“Being born is the most dangerous moment in our life”

Virginia Apgar, MD | 1909– 1974 | Surgeon, Anesthetist, Neonatologist

InfanDx AG | Company Overview

April 2022

Company Highlights
Our Mission: Improving Outcomes in Neonatal Acute & Critical Care

- Founded 2010 by neonatologists & metabolomics scientists
- New management of industry experts succeeding founders in 2021
- Headquartered at BioCampus Cologne, Germany with U.S. subsidiary in incorporation
- Current headcount: 16

- **Diagnostics company** with focus on unmet needs in neonatal acute and critical care
- **First-in-Class HypoxE-Test®:** Lead product in R&D for Hypoxic-Ischemic Encephalopathy (**HIE**) in newborns with a total market potential of €2+ bn
- **Metabolomics** technology platform with granted biomarker IP
- **HIE Biomarker Panel** in advanced clinical development with no competition on the horizon
- **11,000+ blood samples** for validation of biomarkers and IVD products available from dedicated longitudinal studies
- **Technical feasibility** of IVD assay format for routine IVD instrumentation demonstrated

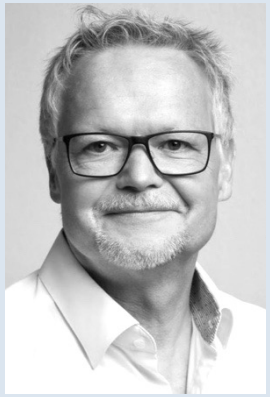
1 | Leadership

InfanDx AG Management Team
70 Years of Combined Industry Experience

Dr. Achim Plum
CEO

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

Academic background in genetics, cell biology and biochemistry



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

Academic training in life sciences

Dr. Gunter Weiss
COO

15+ years of industry experience with focus on biomarker and IVD development. Track-record with successful product approvals in EU, US, and China.

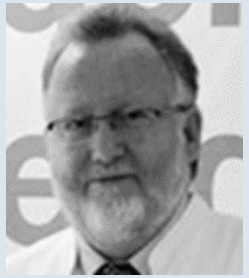
Academic background in biostatistics and computational biology

Dr. Andreas Lischka
Head of Finance

15+ years track record accounting and controlling as well as corporate finance in the biotech industry

Academic background in business administration and human resource management

Key Advisors
Support by Leaders in Neonatology, Metabolomics, and Biostatistics



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
Co-Founder

Prof. Lena Hellström-Westas
Professor for Perinatal Medicine,
Uppsala University,
Sweden

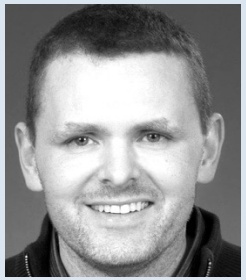
Neonatology, Pediatrics

Prof. Dr. Hans-Peter Deigner
Dean, Faculty of Medical and Life
Sciences, University Furtwangen,
Germany

Metabolomics & Biomarker Expert
Co-Founder

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

2 | Diagnostic Dilemma in HIE

(HIE - Hypoxic-Ischemic Encephalopathy)

Hypoxic-Ischemic Encephalopathy (HIE)
Causes & Consequences

O_2

Hypoxia
Perinatal Asphyxia - birth complication leading to oxygen depriviation around the time of birth

Ischemia
Shortage of blood supply to the infant's brain

Hypoxic-Ischemic Encephalopathy (HIE)
Brain damage as a result of asphyxia and ischemia

Permanent Brain Damage
Lifelong disabilities including cerebral palsy (CP), cognitive disabilities, epilepsy, hearing & vision impairments

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

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

Risk Factors for Asphyxia & HIE
Numerous Complications Put Newborns at Risk

Risk Factors for Asphyxia potentially leading to HIE

- High risk pregnancies
- Umbilical cord issues
- Placenta or uterine complications
- Cervical issues
- Oligohydramnios and Polyhydramnios
- Infections
- Intrauterine growth restrictions
- Labor and delivery errors
- Neonatal health mismanagement

