

InfanDx AG

Company Overview

Dr. Achim Plum | CEO | July 2021

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| The Company

InfanDx AG

Lean Organization with Strong Partner Network



- Focus on diagnostic innovation for newborns
- Founded 2010 in Cologne/Germany by neonatologists, metabolomics scientists, and industry experts
- Headquartered at Biocampus Cologne
- Lead Product in R&D: HypoxE-Test® for Hypoxic-Ischemic Encephalopathy (HIE)

SEED FUNDING & PROJECT MANAGEMENT



METABOLOMICS & BIOSTATISTICS



CLINICAL TRIAL MANAGEMENT



InfanDx AG

Management Team

Dr. Achim Plum

CEO

20+ years of industry experience with focus on diagnostic innovation. Former companies include Epigenomics, Schering, Siemens, Curetis, Ares Genetics, SphingoTec



Wolfgang Kintzel

Chairman of the Supervisory Board

20+ years track record in life science innovation and business leadership with companies like Schering, Tyco Healthcare, amaxa, Cellbox Solutions



Dr. Andreas Lischka

Head of Finance



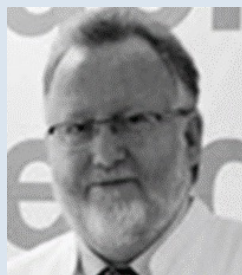
Dr. Carola Steins Rang

Head of Clinical, Quality & Regulatory



Dr. Mostafa Mahmoud

Senior Scientist R&D



Prof. Dr. Peter Bartmann

Former Chief Medical Officer,
Children's Hospital at
University Hospital Bonn, Germany

Neonatology, Clinical Trial Management



Prof. Dr. Axel Franz

Senior Neonatologist
Head of Center for Pediatric
Clinical Studies, University
Hospital Tübingen, Germany

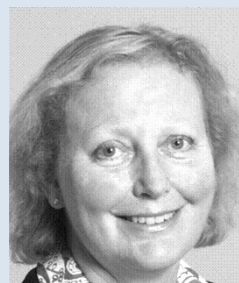
Neonatology, Clinical Trial Management



Prof. Dr. Dr. Matthias Keller

Chief Medical Officer, Children's
Hospital Dritter Orden, Passau
Germany

Neonatology, Pediatrics



Prof. Lena Hellström-Westas

Professor for Perinatal Medicine,
Uppsala University,
Sweden

Neonatology, Pediatrics

Prof. Dr. Hans-Peter Deigner

Dean, Faculty of Medical and Life
Sciences, University Furtwangen,
Germany

Metabolomics & Biomarker Expert



Prof. Dr. Matthias Kohl

Head of Institute of Precision
Medicine, University Furtwangen,
Germany

Biostatistics



Prof. Ola Saugstad

Professor Emeritus of
Paediatrics, Director Dept. of
Paediatric Research, University
of Oslo, Norway

