

A background image showing a microscopic view of cells, likely cancer cells, with a blue and purple color palette. The cells are clustered and have a textured, granular appearance.

# BIOVICA

Treatment Decisions With Greater Confidence

Capital Markets Day

2022-05-17

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# Agenda Capital Markets Day

- Company Overview      Anders
- US Go-to-Market plan      Warren
  - US Sales strategy      Kendon
  - Biovica CLIA Lab      Dan
  - Scientific update      Amy
- Pharma Collaborations      Henrik
- Q&A session      Charlotte





The background of the slide features three distinct clusters of cells, likely representing tumor spheroids or organoids, rendered in a light, semi-transparent style. These clusters are positioned in the upper right, lower right, and lower left areas of the frame. The overall background is a soft gradient of blue and purple hues.

# BIOVICA

Treatment Decisions With Greater Confidence

Company Overview

Anders Rylander

# Agenda

1. Company & Product Overview
2. Clinical Evidence & Collaborations
3. Market & Go-To Market Strategy
4. Team



## About the Presenter

### Anders Rylander, CEO & Board Member

- CEO & main shareholder in Biovica
- Co-founder of Axholmen Management Consulting
- CTO at ICA AB
- Senior Manager at Accenture



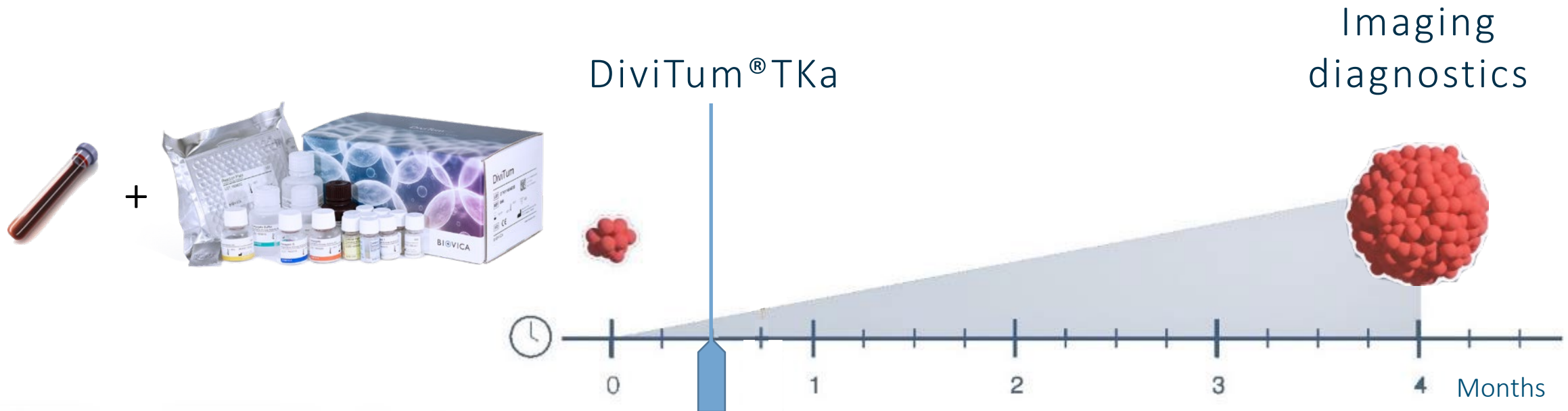


# Biovica Overview

- Founded 2009, based on research performed at Uppsala University
- IPO 2017, traded on Nasdaq First North Premier
- HQ in Uppsala, lab in San Diego
- Regulatory: ISO 13485 certified and DiviTum® TKa CE labeled
- FDA 510(k) submission Q3 2020



# DiviTum®TKa Provides Early Response Indicator of the Effectiveness of Treatment For Cancer Patients








DiviTum®TKa measures cell proliferation rate for faster evaluation of cancer treatment efficacy.



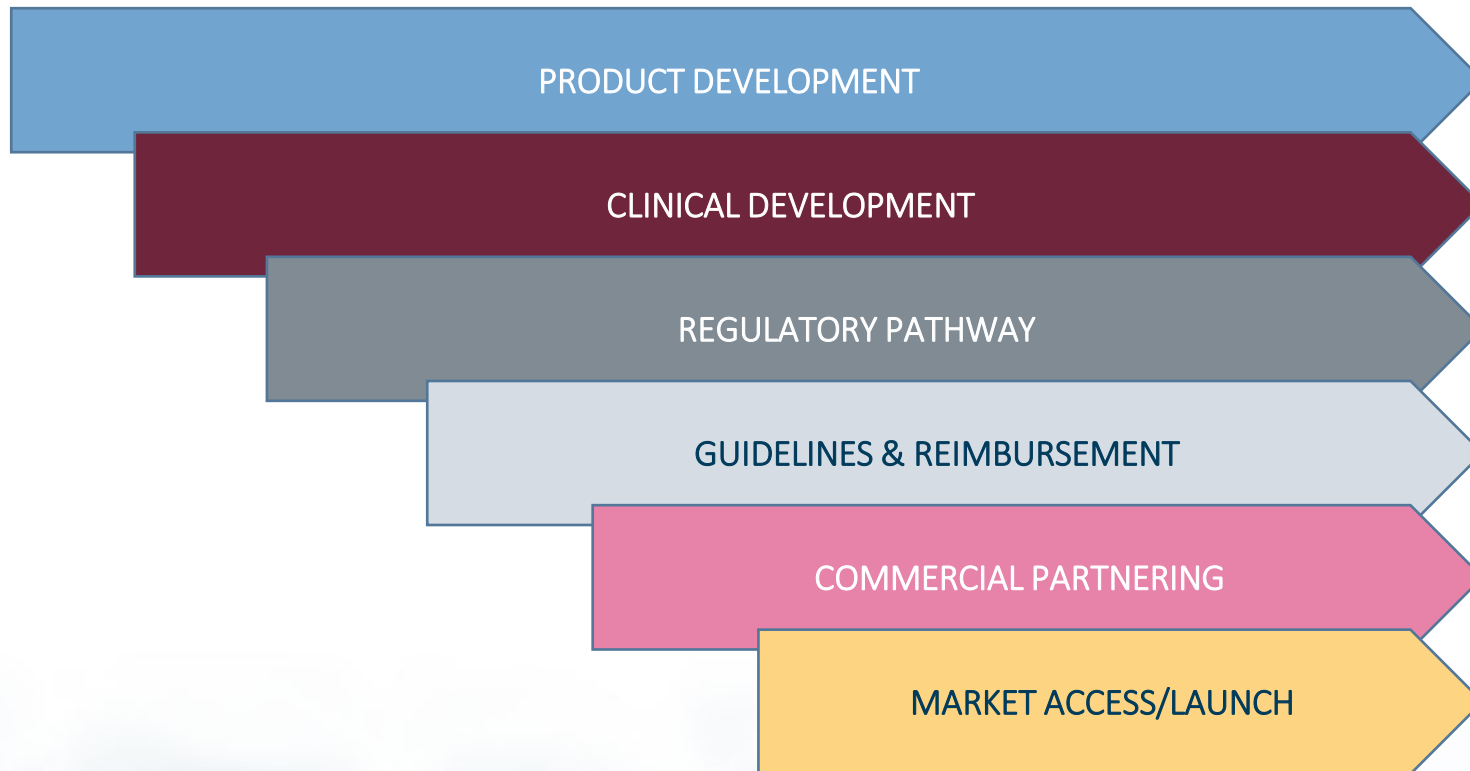
# Strong Clinical Results and Data for DiviTum®TKa Peer-Reviewed & Published in Clinical Oncology Journals

- 24 published and peer-reviewed articles with DiviTum®TKa
- Summary of results from articles:
  - Prognostic: risk for cancer recurrence, progression & survival
  - Monitoring: quick feedback on treatment efficacy

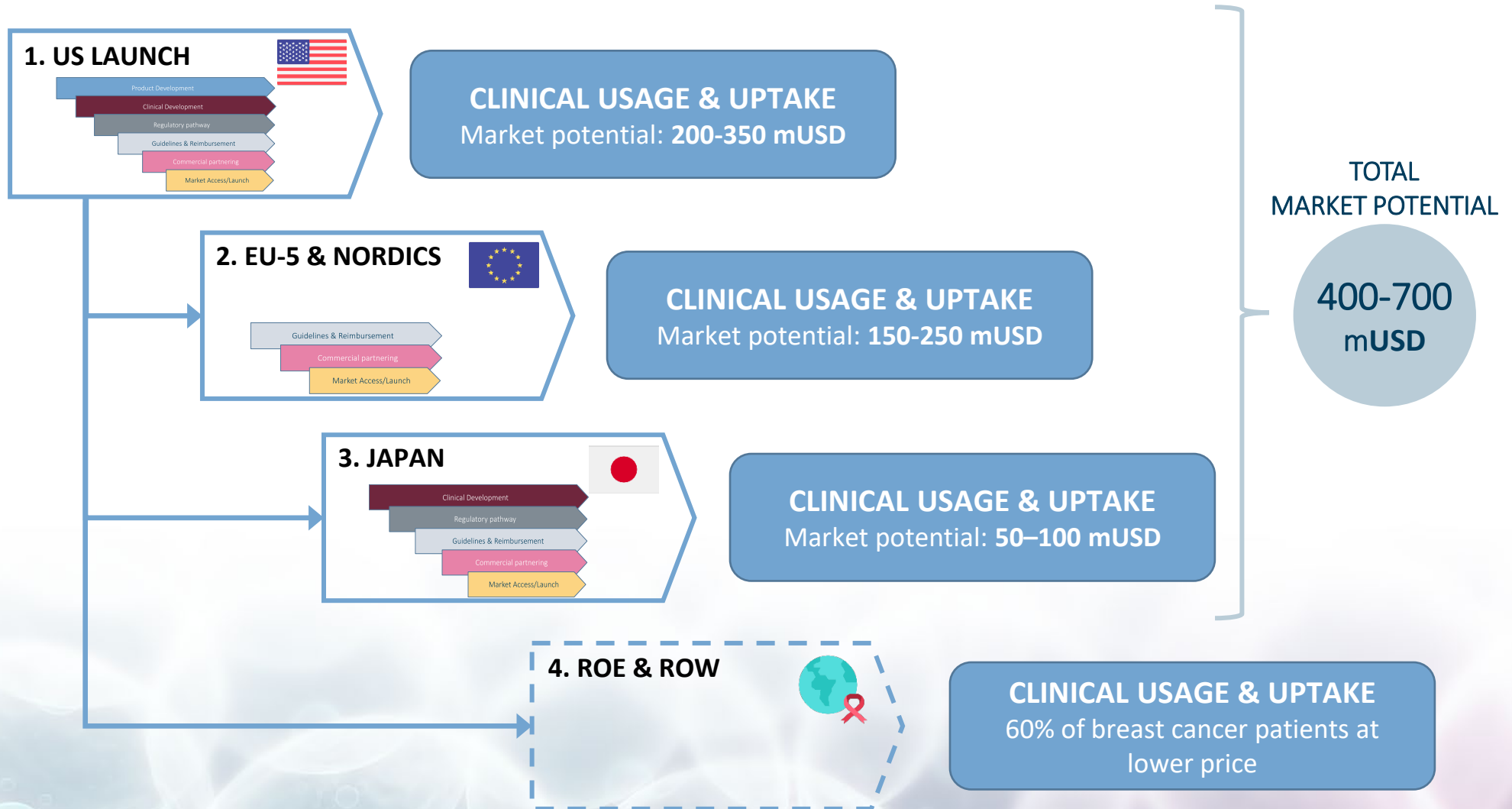
Cancer area	Patients	No of Studies
 Breast Cancer	1,293	13
 Gastrointestinal	713	4
 Lung Cancer	281	2
 Blood Cancer	440	4
 Other	368	1
	3,095	24