1 in 4 newborns at risk

30+ million deliveries globally with one or more risk factors

https://hiehelpcenter.org/medical/causes-risk-factors/

Hypoxic-Ischemic Encephalopathy (HIE)
Therapy by Therapeutic Hypothermia

Neonatal Therapeutic Hypothermia

- Therapeutic NICU[1] intervention to prevent or alleviate permanent brain damage
- Reduced metabolic rate allows brain to recover
- Only guideline-recommended therapy for HIE with no significant adverse physiological side effects when performed adequately (but can affect mother-child bonding)
- Very resource-intensive and expensive…
- … but cost-effective in truly eligible patient population & reimbursed in many healthcare systems

32.5 – 34.5 °C

72 hours

But:

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

[1] NICU = Neonatal Intensive Care Unit

Decision-Making in HIE Today

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

Perinatal risk factors /
Complications during labor

Baseline diagnostics

(standard procedure)

combination of APGAR, pH value, base deficit

only 40 % to 60 % predictive value

6-hour limit!
Apply therapy?

Instrument-based diagnostics

aEEG*

Reliable data after 24 h – too late

MR-Imaging

Reliable data after 3-9 days – far too late

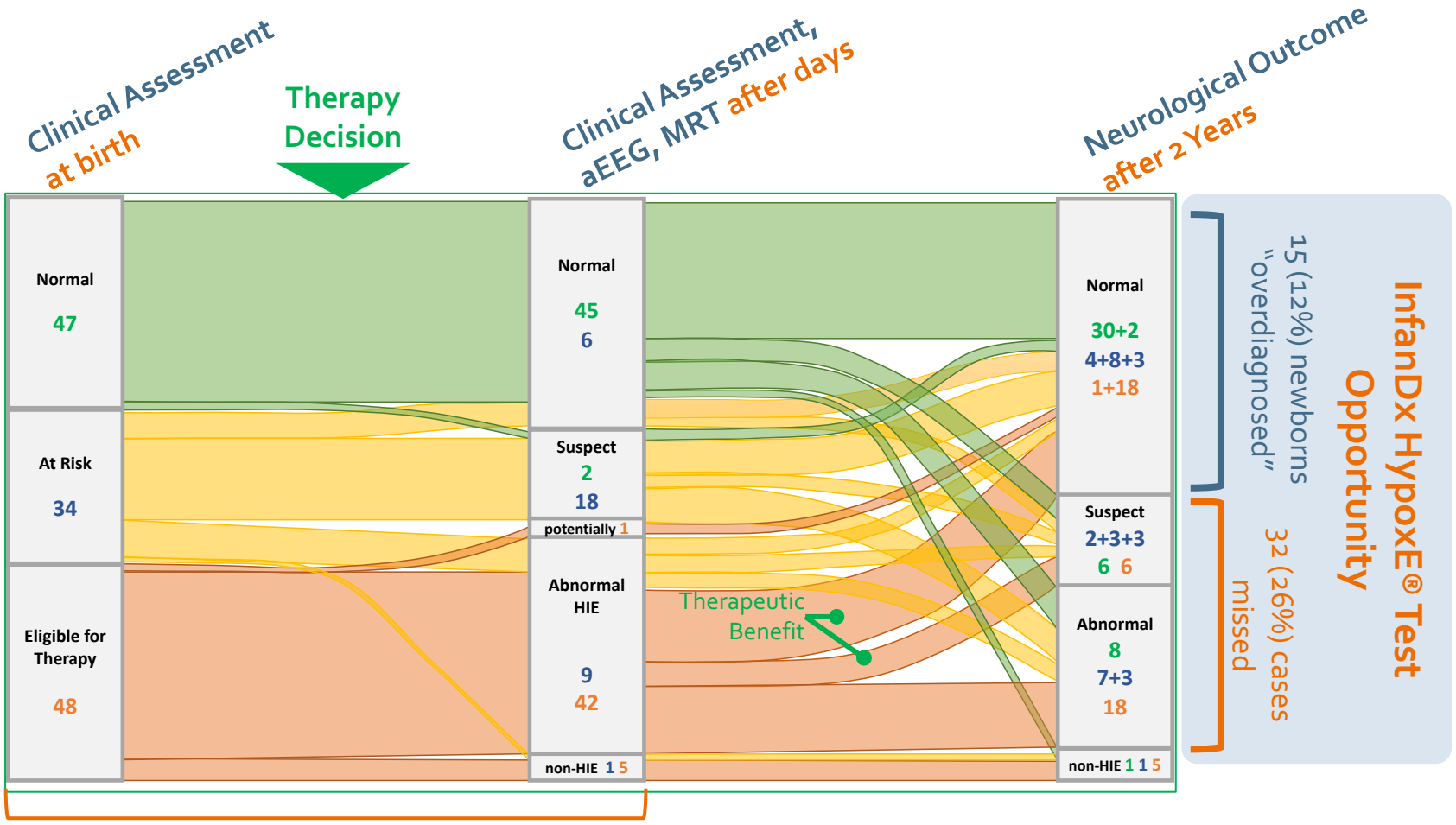
Accept
unnecessary therapy

Accept
serious disabilities

* aEEG = amplitude integrated electroencephalography

Decision-Making in HIE Today
Current Diagnostic Practice Leads to Significant Misdiagnosis

Data from AAMBI Cohort (see slide 21 for study details)



- "For all patient groups, clinical assessment and standard parameters (APGAR scores, umbilical cord blood pH and lactate) **did not enable accurate prediction of longer-term** neurodevelopmental outcome and hence **insufficiently indicated the need for neuroprotective therapies."**