Neonatology, Pediatrics

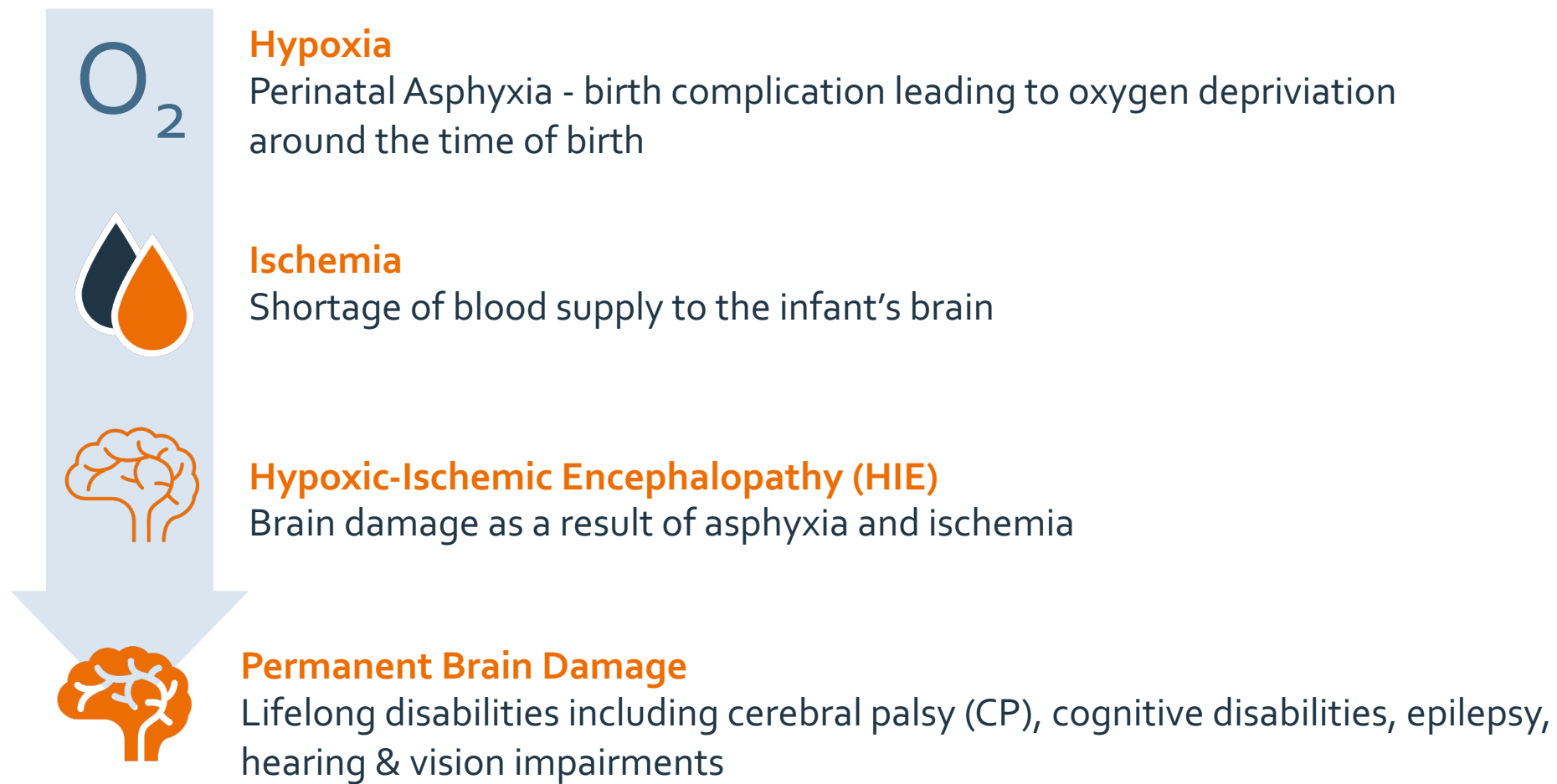




Medical Need

Hypoxic-Ischemic Encephalopathy (HIE)

Causes & Consequences



Perinatal Asphyxia and Hypoxic-Ischemic Encephalopathy

Facts & Figures

Brain injury (hypoxic ischemic encephalopathy, HIE) is the most prevalent outcome from perinatal asphyxia.

Most common cause of death and disability in newborns – 23 % of infant mortality worldwide

Often associated with persistent motor, sensory, cognitive impairment

Perinatal asphyxia is the major cause for infantile cerebral palsy (e.g. spasticity) worldwide

Out of 125 million newborns,
5 – 10 % are at risk



Source: Millar LJ et al. 2017: Frontiers in Cellular Neuroscience; doi: 10.3389/fncel.2017.00078

Hypoxic-Ischemic Encephalopathy (HIE)

Therapy by Therapeutic Hypothermia



Neonatal Therapeutic Hypothermia

Indications to treat (today)

