codex4SMEs success story was only possible through the teamwork of 12 partners from eight countries. Thanks to the efforts of this consortium, the individual ecosystems within the partner regions have formed a unique, diverse network that provides targeted support to companies along the entire diagnostic value chain.



Interreg NWE funding

Total budget:
4.18 million €
ERDF budget:
2.50 million €
Project period:
2017 - 2023

Objective of the project:

Improve healthcare by enhanced adoption of personalised medicine (PM) in NWE and beyond by establishing a network which supports SMEs along the value chain of CDx & Dx development

SMEs received vouchers worth up to:

FOR CONSULTANCY SERVICE & SEMINARS ON BIOMARKER TOPICS
provided by IBBL

3 000€

FOR BIOMARKER VALIDATION
provided by IBBL

100 000€

FOR SAMPLE ACCESS
provided by BBG

10 000€

FOR TRANSLATIONAL ASSESSMENT
provided by EATRIS

4 000€

FOR RESEARCH SERVICE
provided by EATRIS

25 000€

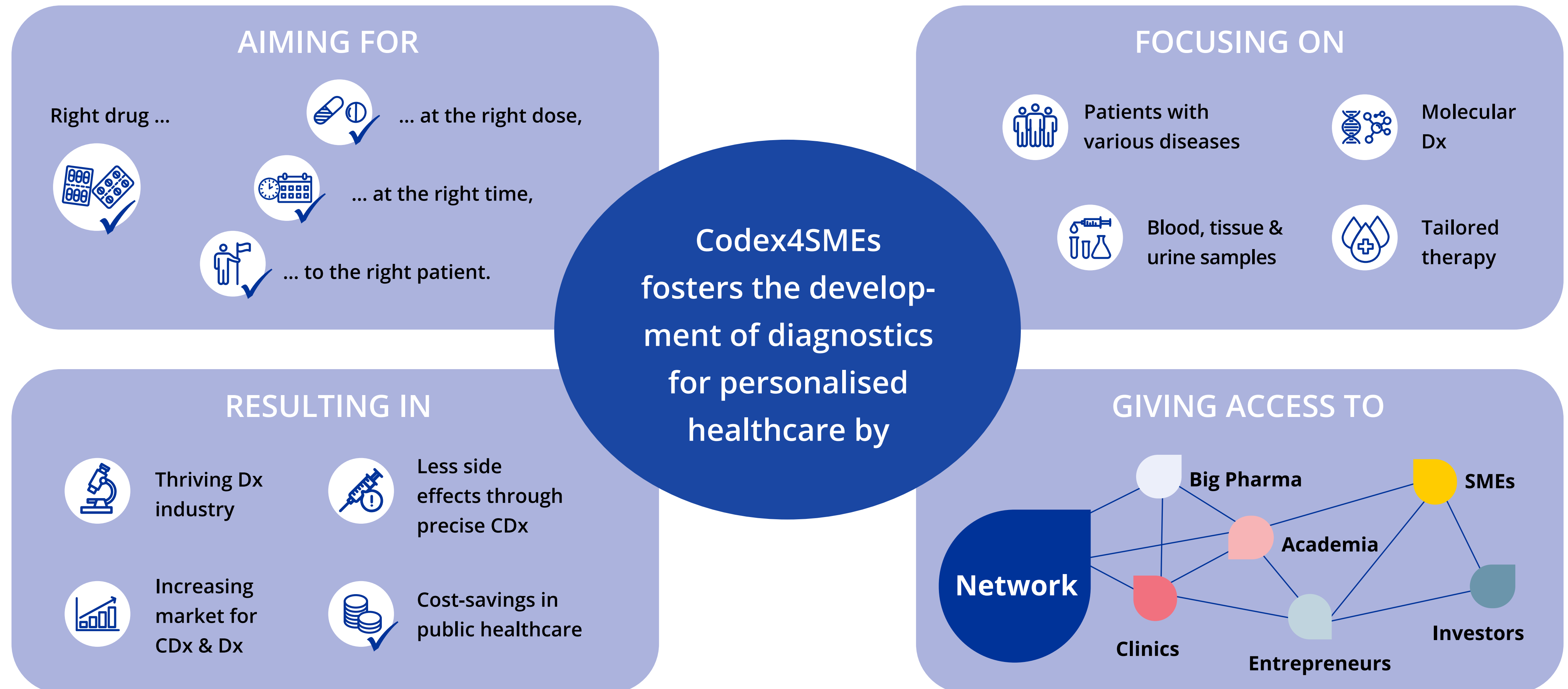
FOR FULL REGULATORY ASSESSMENT
provided by EATRIS