- "The AAMBI cohort provides the opportunity to study metabolomic biomarkers for better identification of hypoxic-ischemic brain injury."

Prof. Dr. Axel Franz
Neonatologist, AAMBI Study PI
University Hospital Tübingen
Germany

Presented at:

3 | Our Solution: The HypoxE-Test®

The InfanDx HypoxE®-Test
Our Solution to Solve the Diagnostic Dilemma in HIE

Perinatal risk factors
Complications during labor

Objective Decision
in <1 hour

Timely Decision with Confidence

InfanDx HypoxE® Test

A First-in-Class Blood Test for HIE…

- Indicating brain damage reliably,
- … on a small blood sample take at birth,
- … analyzed within <1 hour on standard diagnostic equipment,
- … for a very affordable prize.

With Unique Technology Position

- Metabolomics biomarkers,
- … associated with Asphyxia and HIE,
- … protected by 4 granted patent families, and
- … no competition on the horizon.

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 Practice" 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
- Solve urgent medical need in orphan disease
- Clear socio-economic benefit
- > US$ 2 bn savings p.a. in the US alone
- 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

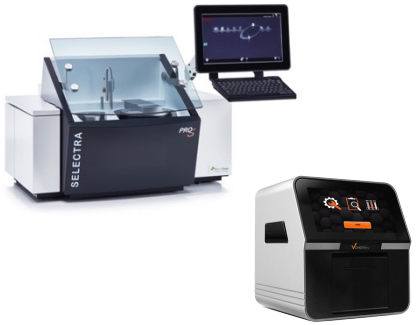
€ 500+ million initial Servicable Addressable Market (SAM)

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

4 | Product Development

InfanDx HypoxE-Test®
Product Concept – Rapid Near-Patient Testing for Any Setting

Routine blood draw at birth



Fully automated test on standard Clinical Chemistry Analyzers

Result interpretation & cDSS[1] (SaaS)

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

Proprietary biomarkers

Broadly Used Analyzers by Partners

Proprietary Algorithm & Software

Targeted Settings

- STAT[2]/Satellite labs near delivery room
- Point-of-care testing in delivery room/NICU