Umbilical cord arterial
pH < 7.00


Abnormal neurological signs,
such as hypotonic muscles
or lack of sucking reflex




5-min APGAR*
score < 5

Need for delivery room
intubation or cardio-
pulmonary resuscitation



 32.5 – 34.5 °C

 72 hours

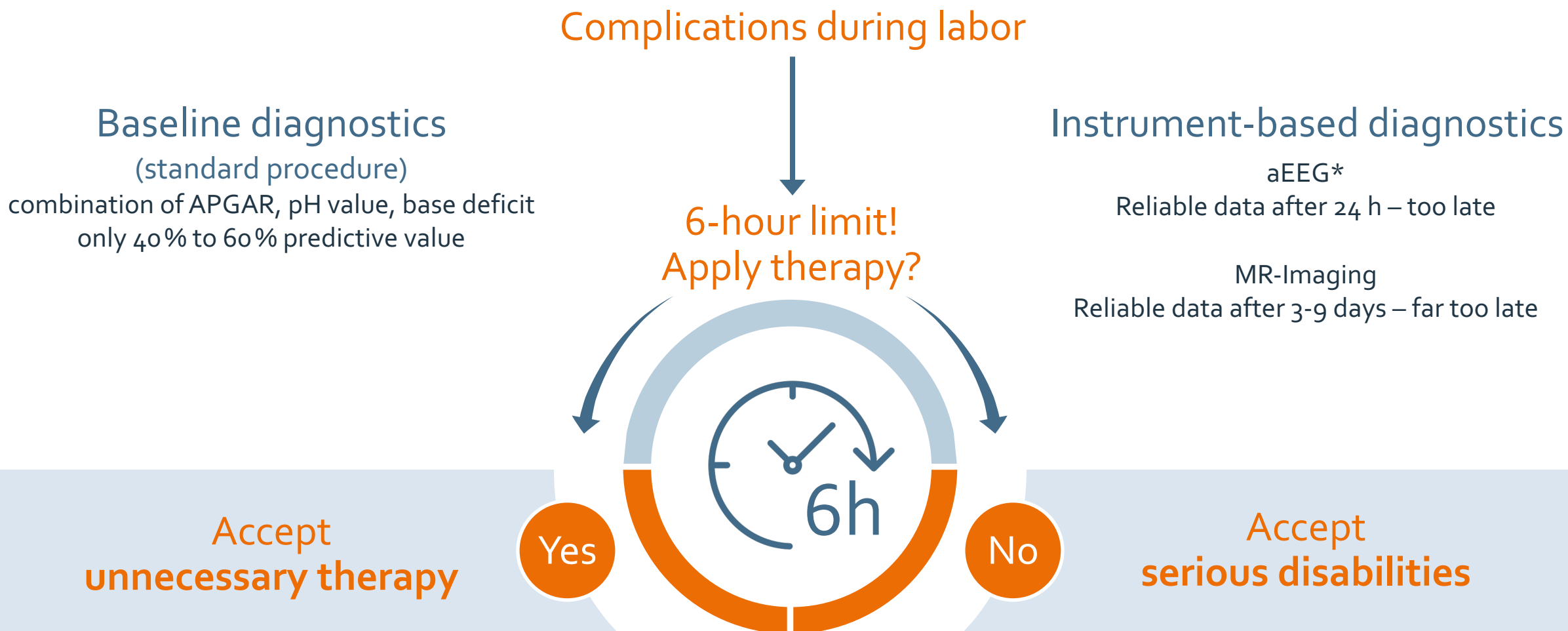
- Therapeutic intervention to prevent or alleviate permanent brain damage resulting from HIE
- Reduced metabolic rate allows brain to recover
- Most accepted therapy for HIE in newborns
- Cost-effective provided eligible newborns can be identified
- Reimbursed in many healthcare systems

But:

Therapeutic Hypothermia needs to be initiated within **6 hours of birth** to be effective

Decision-Making in HIE Today

Diagnostic Dilemma – No Conclusive HIE Diagnosis within 6-Hour Window



* aEEG = amplitude integrated electroencephalography



The HypoxE-Test®

InfanDx HypoxE-Test®

Our Solution to Solve the Diagnostic Dilemma in HIE



Blood Test

Very small blood sample, taken right after birth

Indicates brain damage reliably

Results within therapeutic time window < 6 h after birth



Technology Base

Biomarkers obtained from Metabolomics Research

5 patent families (4 granted)

Complications during labor



 **HypoxE -test®**



6-hour limit!
Apply therapy?