6 000€

FOR MEET&MATCH.DX
provided by
Innovation in Health
BUSINESS GROWTH
provided by Cluster and
Research Partners

2 000€

Personalised Medicine is key to improving healthcare in Europe



Empowering CDx & Dx SMEs with new business skills

Our services for your path towards the market



Discovery & Development



Pre-clinical / Clinical Research



Market

Codex4SMEs
Support



Market Analyses



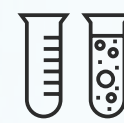
Translational assessment



Full regulatory assessment



Covid-19 research services



Sample access & knowledge transfer



Biomarker validation



Tailored consultancy services
on specific biomarker topics



Interactive online seminar
on biomarker validation



Business growth programme

- Quality management system
- Clinical trial
- Multi-market entry
- IP-strategy
- Pitch training



Meet & Match.Dx

- Partnering with big pharma
& medtech companies

Codex4SMEs
Network

Access to expert insights and to CDx & Dx ecosystems across Europe

1h
Webinars

Personal Approach

Matchmaking

Online Map of
CDx & Dx
Ecosystems

Networking &
Information Events

Virtual Matchmaking
Platform

Success numbers in SME support

>420

SMEs supported via

- Tailored events and workshops
- Visibility in project's map
- Matchmaking events
- Tailored services

4

SMEs supported to introduce new to the market products via

- Modular biomarker validation
- Covid-19 research services
- Consultancy on biomarker topics

>45

R&D collaborations have been initiated with

- Biobanks
- University hospitals
- Enterprises

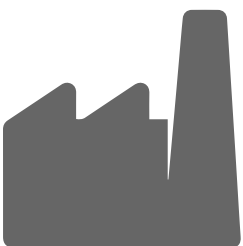
>90

SMEs supported to introduce new to the firm products via

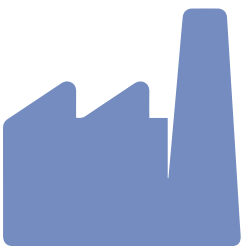
- Sample access & knowledge transfer
- Regulatory & translational assessment
- Meet & Match.Dx
- Business growth
- Biomarker validation