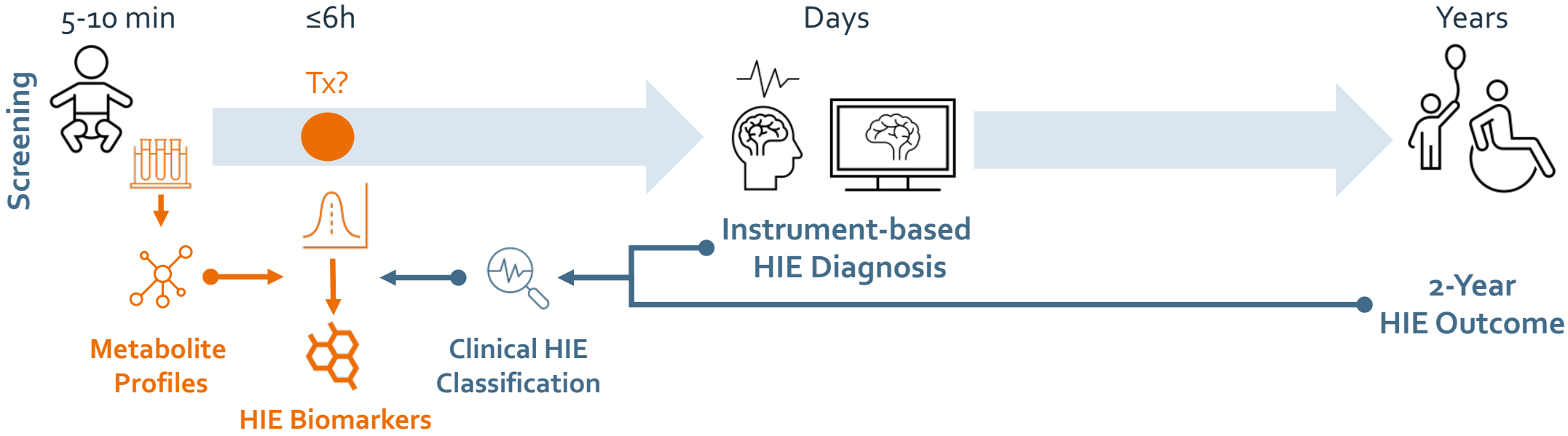
IVD Instrument Platform Access

- IVD Platform partners identified
- Requirement engineering completed
- Feasibility studies ongoing

[1] cDSS: clinical Decision Support System | [2] Short Turnaround Time

Biomarker Identification & Validation in Two Dedicated European Cohorts

Thousands of Samples Sufficient for *all* Required Biomarker and IVD Validation



AABMI

- Biomarker identification
- 155 study subjects
- 3,200 blood samples available in InfanDx BioBank
- Study closed & data curated
- Biomarkers identified/confirmed in Q1-2022

BANON

- Biomarker panel optimization & validation
- IVD test validation (IVDR)
- 553 study subjects
- 8,000 blood samples available in InfanDx BioBank
- 2-year follow-up finalized in Q1-2022
- Panel validation in Q3-2022

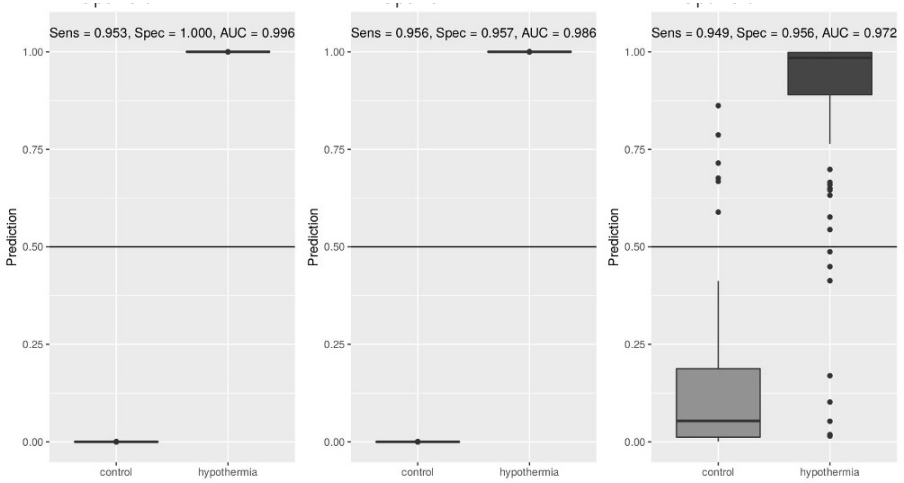
Biomarkers Targeted by InfanDx HypoxE-Test®