Decision with confidence

InfanDx HypoxyE-Test

Value proposition

Parents

- Best care for their baby
- Minimize uncertainty
- Affordable in case of non-reimbursement
- Corresponds to the recommendations of parent organizations (e.g. EFCNI)



Neonatologists

- Urgent medical need
- Certainty about therapy decision
- Avoid legal liability



Hospitals

- "Best care" reputation boosts marketing
- Exclude uncertainty, justify reimbursement
- Affordable in case of non-reimbursement
- Avoid legal liability



Insurances

- Save on decreased morbidity
- Avoid unnecessary treatments



Regulatory

- Clear socio-economic benefit
- > US\$ 2 bn savings p.a. in the US alone
- Solve urgent medical need
- Existing therapy aids regulatory assessment



InfanDx HypoxE-Test®

Market Potential Comparable to Top-Selling Current Diagnostic Tests



15 - 20 million newborns as intended use population

- Critical births (risk group defined according to clinical guidelines)
- Hospital deliveries
- US, EU and most developed emerging countries
- Total annual births worldwide: 140 million in 2019

Up to € 2 billion Total Addressable Market (TAM)

- Test ASP < €100
- Instruments as upside

€ 500+ million initial Servicable Addressable Market (SAM)

- With targeted IVD platforms in EU, USA, RoW (w/o LMICs)
- Distribution based sales channel targeting hospitals
- KOL support in key regions



Product Development

InfanDx HypoxE-Test®

Product Concept – Rapid Near-Patient Testing for Any Setting

- Fully automated
 - w/o plasma prep for lab
 - w/ plasma prep for POC
- Low- to mid-throughput
- Small benchtop or portable
- Random access (or STAT port)
- TAT < 1 h
- Platform-independent data interpretation
- Optional: Availability of other parameters relevant for newborns