# DiviTum®TKa – Key Commercialization Activities

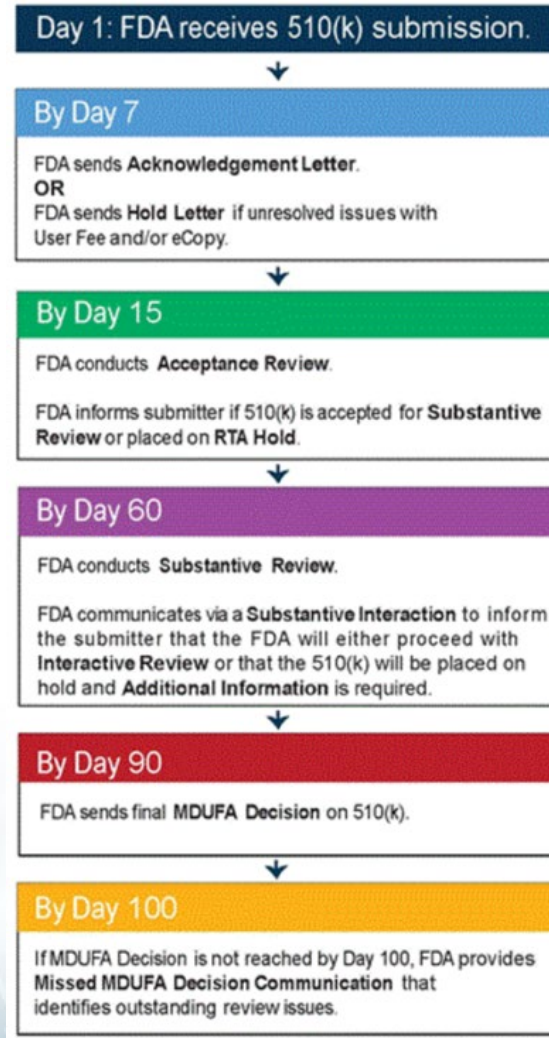


# Geographical Roll-out Plan & Market Potential for DiviTum®TKa in Metastatic Breast Cancer



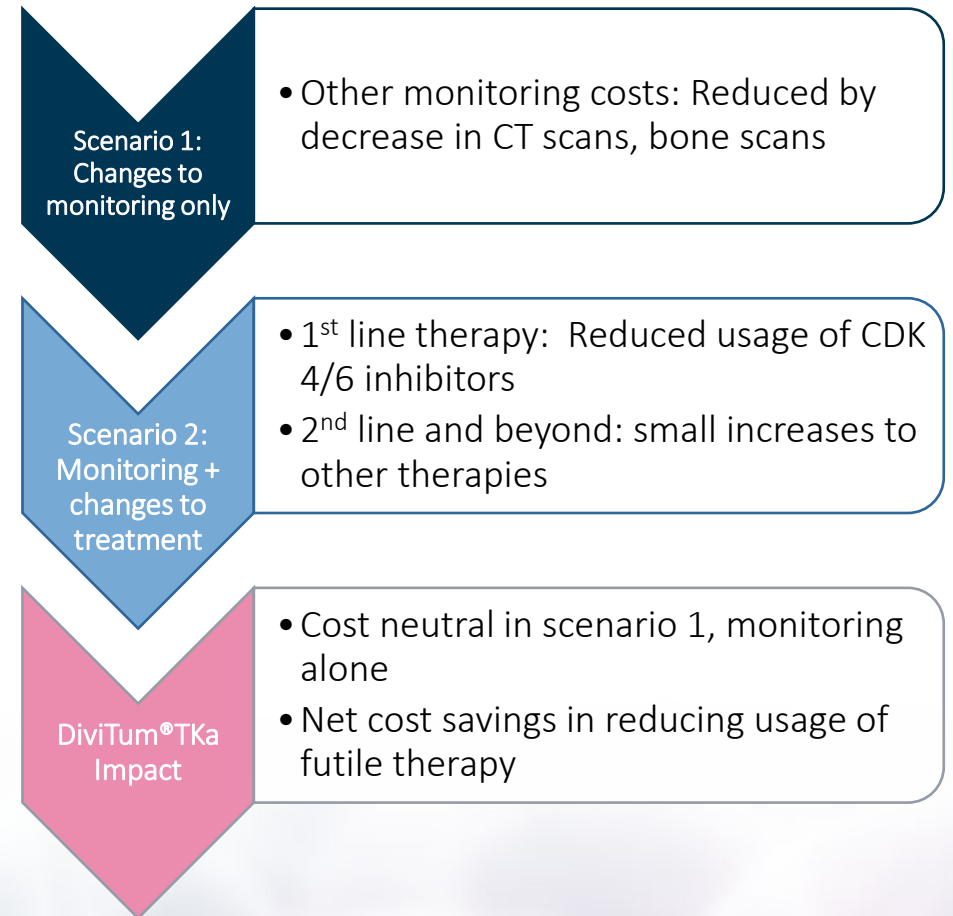
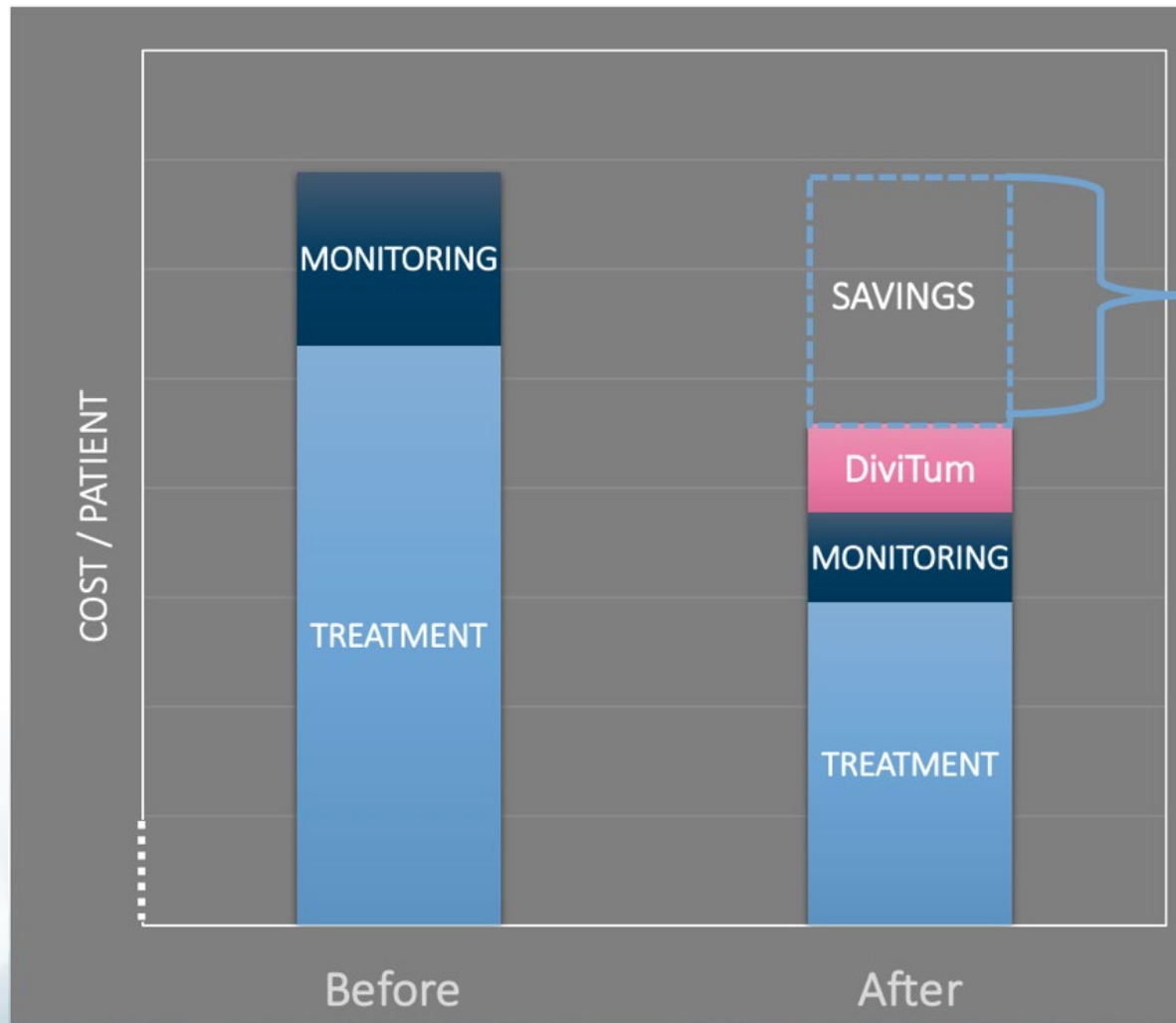


# FDA 510(k) Application



- FDA 510(k) submission Q3 2020
- Positive interactive process with FDA, feedback in February
- Updated application, addressing all raised questions, was submitted on the 28<sup>th</sup> of April
- Next step, MDUFA decision

# Budget Impact Model Results: Addition of DiviTum®TKa to Care Would Lead to Net Savings of 3x the Spend



Strongly positive health economics for DiviTum®TKa with pricing modelled at \$400/test