Biomarkers in AAMBI – Excellent Single Biomarker Performance

Interim Analysis

(Biomarker Example)

at birth | **2h after birth** | **6h after birth**

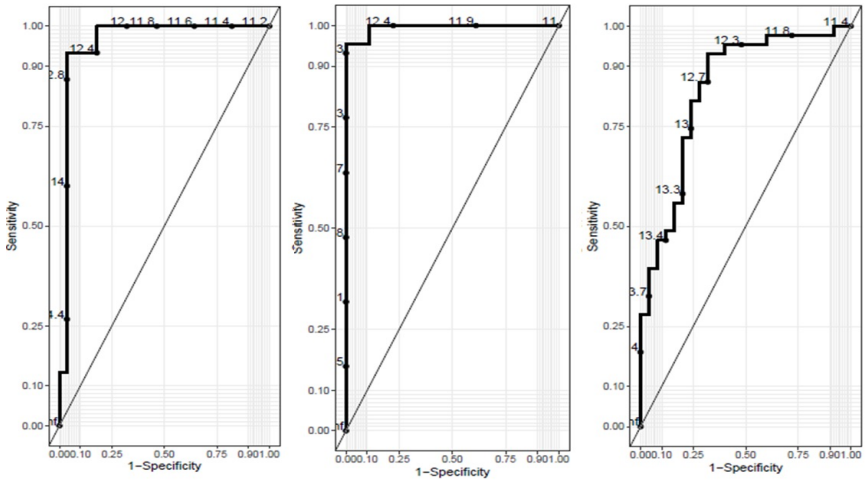


- Numerous candidate biomarkers identified in interim analysis that clearly distinguish patients eligible for hypothermal therapy from controls (by standard of care)

Final Univariate Analysis

(Biomarker Example)

at birth | **2h after birth** | **6h after birth**



- Numerous biomarkers confirmed/ identified in final univariate analysis that are highly informative in the critical timeframe on presence of HIE as defined by composite classifier based on instrument-based diagnosis and neurological assessment after 2-year follow-up

Panel design (combination of 5-7 biomarkers) and interpretative algorithm to be finalized in Q1/2-2022

InfanDx HypoxE-Test®
Product Strategy – Market Introduction Starting in Mid-2022

Market Education

G1 LC-MS LDT

- Reference method for IVD benchmarking and further studies
- Basis for introduction of Laboratory Developed Tests (LDTs) in EU and US
- Early access program for reference sites and studies
- Key opinion leader & early adopter

Laboratory Market

G2 ClinChem IVD Lab Test

- Test for broad selling to hospital labs
- Uses most common diagnostic instruments
- TAT[1] < 1 h
- For EU, US, and RoW[1]

Point-of-Care Market

G3 ClinChem IVD POC Test

- Point-of-Care test for broad commercialization beyond labs
- Rapidly growing market segment
- TAT <20 min
- For EU, RoW

Targeted Launches

LDT
EU
fromQ3-2022
US
from Q1-2023

CE Q4-2023

FDA Q4-2026 (or earlier)

CE Q4-2024

[1]TAT: Turnaround Time | [2]RoW: Rest of World

InfanDx HypoxE-Test®
Feasibility Studies for G1 and G2 Products

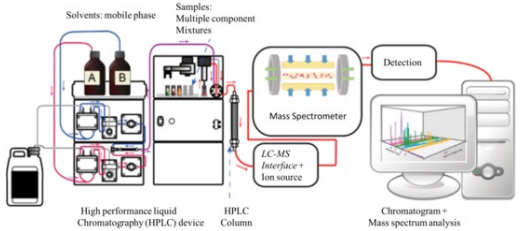
LC-MS & Biochemical Assay feasibility demonstrated for several candidate biomarkers

Assay Principle | **Feasibility Data on Candidate Biomarkers**

G1

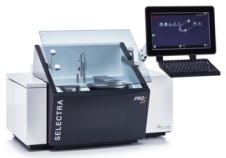
LC-MS LDT

LC-MS



Metabolite	Accuracy (recovery S)			LOQ (CV = 15%)	LLOQ (S/N = 10)	LOD (S/N = 3)
		Intra-Assay-Error	Linearity	µM	nM	nM
	m	Dm	r²			
A	1.0014	2.46%	0.9946	0.499	0.56	0.06
B	1.0011	1.85%	0.9969	0.404	39.00	33.00
C	1.0002	2.79%	0.993	1.033	2.75	0.53
D	1.0000	0.10%	1.0000	0.080	34.00	18.00
E	0.9999	0.43%	0.9999	0.055	7.49	1.67
F	1.0000	0.40%	0.9999	0.036	31.00	17.00
G	1.0000	3.28%	0.9914	25.000	1527.00	166.00
H	0.9996	5.58%	0.9847	419.000		