Routine blood draw
at birth



Fully automated test
on standard
clinical chemistry analyzers



Cloud-based result
interpretation & reporting



< 1 Hour Turnaround Time (TAT) – Actual Test: 15-20 min

Proprietary
biomarkers



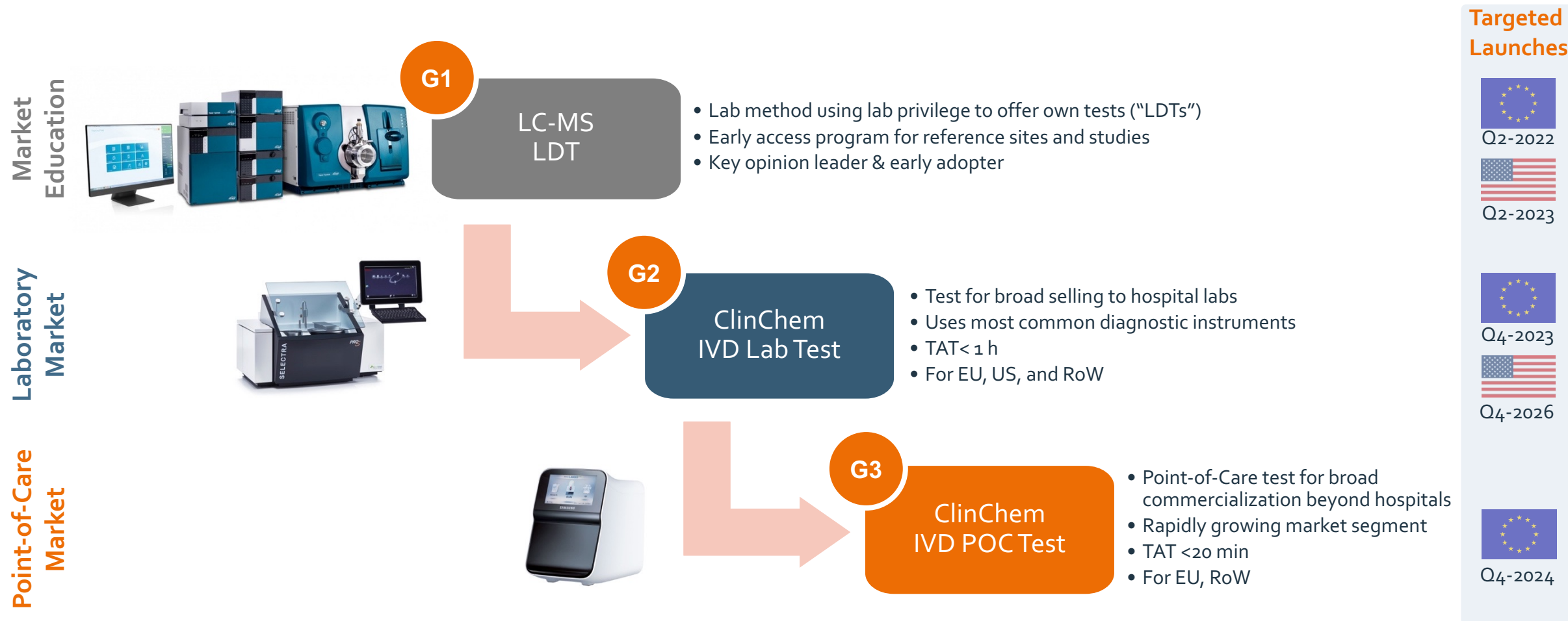
Broadly
Used
Analyzers
by Partners



Proprietary
Algorithm &
Software

InfanDx HypoxE-Test®

Product Strategy – Market Introduction Starting in Mid-2022



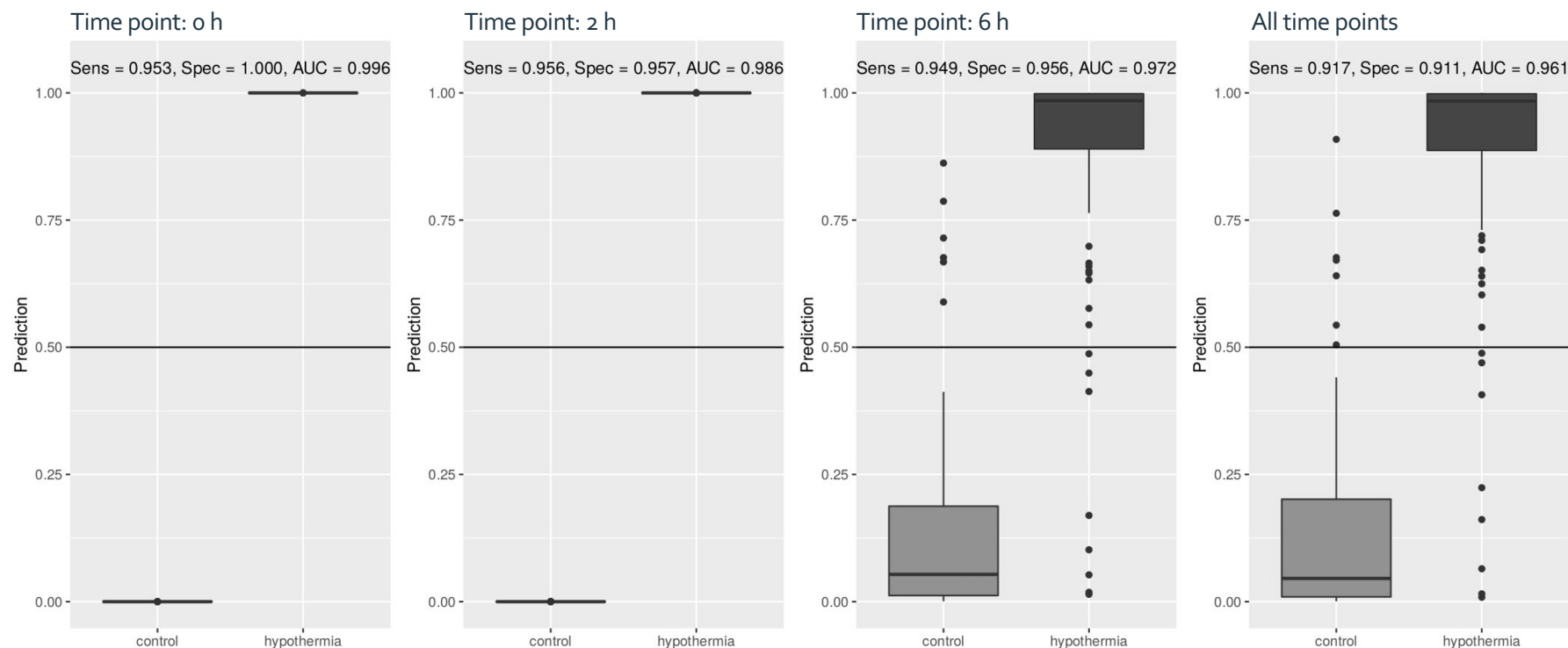
InfanDx HypoxE-Test®

Candidate Biomarkers – Excellent Single Biomarker Performance



Interim analysis using
hypothermal
treatment (yes/no) as
surrogate endpoint
yielded

AUCs of >0.95,
92% sensitivity, and
91% specificity.