Support for diagnostics SMEs across Europe

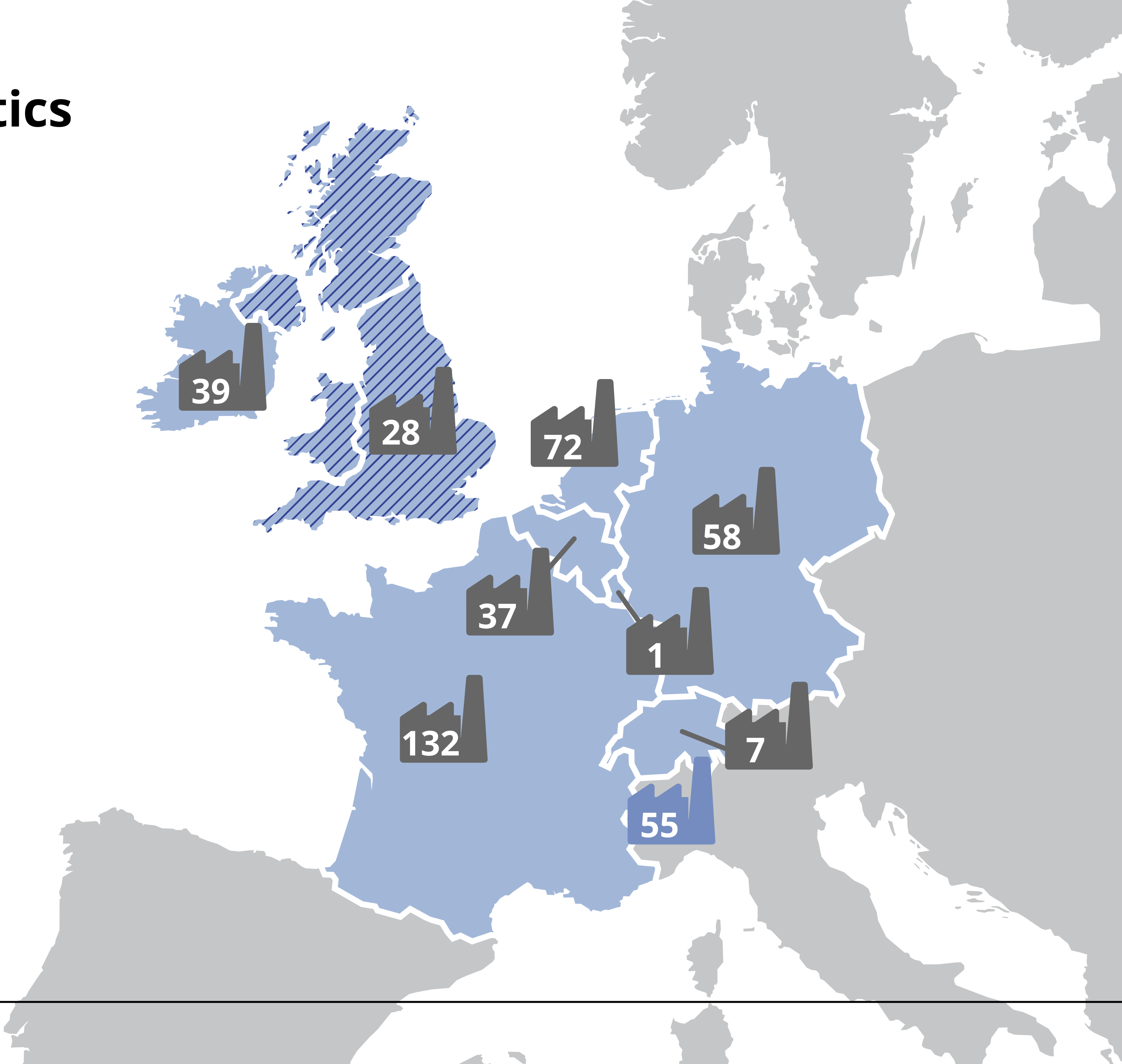
More than 420 SMEs received
tailored services throughout
Northwest Europe and beyond.



SME in NWE countries



SME beyond NWE countries



Services



Biomarker validation

- Pre-analytical validation to assess the variables dealing with biomarker robustness
- Analytical validation to assess the characteristics of the method of choice
- Clinical verification to offer, on a smaller scale, the foreseeable outcome of a true clinical validation of a potential clinical validation, thus decreasing the chances of future cross-validation failures



Tailored consultancy services on specific biomarker topics

- Coaching and consultancy for a strategic biomarker development.
- Enhancing successful validation and translation of SME's BM into a diagnostic product or algorithm with diagnostic, prognostic, or predictive value.

The best advantage of the project was to receive independent and objective data and evidence regarding our project development.



Mediagnost GmbH, Germany

Metabrain Research SA intends to develop further therapeutics in conjunction with CDx and can build on the knowledge gained in Codex4SMEs for these projects for which it intends to set up new collaborative R&D partnerships following its PRO approach.



Metabrain Research SA, France



Interactive online seminar on biomarker validation

- Introduction to biobank networks, services and opportunities for collaboration with the largest European biobank infrastructure BBMRI-ERIC
- Hands-on examples of collaborations between SMEs and biobanks
- IVDR-compliant market introduction of new biomarker-based diagnostics

About IBBL

IBBL (Integrated BioBank of Luxembourg) is the lead Biobank for the Biomarker validation services within the Codex4SMEs project. IBBL is an autonomous not-for-profit institute dedicated to helping researchers bridge the gap between bench and bedside. To accelerate the translation of biomarkers into the clinic, IBBL has developed a biomarker validation service that takes biomarker candidates through the pre-clinical validation from discovery right up to clinical validation.