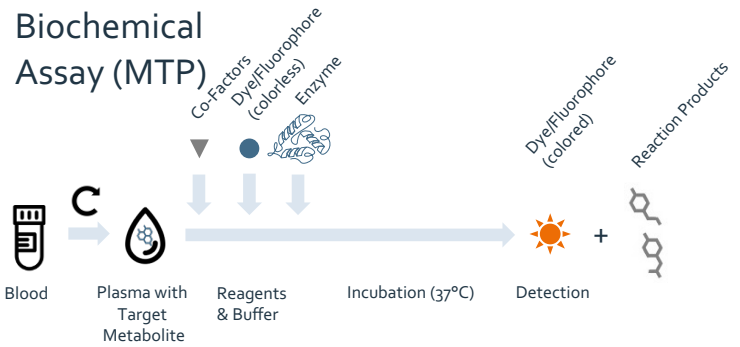
- Time to result in less than 2 hours feasible **>>> aiming at further shortening to 1 hour**
- Implemented on standard lab equipment (Research-use Only)
- Can be confectioned to minimize handling steps and allow single sample handling



G2

ClinChem IVD (Lab)

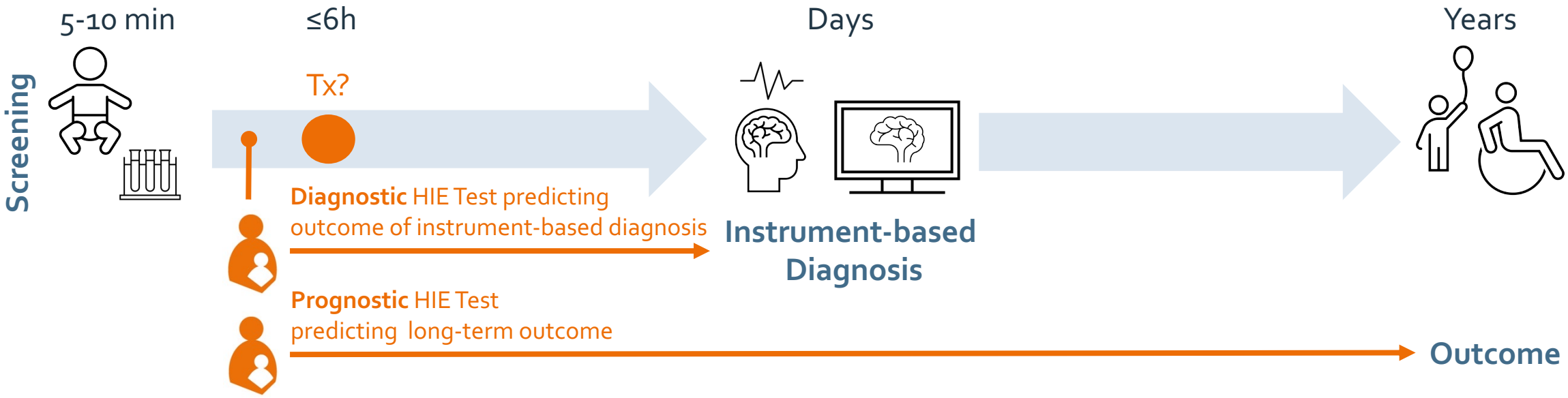
Biochemical Assay (MTP)