# Biovica Commercial Roadmap

Legend

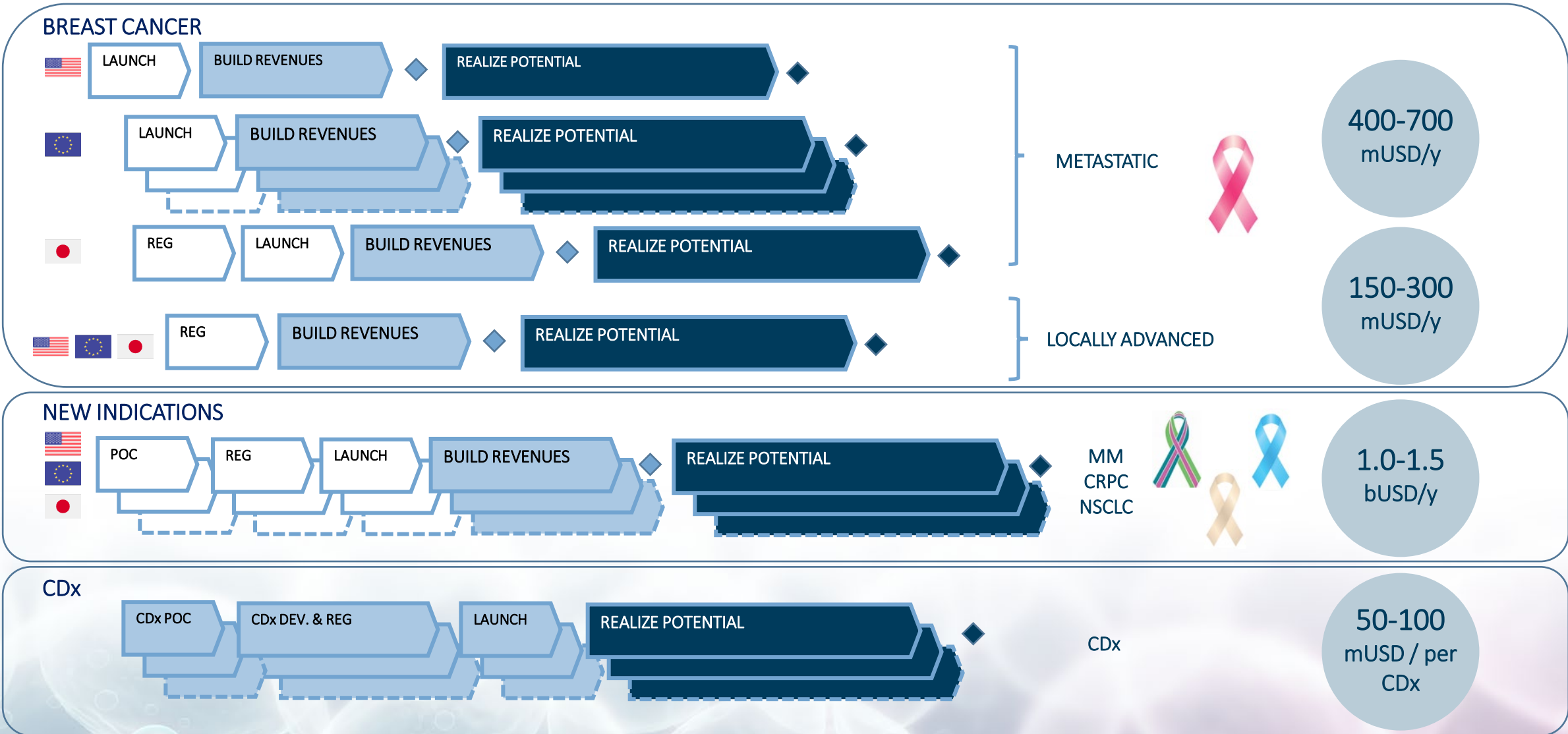
◆

 15% of market potential

◆

 50% of market potential

## MARKET POTENTIAL





# Management Team & Key Personnel



**Anders Rylander**

CEO

Holdings: 3,575,640 A-shares,  
379,756 B-shares, 90,000 warrants



**Cecilia Driving**

EVP CFO

Holdings: 20,000 B-shares,  
65,000 warrants



**Helle Fisker**

VP Commercial Europe

Holdings: 20.000 warrants



**Tomas Andersson**

VP Operations

Holdings: 40,000 warrants



**Joakim Arwidson**

VP Regulatory & QA

Holdings: 20.000 warrants



**Henrik Winther, Ph.D.**

SVP Business Development

Holdings: 20.000 B-shares, 20,000 warrants



**Warren Cresswell**

President Americas

Holdings: 100.000 warrants



**Dan Kiser**

Head RA&QA & Lab Operations

Holdings: None



**Kendon Richards**

Executive Sales Director

Holdings: 15.000 warrants



**Amy Williams, Ph.D.**

Head of Clinical Dev. & Medical Affairs

Holdings: 15.000 warrants



**Mattias Bergqvist**

Clinical Development Director

Holdings: 65,540 B-shares

# Board of Directors



**Lars Holmqvist**

Chairman  
Holdings: 534,536 B-shares,  
100,000 warrants



**Annika Carlsson Berg**

Board Member  
Holdings: 50,000 warrants



**Maria Holmlund**

Board Member  
Holdings: 9,750 B-shares,  
75,000 warrants



**Henrik Osvald**

Board Member  
Holdings: 624,106 B-shares,  
50,000 warrants



**Jesper Söderqvist**

Board Member  
Holdings: 41,085 A-shares,  
38,200 B-shares, 75,000 warrants



**Jarl Ulf Jungnelius**

Board Member  
Holdings: 75,000 warrants



**Marie Louise Fjällskog**

Board Member  
Holdings: 45,000 warrants



**Anders Rylander**

Board Member & CEO  
Holdings: 3,575,640 A-shares,  
368,956 B-shares, 90,000 warrants

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# BIOVICA

Treatment Decisions With Greater Confidence

US Go-To Market Plan

Warren Cresswell



# Agenda

1. Go-to-Market Strategy
2. Critical Success Factors
3. Our Immediate Focus



## About the Presenter

### Warren Cresswell, President of the Americas

- 25-years of Diagnostic Experience in Medical Device (IVD 510(k) & PMA), CLIA Lab (LDT), and Pharma
- Built Dx Orgs, Developed & Launched High Value Multi-Analyte Algorithm Based Dx Assays, and Implemented Effective Reimbursement Strategies
- Executive Leadership, Commercial, BD & Operations



## US Healthcare Market Entry

- DiviTum® TKA addresses a significant *unmet medical need*
- Our *go-to-market strategy* is well thought out, executable and aligns with the most successful high value diagnostic companies in the US
- Our US *team* is highly experienced in launching novel, high value diagnostic products that change the standard of care
- We are committed to investing in *clinical utility data*
- Our KOL & Pharma *partnerships* are invaluable to long-term success



# US Go-to-Market Strategic Options



## Distributor Model

Requires FDA cleared IVD via 510k or PMA, restrictive labeling

Market that does not support building a Biovica commercial organization

There is existing or easily achievable product demand

Market has an established reimbursement channel



## Direct Sales to Clinical Labs

Requires FDA cleared IVD via 510k or PMA, restrictive labeling

Existing market demand:

- Standard of Care
- Companion Dx

Established reimbursement with public & private insurance companies



## CLIA Lab Model

FDA clearance or LDT (no label restrictions), immediate market entry

Demand generation required

Building clinical evidence through KOL & Pharma partnerships is required

Establishment of reimbursement is required

# Successful High Value Dx Companies Follow the CLIA Lab Go-To-Market Strategy

Managing *critical success factors* position the company for long-term sustainable growth. Key critical success factors include:

1. *Stakeholder Relationships* - patient, physician and payer
2. *Reimbursement* – insurance coverage, value and utilization
3. *Access* – availability to all patients
4. *Sample Biobank* – deep analysis and fuel pipeline development
5. *Data Development & Mining* – understanding product utilization, utility & correlation

# CLIA Lab Enables Ownership of *Stakeholder Relationships*

## Patients

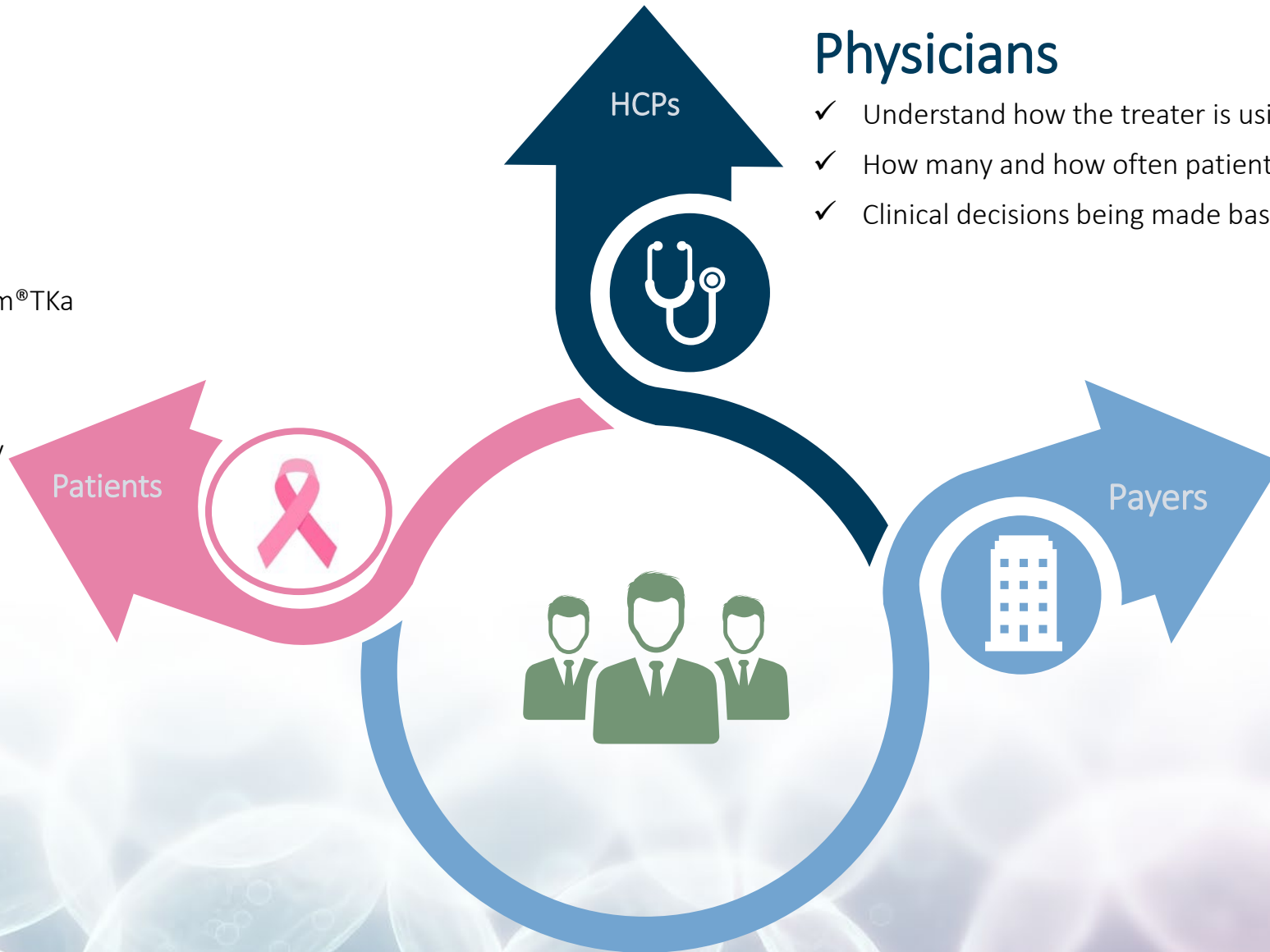
- ✓ Who is using DiviTum®TKa
- ✓ Testing occurrence
- ✓ Test results
- ✓ Response to therapy
- ✓ Engage the patient

## Physicians

- ✓ Understand how the treater is using DiviTum®TKa
- ✓ How many and how often patients are being tested
- ✓ Clinical decisions being made based on test results

## Payers

- ✓ Public insurance such as Medicare and Medicaid
- ✓ Private such as United, Kaiser, Cigna, Anthem, etc.
- ✓ Hospitals
- ✓ Patients



# CLIA Lab Enables Management of *Reimbursement*

## Public Insurance



## Hospitals & General Reference Labs



Separate  
Reimbursement  
Channels

## Private Insurance



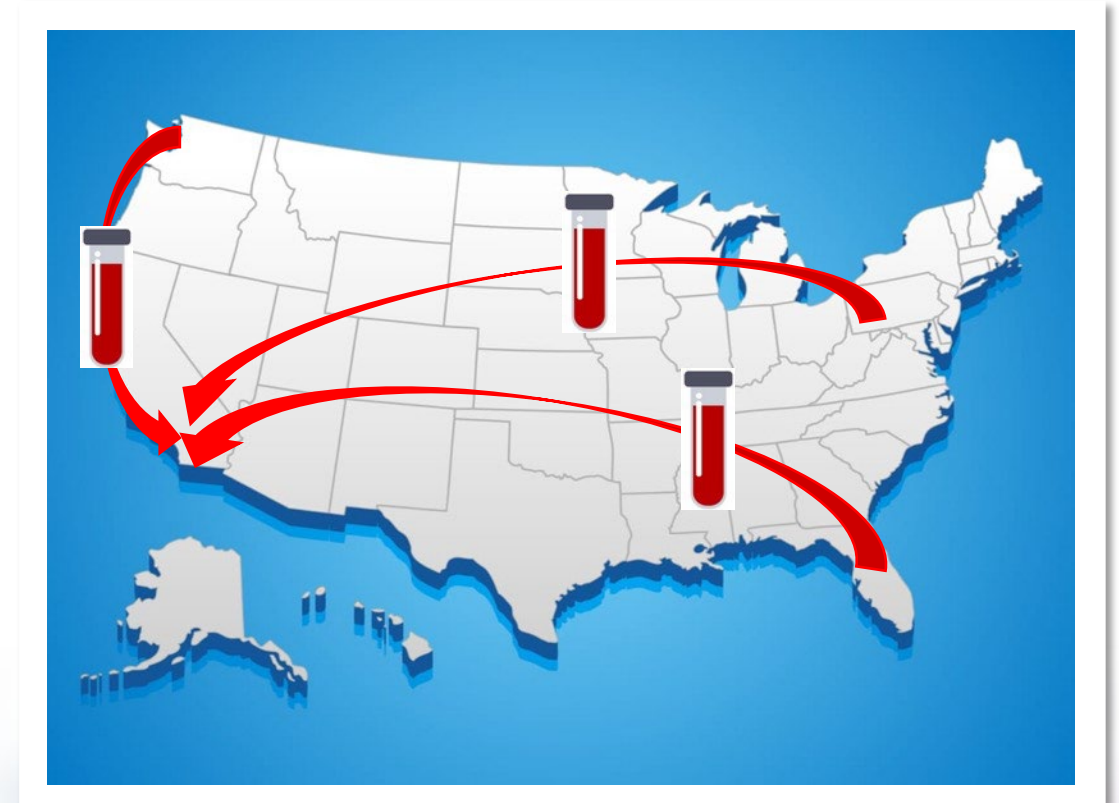
## Patients





## CLIA Lab Enables Expanded *Access* to Use DiviTum®TKa

- A CLIA lab enables *Patient Access* to DiviTum®TKa anywhere in the US
- Samples will be sent to San Diego via next day air
- Test results provided within 24 hours after sample acquisition



## CLIA Lab Enables the Creation of a *Sample Biobank*



- Patient samples will be collected with consent
- Samples will be further analyzed and the data interrogated
- Accelerates our product pipeline opportunities
- Biobank is an asset that continues to mature over time