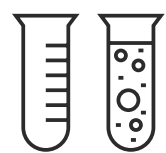
“The course attended led to a re-thinking of what is needed for our purposes and what can and should be implemented. We incorporated different strategies on how to ensure a high quality of our banks and how to best organize its storage.”

Mimetas, The Netherlands

“The biggest advantage is the capacity of Codex4SMEs to provide access to patient’s samples to facilitate the validation of early concept in the area of cancer research.”

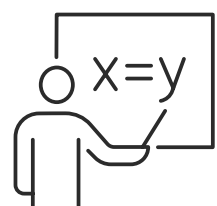
Life&Soft, France

Services



Free sample access

- The aim is to support SMEs in accessing clinical samples
- SMEs get: Support in testing and establishing new methods of in vitro diagnostics.



Knowledge transfer

- Aim is to support SMEs in gaining knowledge about biobanks and sample processing.
- SMEs get: tailored training on sample collection, quality management in biobanks and clinical sample processing.



About BBG

Biobank Graz is one of the largest and most well-known clinical biobanks in the world. Around 20 million individual specimens of body fluids and human tissue are stored here. Biobank Graz allows access to these specimens and associated data for scientific research purposes. The common goal is to develop approaches to diagnosing and treating disease.

Services



Translational assessment

- aim: to support SMEs in assessing and optimising the translational feasibility of their projects
- SMEs get: Full assessment of their translational research projects providing insight in health economics, IP and regulatory pathways



Full regulatory assessment

- aim: to support SMEs in assessing and optimising the regulatory strategy of their projects
- SMEs get: Full expert advice on the regulatory requirements for their diagnostics & access to EATRIS Regulatory Database

We are pleased with the regulatory help and advice. It has helped us get a better understanding of our product in regulatory terms and provided us understanding on how to proceed. Thanks for the help and valuable insights"



Omnigen B.V., Netherlands



Thanks for sending the draft. I'm so happy with the content. It's very detailed and specific for our device. So, this report is of great value to us. A big thank you from our side for all your efforts!"

IMcoMET B.V., Netherlands

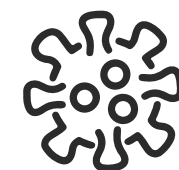
eatris

European infrastructure
for translational medicine

I think the report is comprehensive and well-written. We extracted some relevant data and references to support our case. I also had some nice "aha" moments while reading it. We will take your feedback and recommendations very seriously, and work towards a de-risked version of our plan. I want to thank you and your team incredibly for this piece of work."



Rapidemic, Netherlands



Covid-19 research services

- To help SMEs to find the latest COVID-19 related technologies and core facilities from 150+ top-tier EATRIS institutions
- SMEs get: Face-to-face time with European (pre-)clinical experts in COVID-19 & access to COVID-19 biosamples and technologies

About EATRIS

EATRIS is the European infrastructure for translational medicine. We bring together resources and services for research communities to translate scientific discoveries into benefits for patients.

I was impressed by how Meet&Match.Dx secured engagement with such large organisations like GSK Germany and identified challenges they had. It was an excellent way for startups to obtain airtime with these people.”

Oxford Immune Algorithmics, UK

Codex4SMEs provides wonderful business development opportunities for startups. The programs help identify and meet decision makers in large pharma and diagnostics companies. This is a catalyst for collaborative projects and growth of our business.”

1DROP AG, Switzerland



Services



Meet & Match.Dx

- A challenge-based acceleration program
- Access to European MedTech corporations
- Partnership exploration meetings

About Innovation in Health

Innovation in Health is a healthcare innovation consultancy dedicated to connecting start-ups, industry leaders, hospitals and researchers in the healthcare and life sciences industries. With a strong network of experts, global ecosystem and tailored programs, Innovation in Health supports individuals and organizations at all stages on their path to success and helps them navigate the complex and ever-changing world of healthcare.

Business Growth

We used the market access service, because specific market information is key for our decision-making process where to apply our technology to. The biggest advantage was that we selected, based on market data, two compounds for development.”