Number	Metabolite	LOD/LOQ	Intra-Assay CV	Inter-Assay CV	Recovery
1	A	320 /500 µM	1.8 %	5.8 %	84 ± 4.4%
2	B	5.28/15.3 µM	1.77%	6.8%	95 ± 1.5%
3	C	41/78 µM	2.3 %	6.6 %	94.25 ± 11%
4	D	30.4/200 µM	3.54 %	3.73 %	103 ± 15%
5	E	4 µM	1%	7.2%	115± 4 %
6	F	3/6.8 µM	0.68%	11%	In progress (plasma Validation)
7	G	0.88/14 µM	1.12%	4.64 %	In progress (plasma Validation)
8	H	15 µM	2.68%	4.1%	99%
9	I	5µM	1.02%	2.5%	89%
10	J	25µM	2.4%	4.5%	83%
11	K	10µM	3.4%	2.5%	80%
12	L	-	-	-	In Progress (plasma Validation)
13	M	-	-	-	In Progress (plasma Validation)

- If enzymes are available, assay development is straight-forward
- All assays show excellent performance in multititer plate (MTP) format
- **Customization to G2 IVD Platform for laboratory use ongoing**
- G3 POC Assay adaption to follow

US Strategy
Aim for Early Market Entry with Diagnostic Claim – Add Prognostic Claim Later



Clinical Trial

- Compare HIE Test on blood sample against classifier based on instrument-based diagnostic
  - > 1st FDA Submission (aiming at *De Novo* pathway)
- Validate prognostic claim against 2-year outcome
  - > 2nd FDA Submission (PMA pathway)

- Q4-2021: Incorporation of a US-subsidiary
- H1-2022: FDA pre-submission meeting (targeted)[1]
- Q3-2022: Set-up of Clinical Operations in USA
- Q4-2022: Initiation of US-Trial

[1]Subject to FDA availability (Covid-19)

5 | Go-to-Market & Milestones

Business Plan
Go-2-Market – The Big Picture

EUROPEAN & RoW MARKET ENTRY in 2022/23

SAM

About EUR 200 million of initial Serviceable Available Market (SAM) for InfanDx products

Market Segment

Initial focus on Tier 1 Reference Sites in EU ('Lighthouses') for KOL support followed by Tier 2/3 Hospitals in EU and Tier 1-3 in RoW

Products

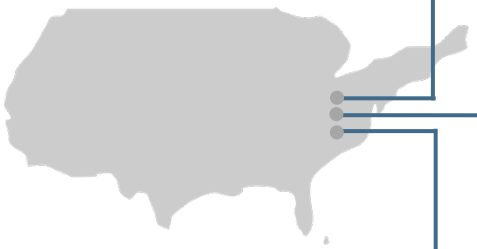
Tier 1 (Early Adopters): G1 LDT (2022)
Tier 1/2: G2 IVD Lab (2023)
Tier 3: G3 IVD PoC (2024)

InfanDx: "SEEDING"

- Commercial proof-of-concept
- EU / US / RoW

LICENSING: "HARVESTING"

- High-volume markets building on commercial proof-of-concept.
- Further geographic expansion into China and RoW



US MARKET ENTRY IN 2023/2026

SAM

About EUR 100 million of initial Serviceable Available Market (SAM) for InfanDx products

Market Segments

Initial focus on Tier 1 Reference Sites ('Lighthouses') for KOL support followed by other Tier 1 and the Tier 2 Hospitals