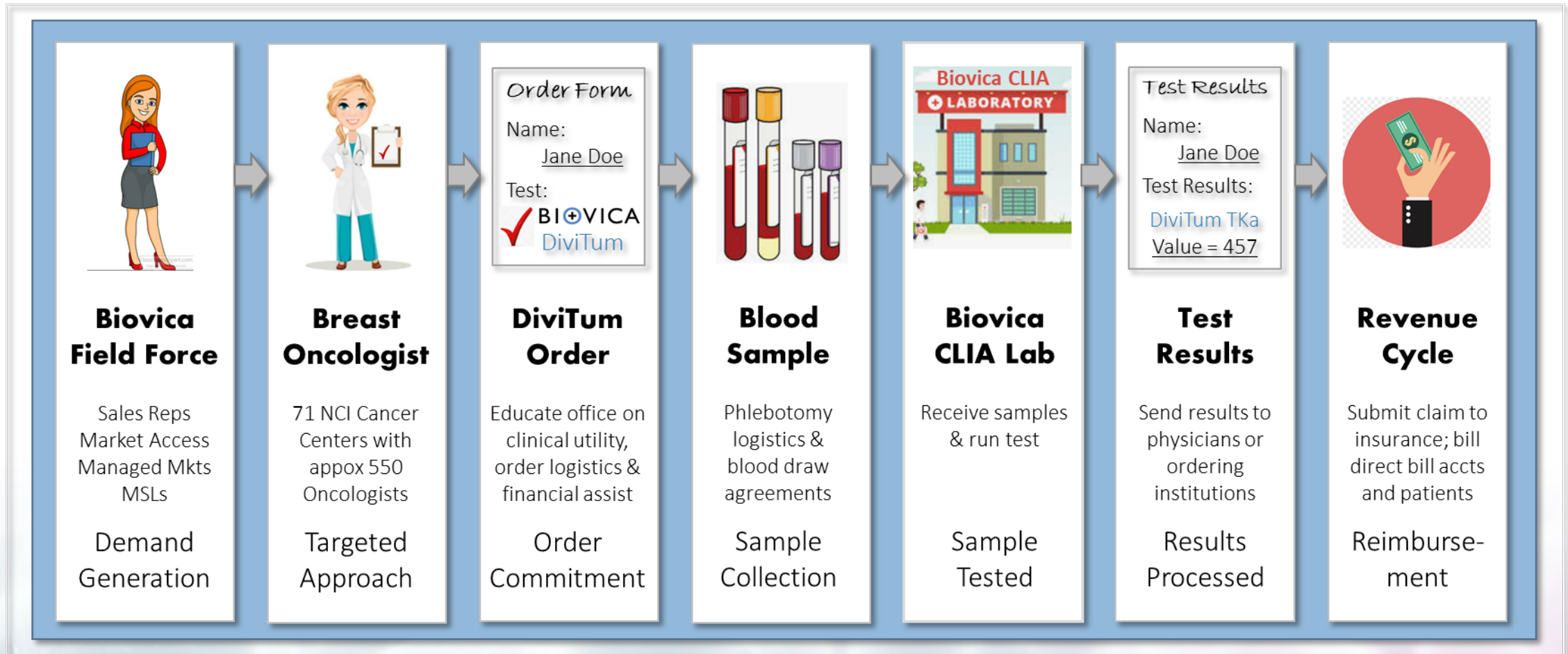
## CLIA Lab Enables *Data Development & Mining*

- Data creation will happen quickly once DiviTum®TKa is launched
- Data will drive:
  - Product positioning
  - Product development
  - Lifecycle management
  - Publications
  - Clinical dossier
  - Other applications



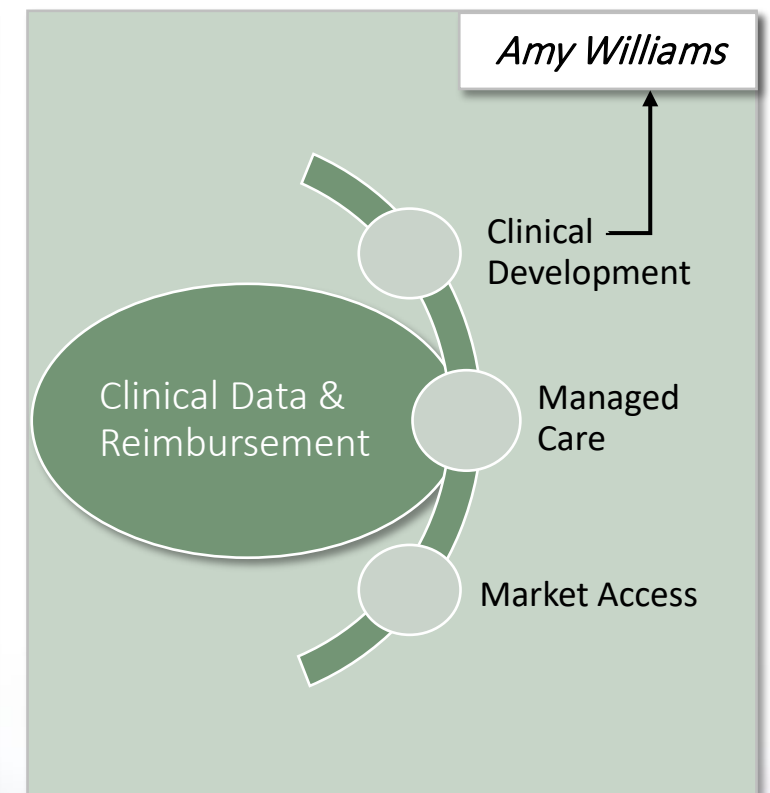
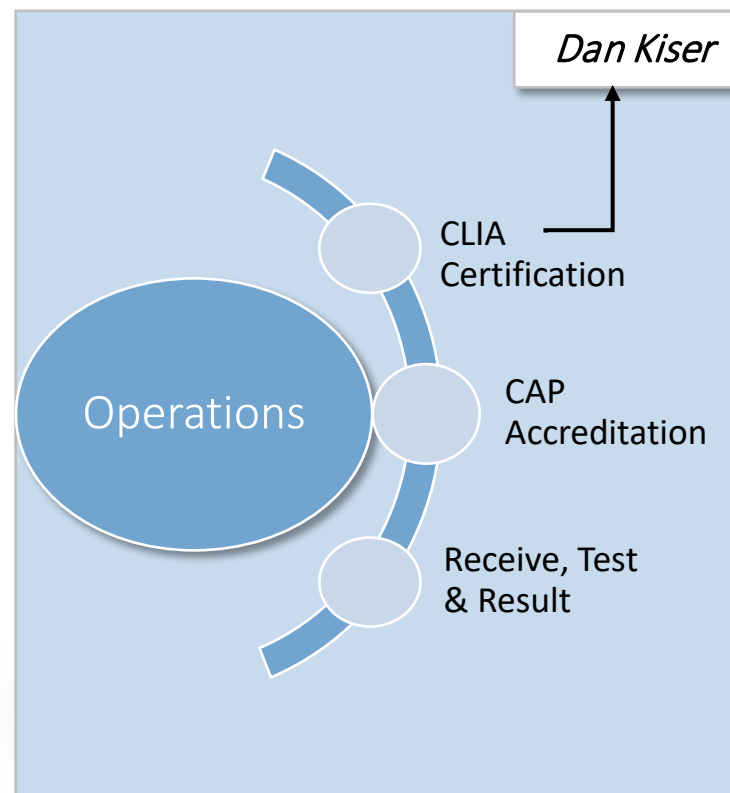
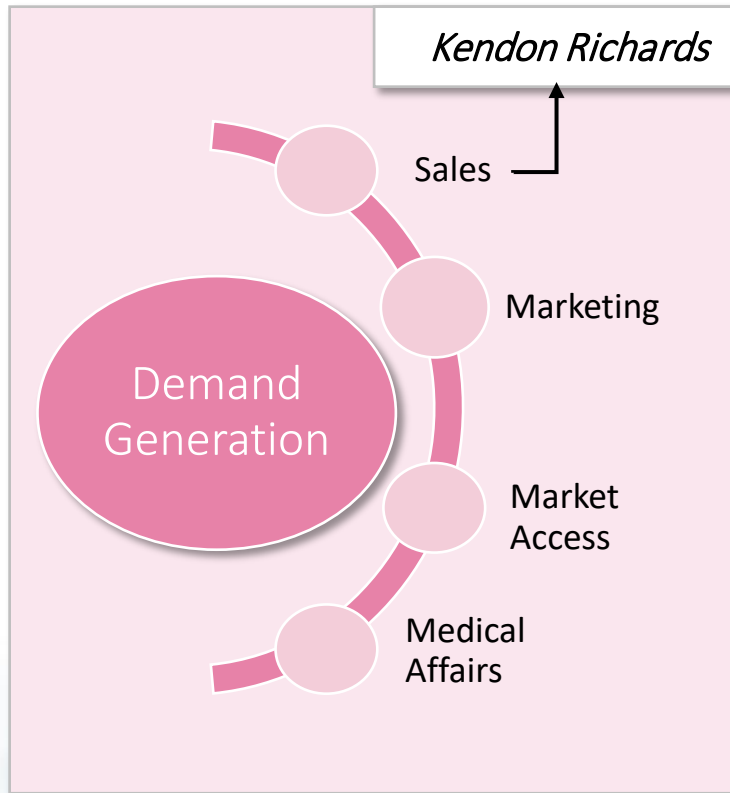


# The CLIA Lab Model Enables Management of the Entire Business Process





# Our Immediate Focus



*Highly experienced candidates have been identified for nearly every US-based position*

A background image showing a microscopic view of cells, likely cancer cells, with a blue and purple color palette. The cells are spherical and have a textured, granular surface.

# BIOVICA

Treatment Decisions With Greater Confidence

US Sales Plan

Kendon Richards

# Agenda

1. Specialty Dx Selling Process
2. Establishment of Specimen Channels
3. Reimbursement Pathways
4. Sales Organization Staffing
5. Physician Targeting





## About the Presenter

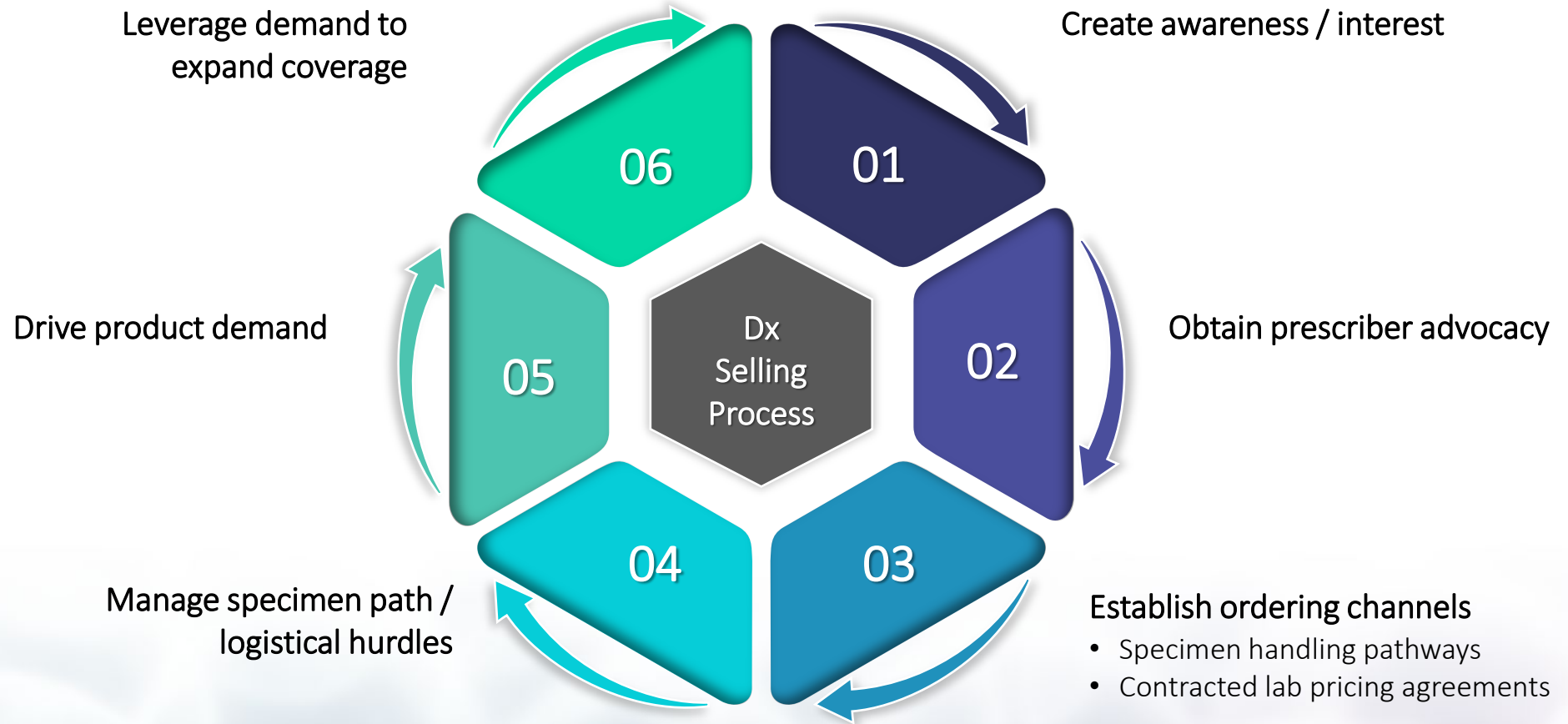
### Kendon Richards, Executive Director of Sales