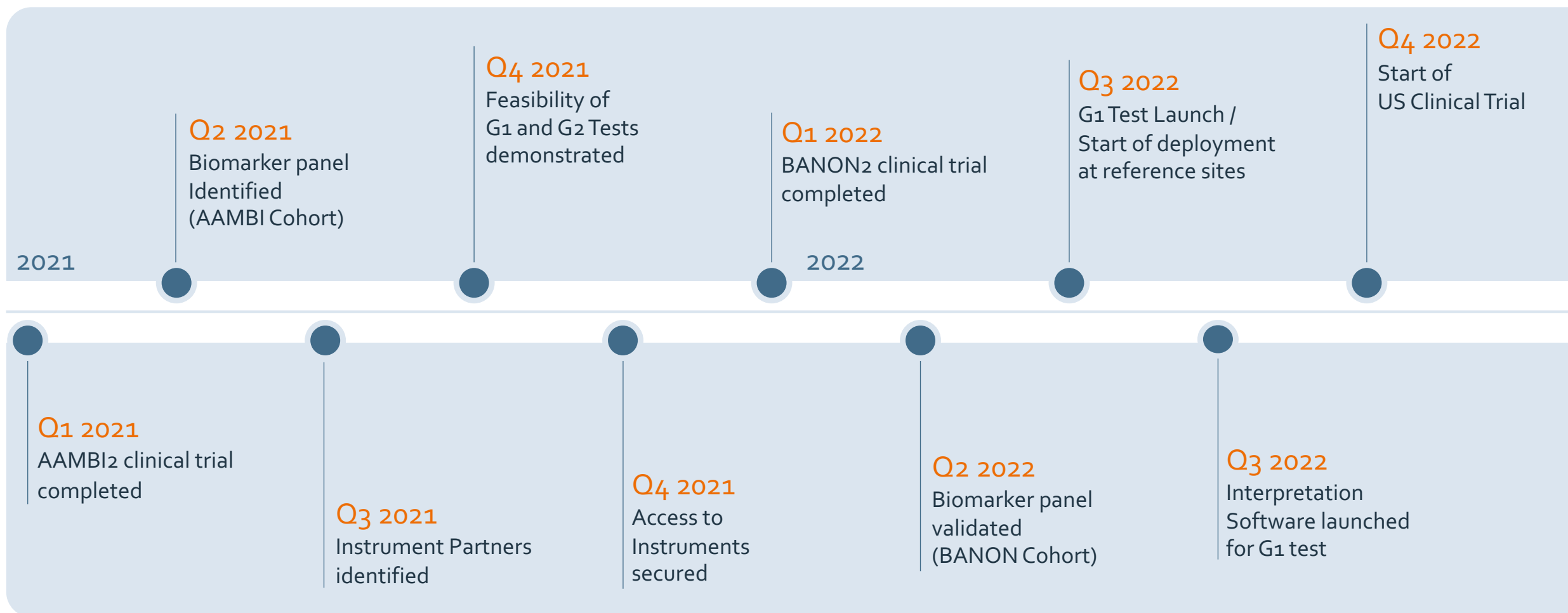


Combination of up to 4 biomarkers further increases performance

Design freeze of final panel and algorithm in Q2-2021 (Endpoint: 2 year HIE outcome)