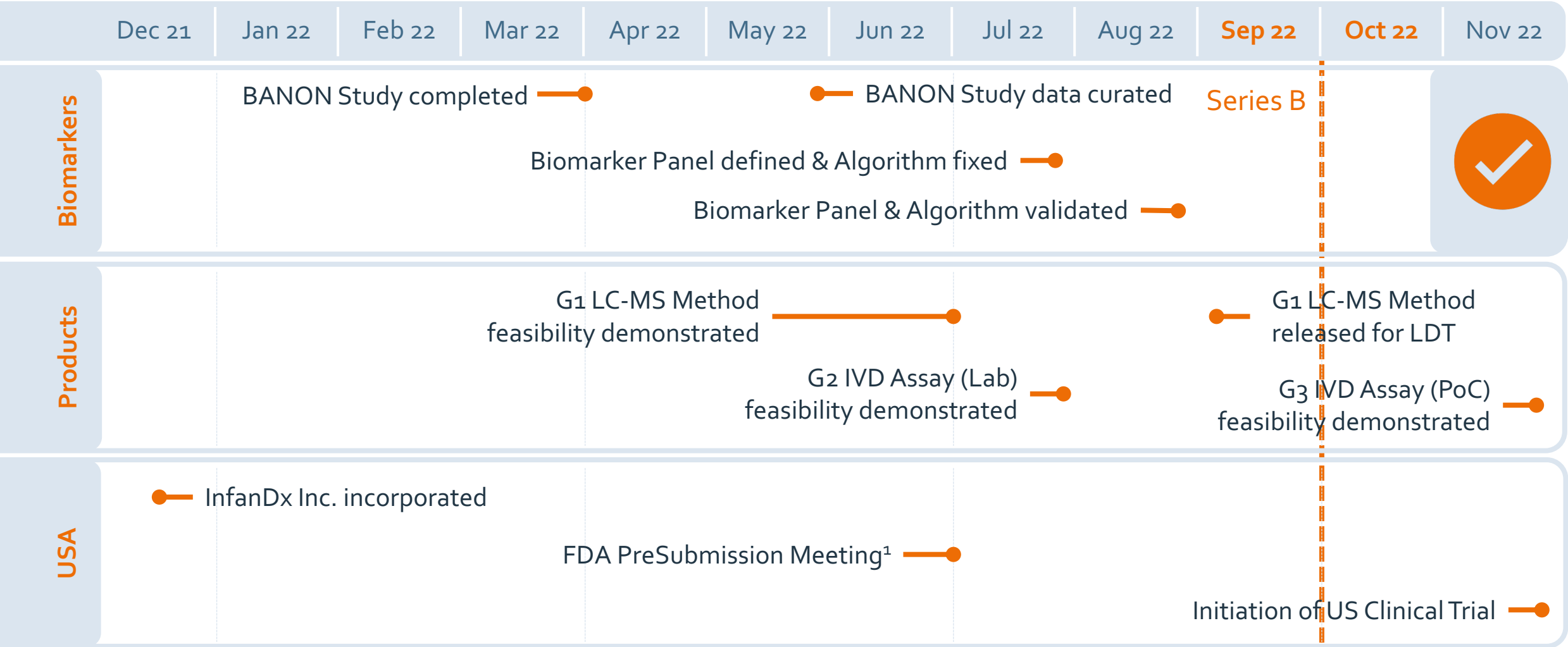
Products

G1 LDT for early adopters starting from 2023 followed by G2 IVD in 2026

Alternative study design may expedite timeline for IVD launch in US

2021/22 Near-Term Value-Drivers

Numerous Key Milestones Scheduled in the Run-Up to a Series B



[1]Subject to FDA availability (Covid-19)

Milestones & Exit Options

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				
KOL SUPPORT		LDT (EU)	LDT (USA)			
CE-IVD (IVDR)			G2 IVD LAB	G3 IVD POC		
USA-FDA					←	G2 IVD LAB
LICENSING					1st Deal	
MARKET					Commercial PoC	EBIT Break Even
EXIT OPTIONS				(US) IPO ●	——— ●	
				M&A ●	——— ●	

6 | Summary

InfanDx' Equity Story
Summary

- **Mission:** Diagnostic innovation to improve outcomes in neonatal acute & critical care
- **Lead product in R&D:** First-in-Class HypoxE-Test® for early diagnosis of Hypoxic-Ischemic Encephalopathy (HIE)
- **Attractive market opportunity:**
  - 10% to 15% of all newborns at risk
  - € 2 billion TAM | € 500+ million SAM
- **Progressive business model:**
  - Established IVD reagent business combined with Software-as-a-Service (SaaS) for clinical decision support
  - Market "Seeding" with own products | "Harvesting" by licensing
- **Low-risk product strategy:** Leveraging widely used diagnostics platforms for rapid commercial deployment
- **Biomarkers found:** Individual biomarkers identified | panel design in Q1/2-2022 | validation in Q3-2022
- **Unique competitive position:** strong IP position with granted patents on biomarkers | no visible competition
- **Near-term market introductions:** LDT in EU from Q3-2022 | CE-IVD from Q4-2023
- **Further strategic focus on US:** US clinical trial for FDA submission starting in Q4-2022 | LDT from early 2023
- **Defined commercial strategy:** Targeting commercial proof-of-concept by 2025 and EBIT break-even by 2026

Thank You

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