- 25+ years of Pharmaceutical and Specialty Diagnostic Experience
- Built Pharma and Dx Sales Orgs, Successfully launched 15 products (8 in the Specialty Dx space), Led Salesforce Integration and Implementation of Effective Reimbursement Strategies
- National Sales Leadership, National Accounts Leadership and Marketing Brand Team Member



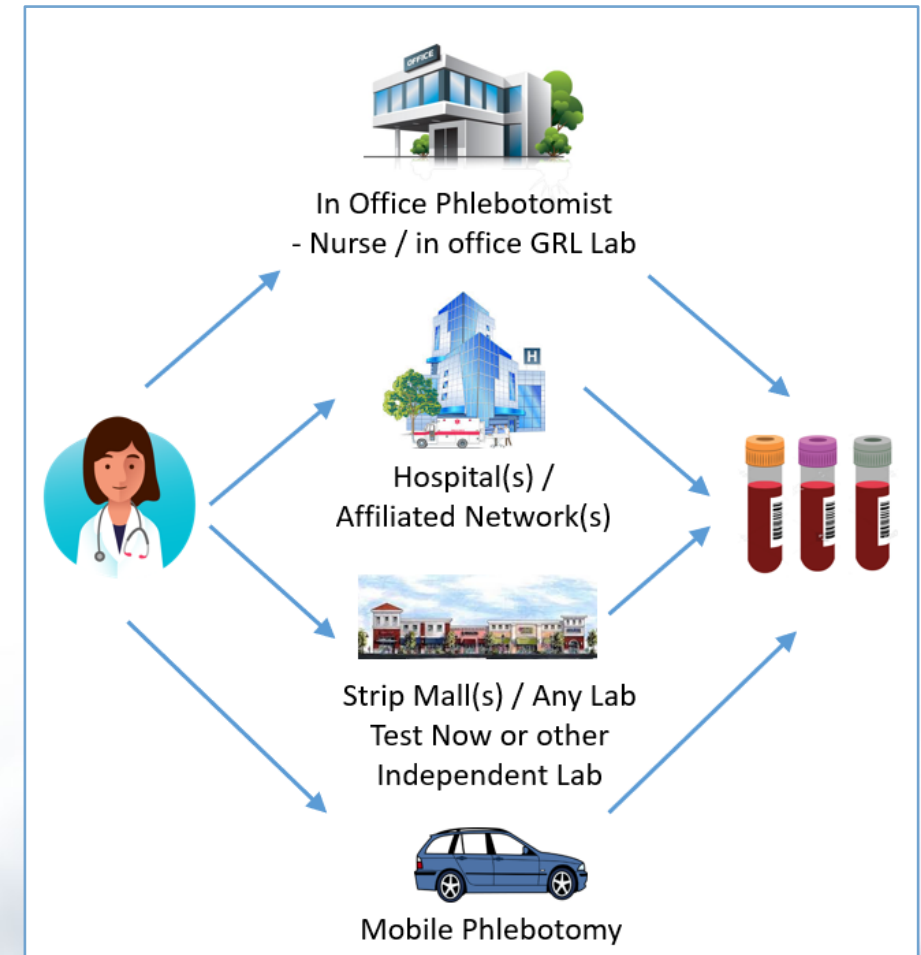


# Selling Process for Dx Specialty Products



# Dx Specialty Products Selling Process

- HCPs use a variety of routes to have blood drawn
- HCPs in the same office may prefer different specimen channels or have access to different channels
- Insurance coverage and in-network privileges at local Hospitals / IDN's influence a prescriber's access to testing
- Sales representatives at specialty laboratories must be skilled at addressing logistical issues and HCP/Account preferences



# Specimen Access Channels

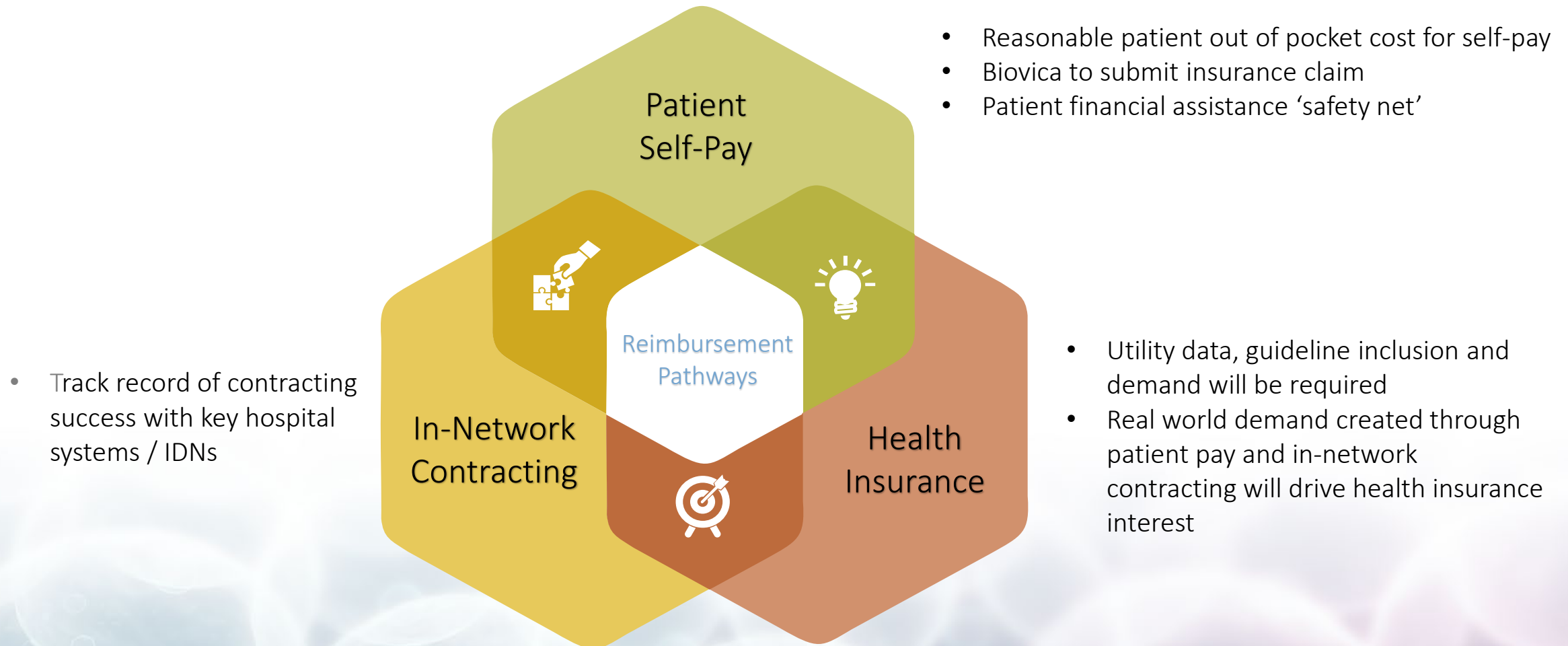
Establish channels for specimens to be routed to the Biovica CLIA Lab

- Partner with in-office phlebotomists
- Contract with Hospitals / IDNs
  - Specimen handling agreements
  - Contracting / Lab pricing agreements
- Routing specimens through General Reference laboratories
- Specimen Handling Agreements with local and regional laboratories
- Mobile phlebotomy



## 3 Key Pathways for DiviTum®TKa Reimbursement

Patient *out-of-pocket* costs can vary from office to office and patient to patient.