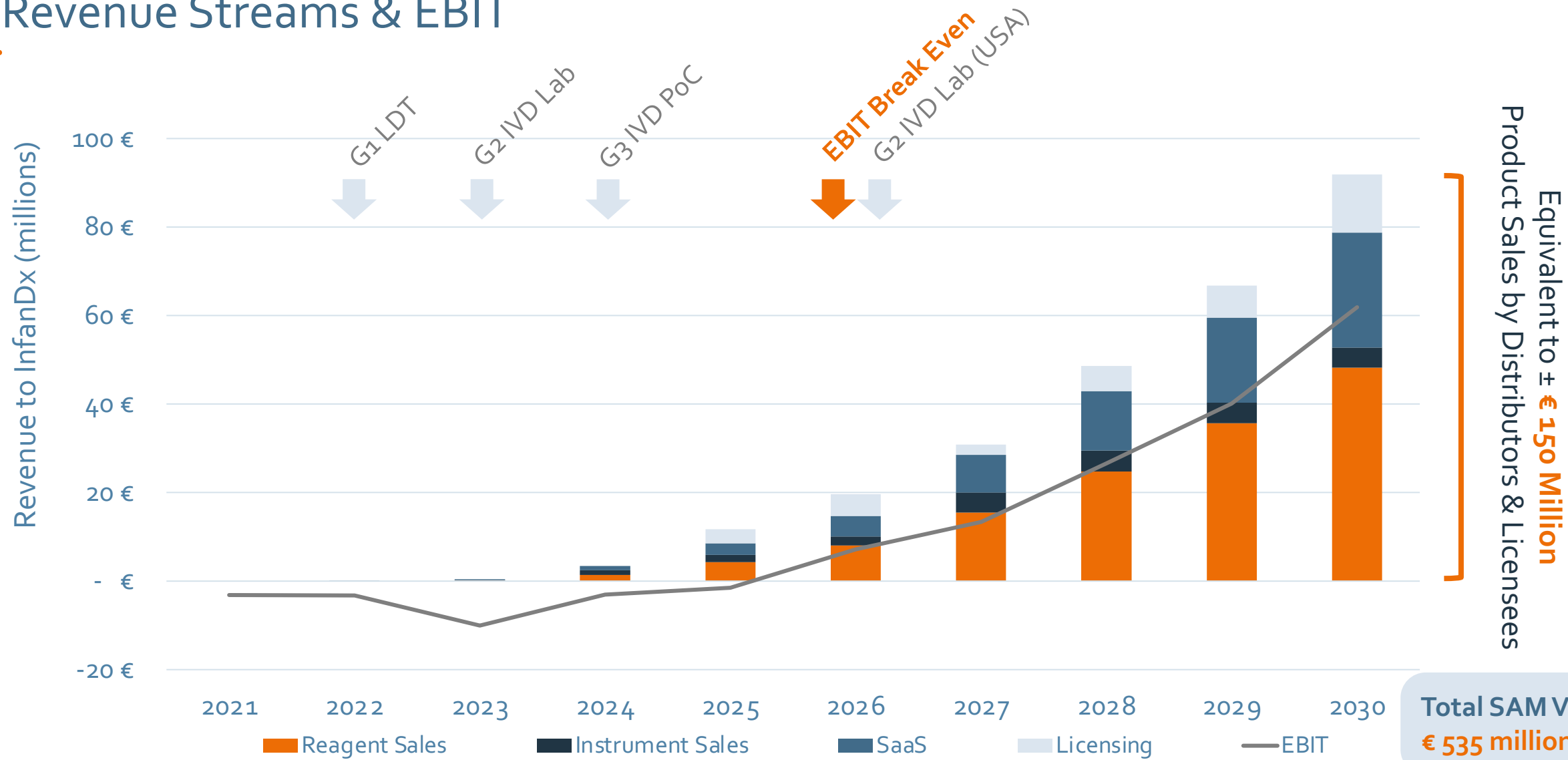
2021/22 Product Development & Launch Milestones