PharmaCytics, The Netherlands

The pitch training was very well organised with initial brief and to the point webinars and subsequently two personal web based sessions and it finished with F2F practicing. Especially the direct feedback on the content of the presentation, but also how it was presented was very useful and really helped to shape the message towards investors”

PharmaCytics, The Netherlands



Services



- QMS
- IP Strategy
- Clinical Trial Masterclass
- Multi-Market Entry
- Pitch Training
- Market Access
- Reimbursement

About the Business Growth Programme

A special package for SMEs from the Dx sector.

The cluster and research partners have an extensive range of services offered by regional network stakeholders. Companies benefit from this broad range of expertise to get ready for the market.

Learn more about the mission of Cluster and Research Partners on next page!

Cluster and Research Partners the Business Growth accelerators for SMEs



As an economic developer, STERN shapes the future by promoting innovation in life sciences.



BOM: catalyzing change in the province of Noord-Brabant, the Netherlands.



CÚRAM is a world leading research centre designing the next generation of 'smart' medical devices.



A life sciences cluster organisation supporting companies to create value and access new markets.



InnovationQuarter: organisation to stimulate the innovation potential in the greater Rotterdam – The Hague area.



Medicen, a Paris Region cluster, aims to transform scientific innovation into value propositions.



LMPI drives precision health, developing novel diagnostics and therapies for patient and societal benefit.



WestBIC as a Business Innovation Centre brings jobs in life sciences and wealth to their region.

Codex4SMEs teams up with European projects in the field of personalised healthcare

Many European initiatives have joined forces to increase the impact of support measures for SMEs. Through the merged supports, SMEs have been empowered to receive the most appropriate support for them.



BIC made the commercialization of biomarkers more manageable with respect to regulatory, clinical and business aspects.



Boost4Health accelerate the internationalisation of life science regions in North West Europe.



The BeYond-COVID project aims to make COVID-19 data accessible to scientists in laboratories, medical staff in hospitals or government officials.



CELIS helps clusters, networks and business and innovation support organisations to initiate cross-sectoral and inter-regional cooperation.



DIGI-B-CUBE promotes cross-sectoral collaboration of SMEs with Artificial Intelligence, Cognitive Computing Digital Technologies, and Bioimaging-Biosensing-Biobanking industries.



MATMED supports actors in the fields of advanced materials, medical devices and regenerative medicine.



SAPHIRE supports inter-regional collaborations and help identify opportunities for financing or investment by the Framework Programme, the Structural Funds or the EIB.



The Vanguard Initiative promotes interregional collaboration to develop new value chains and accelerate the adoption of innovative technologies that offer solutions to the societal challenges of European regions.

Codex4SMEs facilitates access to synergistic biobanks

To increase the range of clinical samples, companies have the opportunity to access numerous public banking networks and private providers of biospecimens.



Biobank Graz is one of the largest and most well-known clinical biobanks in the world. Around 20 million individual specimens of body fluids and human tissue are stored here.



BBMRI-ERIC is a European research infrastructure for biobanking connecting the main players from the biobanking field – researchers, biobankers, industry, and patients – to boost biomedical research.



The BBMRI.be network connects 18 Belgian biobanks such as hospitals, universities and research centers offering samples, data and expertise on biobank topics.



Finnish Biobank Cooperative (FINBB), as a member of BBMRI-ERIC, is a one-accessshop for effortless access to Finnish biobank materials and biodata.



In.vent Diagnostica GmbH offers services for the procurement of biological material of human origin, e.g. innovations, research, development, clinical trials, production, controls, standardization.

Impact on regional Dx ecosystems



THE CODEX4SMES PROJECT ENHANCES THE REGIONAL CAPACITIES

- building a pan-European network connecting stakeholders and raising the visibility of Dx actors,
- increasing the TRL of products and services through tailored support for Dx SMEs,
- fostering regional development to accelerate business growth, and
- initiating the development of new products and services to promote personalised healthcare.

Contact

**YOU ARE WELCOME TO CONTACT
US FOR MORE INFORMATION ABOUT
THE INTERREG NWE CODEX4SMES NETWORK.**

Project coordination of Codex4SMEs

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