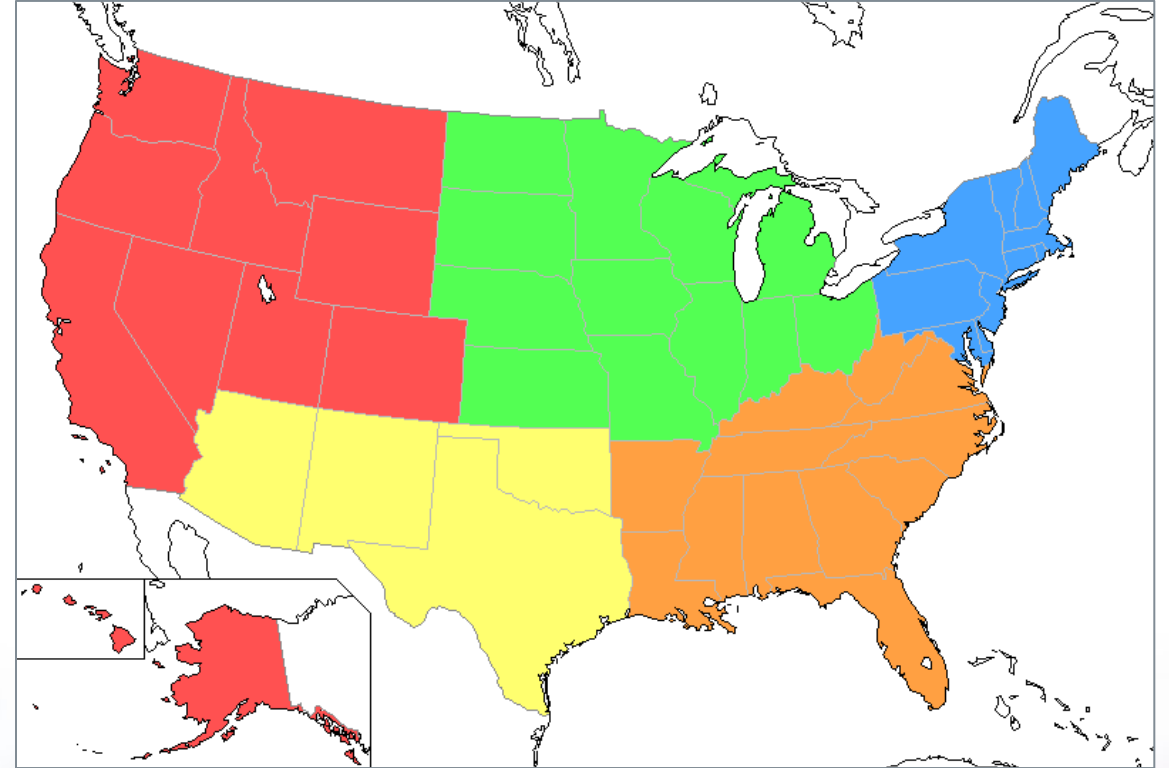




# Sales Structure

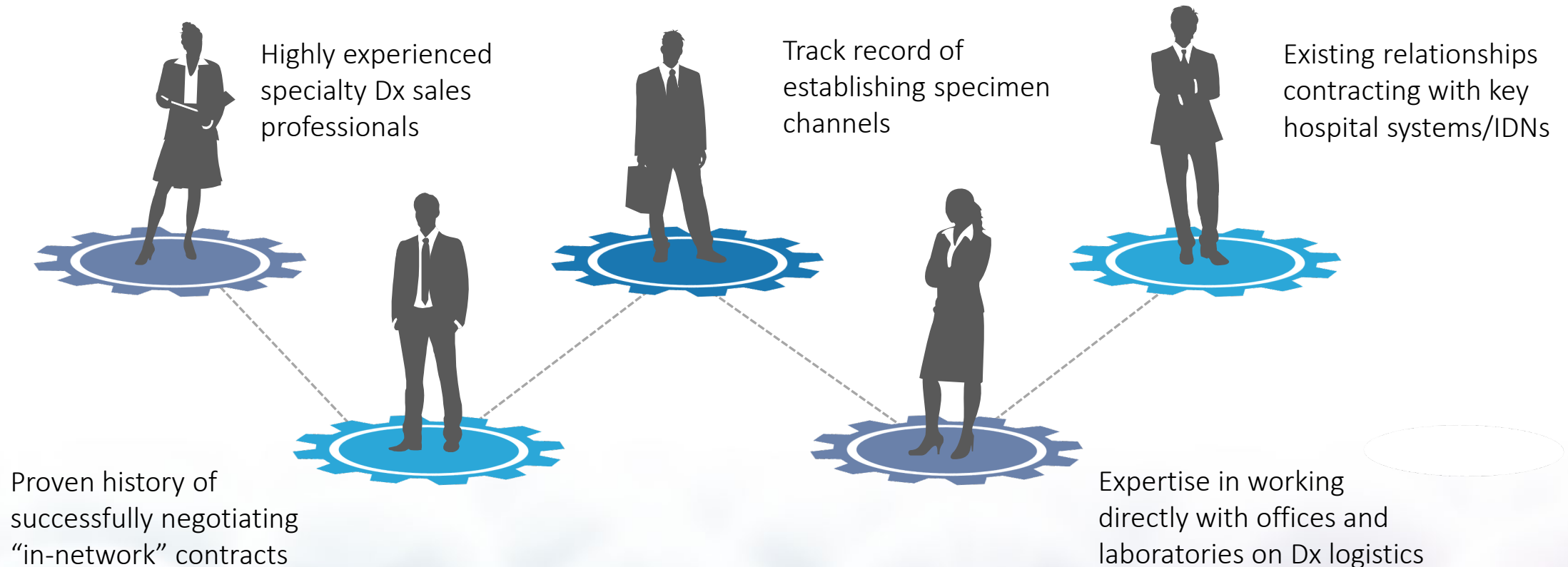
- Well balanced Regions constructed to optimize efficiencies and drive sales
- Strategically segment/target customers; allocate call capacity against HIGHEST potential customers

- ✓ Right *Customer*
- ✓ Right *Message*
- ✓ Right *Frequency*



# Building a World Class Dx Sales Team

*Hiring the Right People Using Extensive Network*



# Targeting HCPs With The HIGHEST Potential To Order DiviTum®TKa In Areas Where Business Will Be Accessible



A background image showing a microscopic view of cells, likely cancer cells, with a blue and purple color palette. The cells are spherical and have a textured, granular surface.

# BIOVICA

Treatment Decisions With Greater Confidence

US CLIA LAB

Dan Kiser



# Agenda

## U.S. Commercial Lab for DiviTum<sup>®</sup>TKa

1. Staff
2. Regulatory
3. Quality
4. Operations



## About the Presenter

### Dan Kiser, Quality, Regulatory & Lab Operations

- 25-years Regulatory & Operations in CLIA, IVD, Medical Device & Pharma
- Certified ISO Lead Auditor and Six-sigma Black Belt



## Key Lab Personnel

### Curtis McGuyer, MD, Laboratory Director

- Board-certified in anatomic and clinical pathology, as well as cytopathology
- CAP Regional Commissioner for Laboratory Accreditation CMS Region 10



# Regulatory Overview




## Commercial Laboratory

- CLIA Certificate of Registration – Allows nonwaived (high complexity) testing until the laboratory is surveyed or accredited
- CAP Accreditation
- CLIA Certificate of Accreditation (COA)
- New York State Clinical Laboratory Evaluation Program
- Washington State Department of Health
- ISO 15189:2012 - Quality and Competence in Medical Laboratories

## Collection Kit Manufacturing & Distribution

- FDA Establishment Registration
- CDPH Manufacturing License
- ISO 13485:2016

### Serum Collection Kit

REF

 1002  

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BIOVICA Inc.  
6195 Cornerstone Court, SU 100  
San Diego, California USA 92121


### BI+VICA

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GLOVES


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LINER



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COLLECTION


- 01 – 

TRANSPORT


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1000-A



# Laboratory Quality

## Quality System

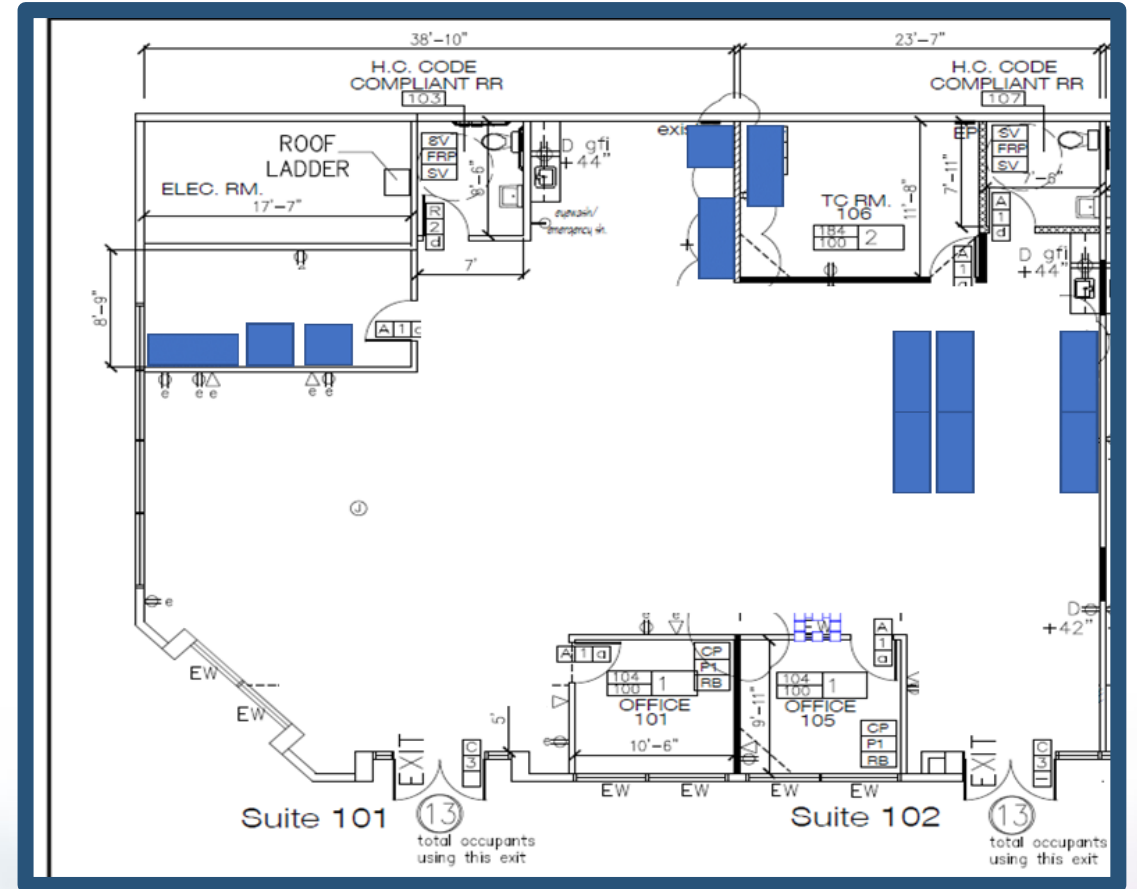
- Laboratory Quality Management Plan & Safety Manual
- HIPAA Compliance
- Material & Equipment Controls
- Process Validation (Sample Collection, Prep, Testing, & Reporting)
- Retained Samples (Biobank)

## Operational Excellence

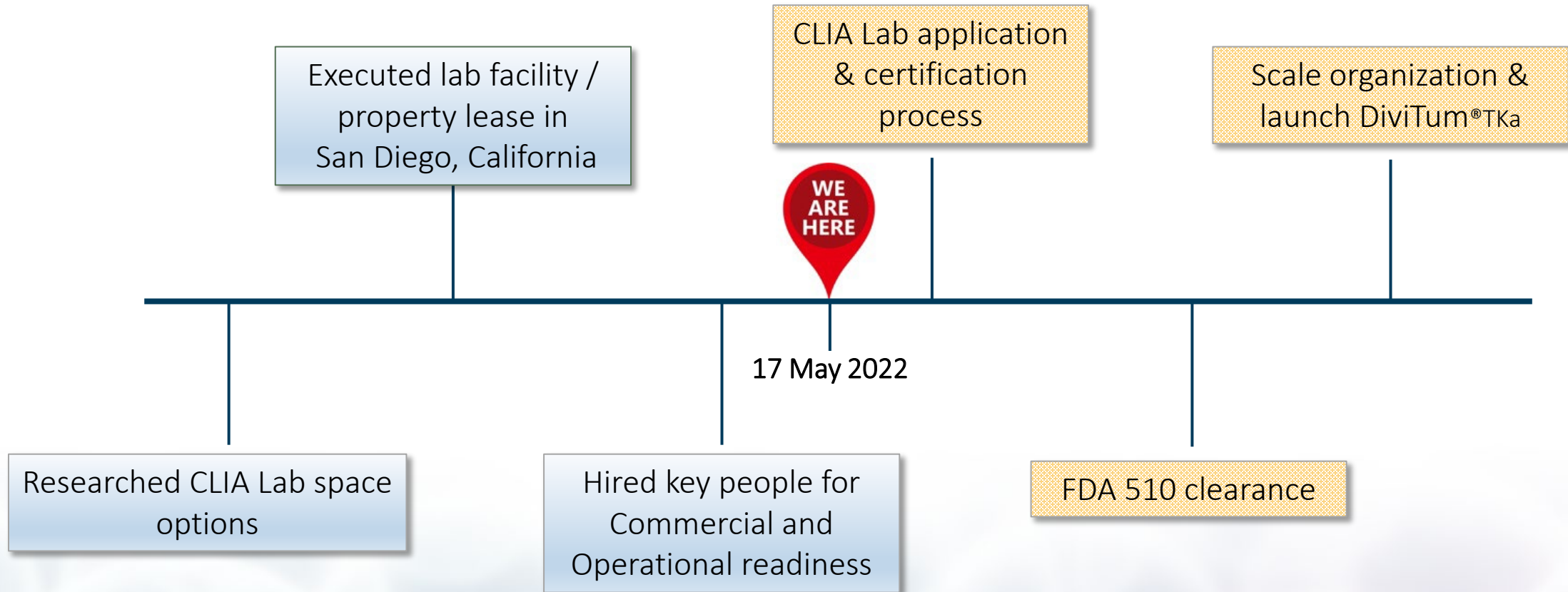
- Test Results to the ordering physician within 24hrs if needed
- Option to use batch testing to maximize plate utilization
- Positioned to scale US operations to meet customer demand
- Cloud based (LIMS) & Harmonized Documents (eQMS)
- Recycle samples collection kit packaging to reduce environmental impact



# Lab Facility Operations



# US Operations Milestones





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# BIOVICA

Treatment Decisions With Greater Confidence  
Clinical Evidence & Collaborations  
Amy Williams



# Agenda

## DiviTum<sup>®</sup>TKa Clinical Development Update

1. New DiviTum<sup>®</sup>TKa clinical data from 2021/22
2. Expansion of clinical utility for DiviTum<sup>®</sup>TKa based on new data
3. US Scientific Advisory Board feedback
4. Upcoming ASCO presentation: DiviTum<sup>®</sup>TKa versus ctDNA



## About the Presenter

### Amy Williams, PhD, Head of Clinical Development and Medical Affairs

- PhD in Pathology from Boston University School of Medicine
- 20+ years of experience in oncology drug development – from discovery through launch and beyond
- Most recent experience with Novartis Oncology, Breast Cancer Team
  - Supported Femara, Zometa, Afinitor, Piqray, Kisqali, etc