Numerous Key Value Drivers Can be Achieved in Near-term



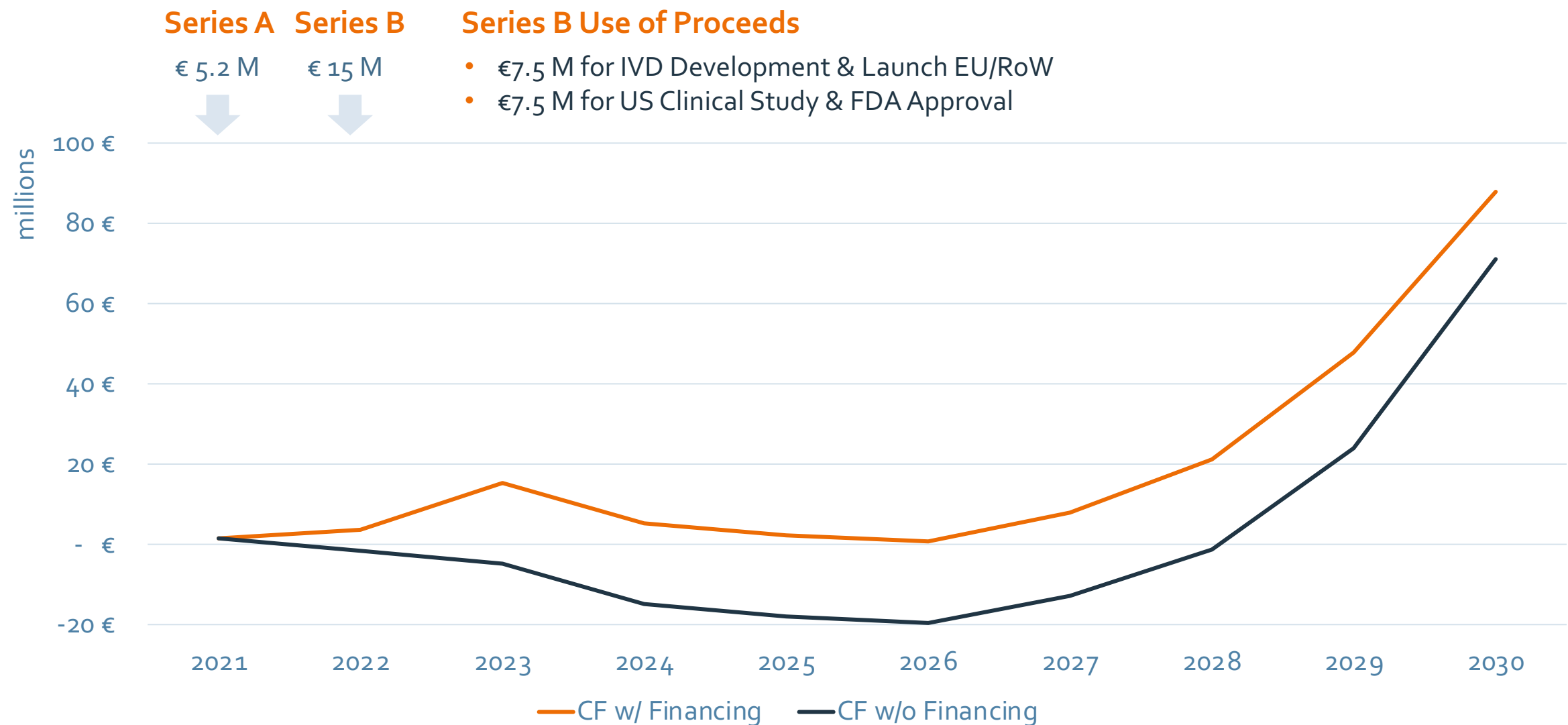
10-Year Business Plan

Revenue Streams & EBIT



10-Year Business Plan

Cash Flow – 10 Years



Milestones & Exit

Industry-typic value-inflection points and de-risking leading to exits

VALIDATION BY	2021	2022	2023	2024	2025	2026
SCIENCE	Final Biomarker Panel	Biomarkers validated				
PATENTS	4 Patent Families	Further IP to be filed				
CE-IVD Approvals			G2 IVD LAB	G3 IVD POC		
USA-FDA Approval						G2 IVD LAB
LICENSING					1st Deal	
MARKET					Commercial PoC	EBIT Break Even





| Summary

InfanDx' Equity Story

Summary

- Founded by leading clinicians and industry experts with the mission to improve outcomes in neonatal critical care through better diagnostics
- Lead product HypoxE-Test® for early assessment of severity and prognosis of Hypoxic-Ischemic Encephalopathy (HIE) to prevent or alleviate lifelong disabilities through timely therapy
- With 5% to 10% of all newborns at risk, the HypoxE-Test® is a unique € 2 billion market opportunity, of which € 500 million are serviceable initially
- Candidate biomarkers with excellent performance potential in advanced clinical validation – final biomarker selection in Q2-2021, final biomarker panel validation in Q2-2022
- Partnering-based strategy leveraging existing diagnostics platforms for laboratories and the point-of-care for rapid commercial deployment
- Launch of a G 1 early adopter test and cloud-based interpretation software expected for mid-2022
- Launch of G2 clinical chemistry test for broad commercialization expected for Q4-2023
- Lean and effective organization leveraging a strong scientific and clinical network

Thank You

InfanDx AG

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