# Key Clinical Development Personnel

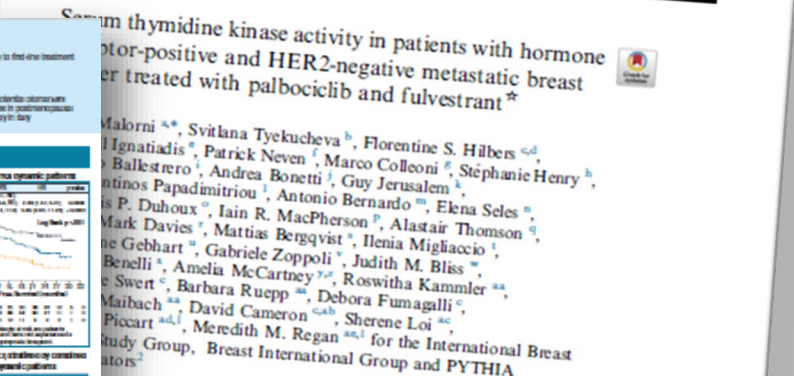
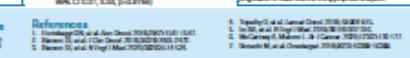
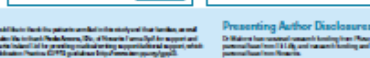
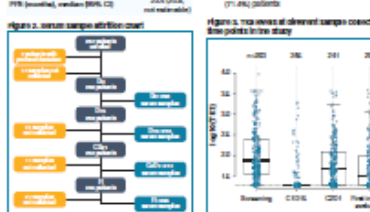
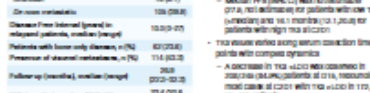
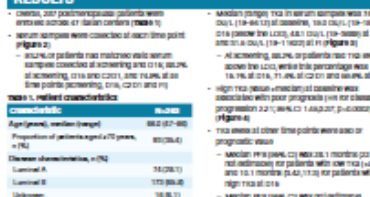
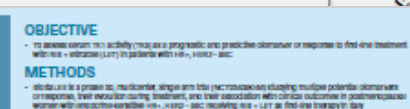
## Mattias Bergqvist, Clinical Development Director

- 10 years at Biovica as Clinical Development Director
- 15 years at AstraZeneca, Therapy Area Director Oncology Nordics, Global Brand Manager Breast Cancer
- Responsible for directing ex-US clinical trial program





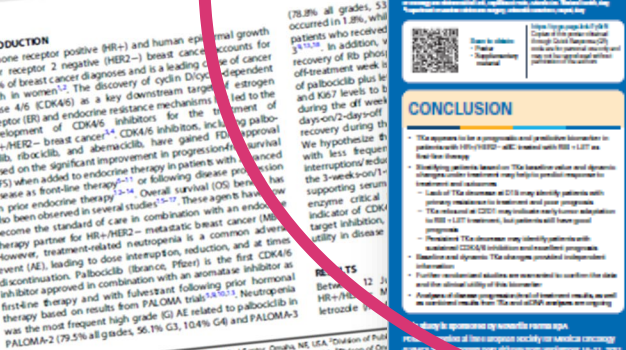
- Key clinical trial readouts in 2021-22 provided meaningful data that strengthened the unique value proposition for DiviTum®TKa

[illegible]



- Key clinical trial readouts in 2021-22 provided meaningful data that strengthened the unique value proposition for DiviTum®TKa

BioltaLEE Study  
ESMO September 2021



# CDK4/6 Inhibitors in Breast Cancer

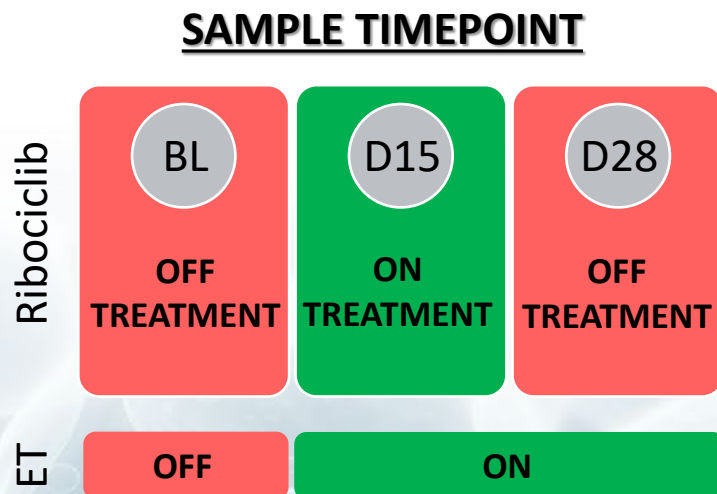
- Almost ALL HR+ mBC patients will be prescribed a CDK4/6 inhibitor at some point during their course of therapy
- If given in the first line metastatic setting, most patients will remain on a CDK4/6i based therapy for 2-3+ years
- Other than ER/PR positivity, there is no biomarker that can predict benefit for a CDK4/6 inhibitor
- The identification of a biomarker of response and resistance to CDK4/6 inhibition remains an important yet unmet need in oncology.
- Biovica has very strong data suggesting that DiviTum can serve as a biomarker of CDK4/6i response





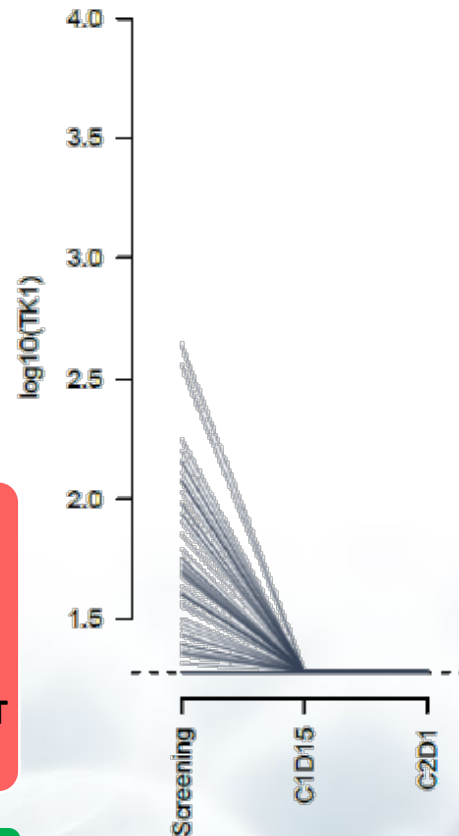
# BioltaLEE Data Shows 3 Distinct TKa Patterns

- 287 HR+ Her2- mBC patients
- 1<sup>st</sup> line therapy with ribociclib + letrozole
- TKa analyzed at BL, C1D15, C2D1, the on-treatment TKa values were used to identify patterns



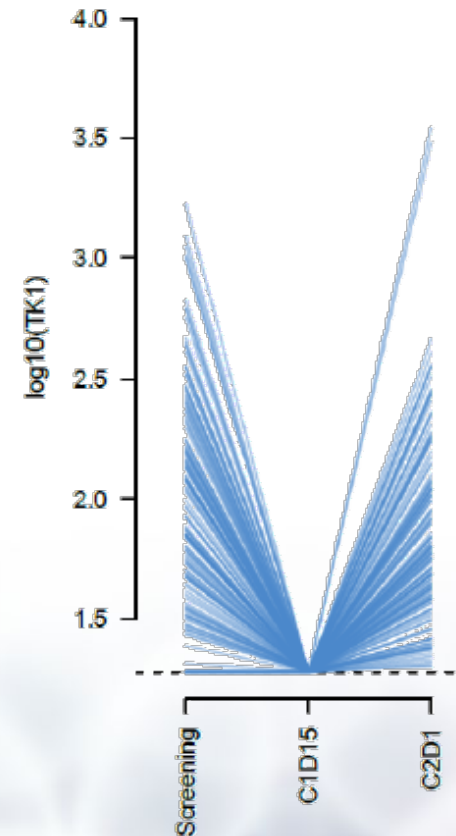
## PATTERN 1 (n=62)

TKa < LOD at C1D15 and at C2D1



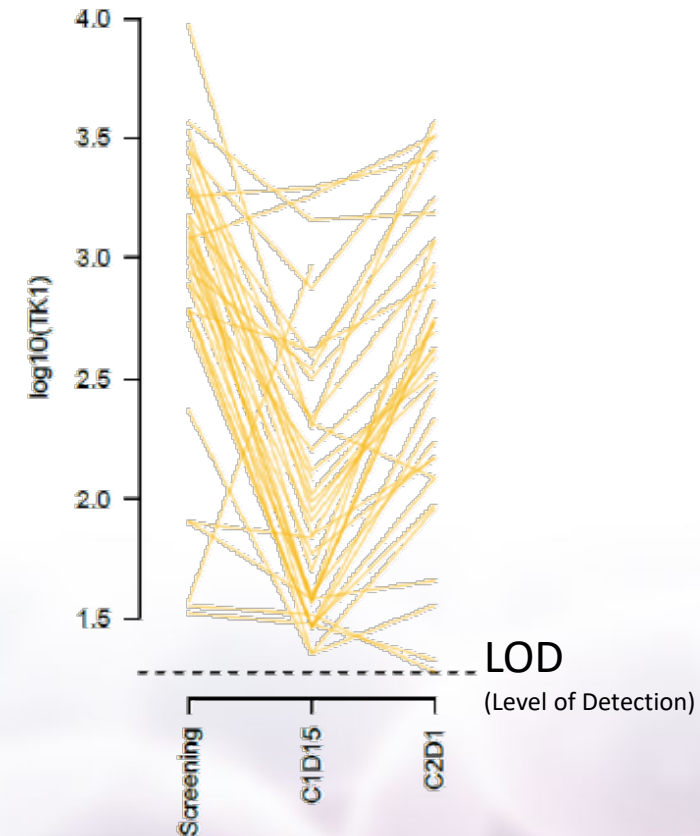
## PATTERN 2 (n=135)

TKa < LOD at C1D15 and > LOD at C2D1

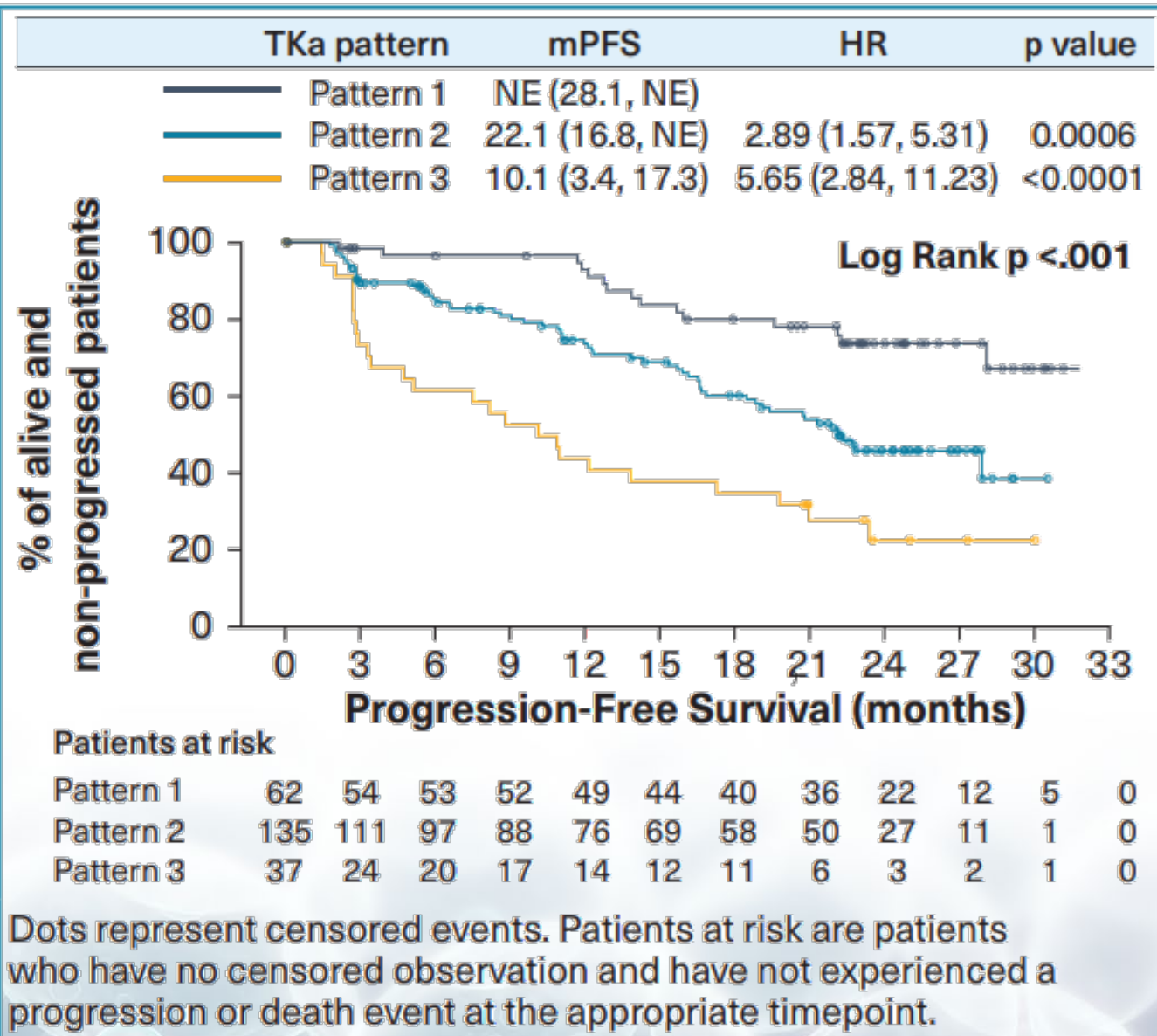


## PATTERN 3 (n=37)

TKa > LOD at C1D15



# TKa Patterns Correlate with Patient Outcome



Pattern 1: TKa <LOD at D15 and C2D1

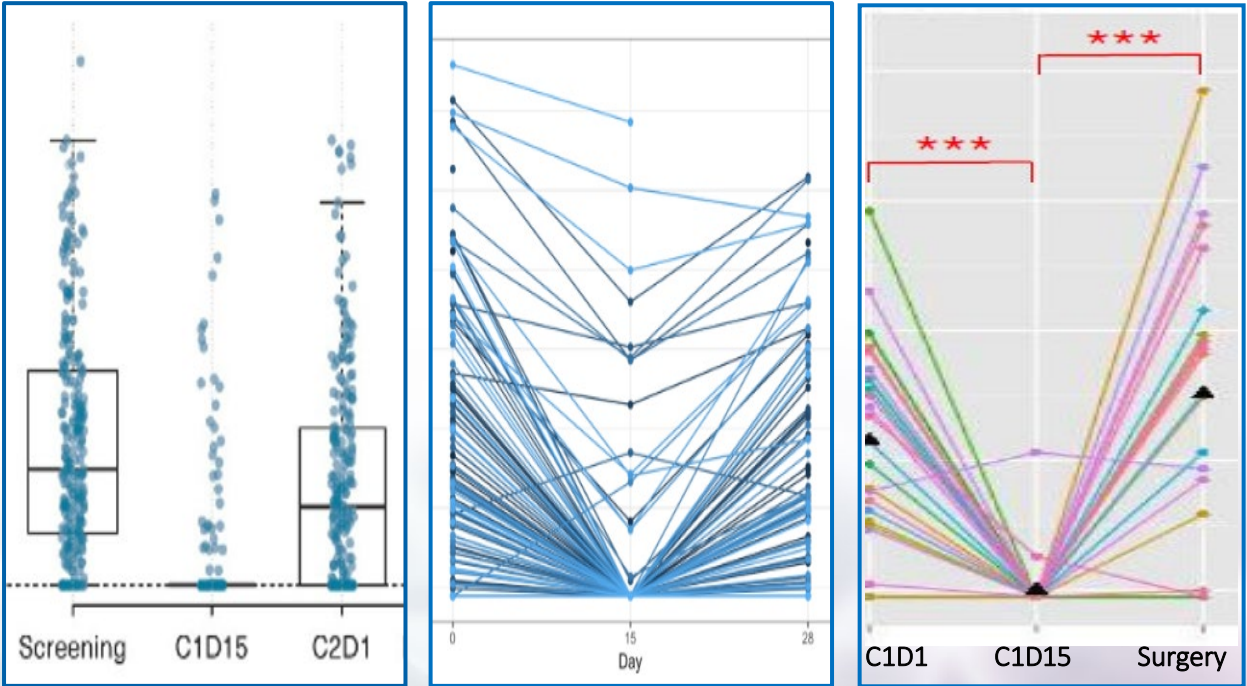
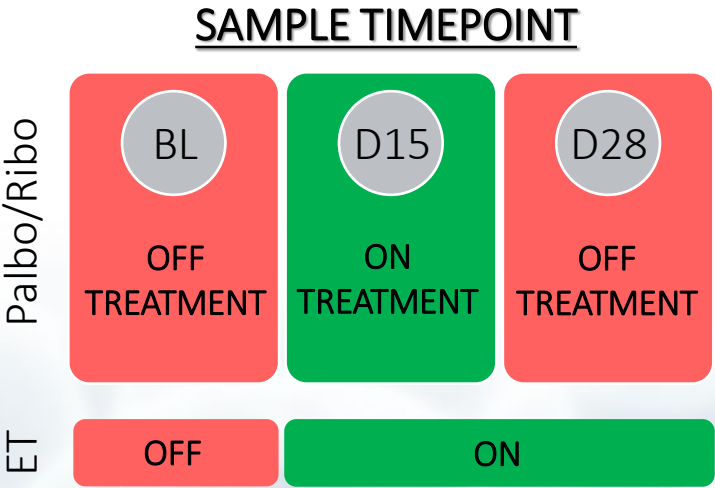
Pattern 2: TKa <LOD at D15 and >LOD at C2D1

Pattern 3: TKa >LOD at D15 and C2D1

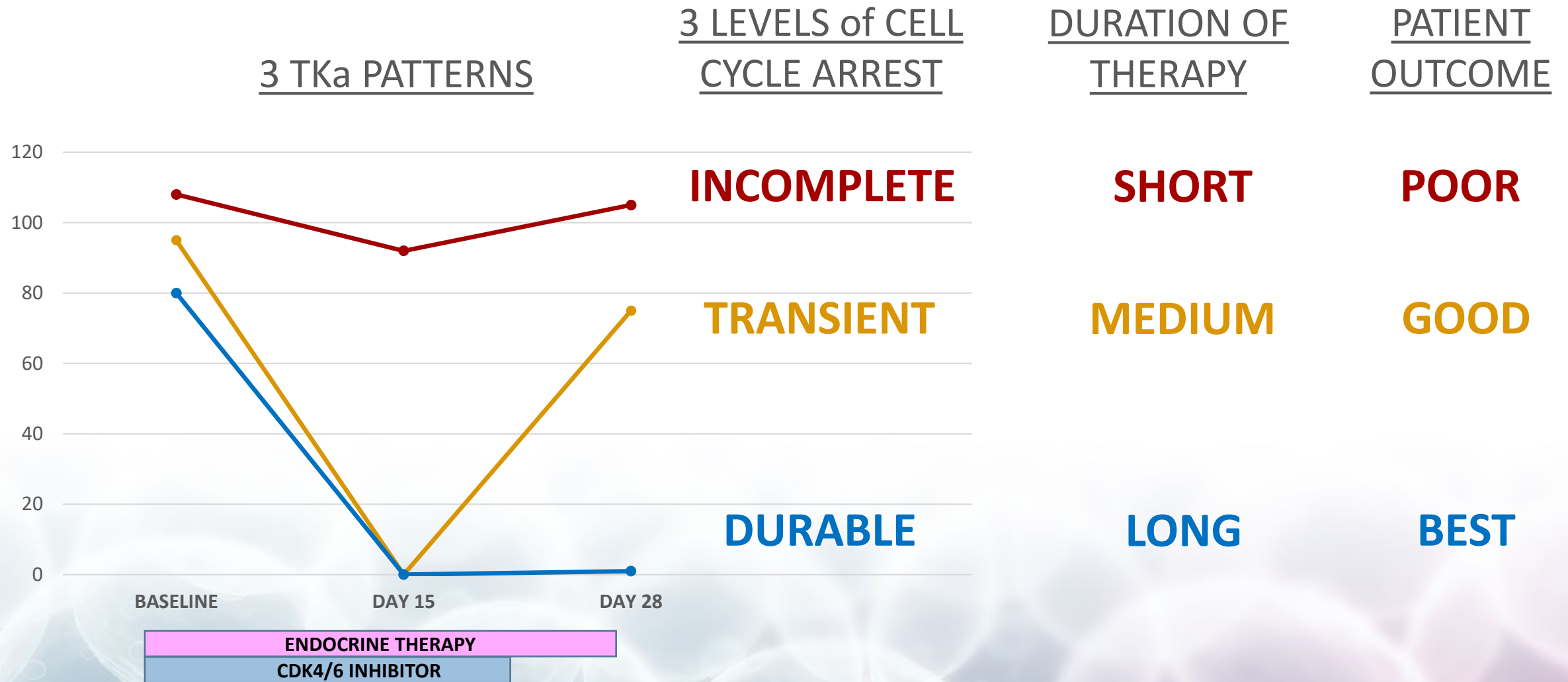


# Consistent TKa Patterns Observed Across CDK4/6 Inhibitor Trials

	BioltaLEE (n=287)	PYTHIA (n=108)	NeoPalAna (n=43)
% BELOW LOD on C1D15	85%	83%	86%
NO REBOUND on D28	31%	45%	32%
REBOUND on D28	69%	55%	68%

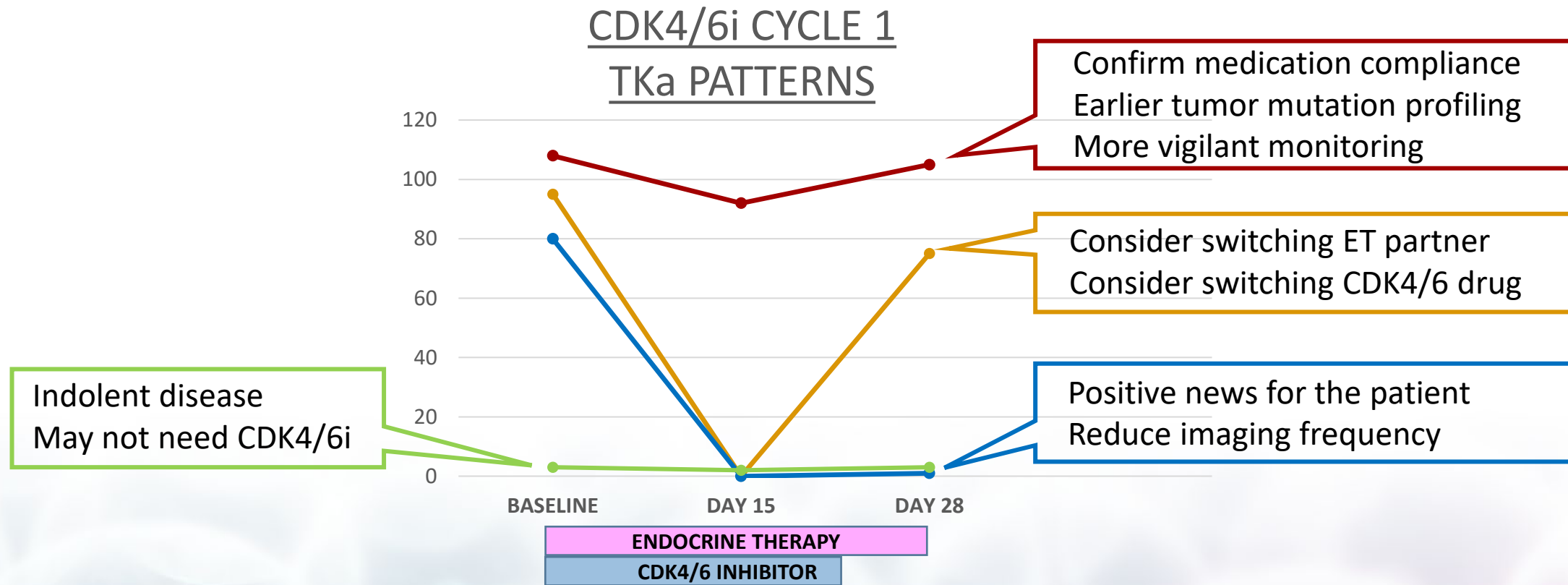


# Cycle 1 TKa Dynamics Predict Tumor Response and Patient Benefit to CDK4/6 Inhibitor Based Therapy



# Utility of DiviTum-TKa in Clinical Practice

## Prediction of CDK4/6i response based on cycle 1 TKa pattern

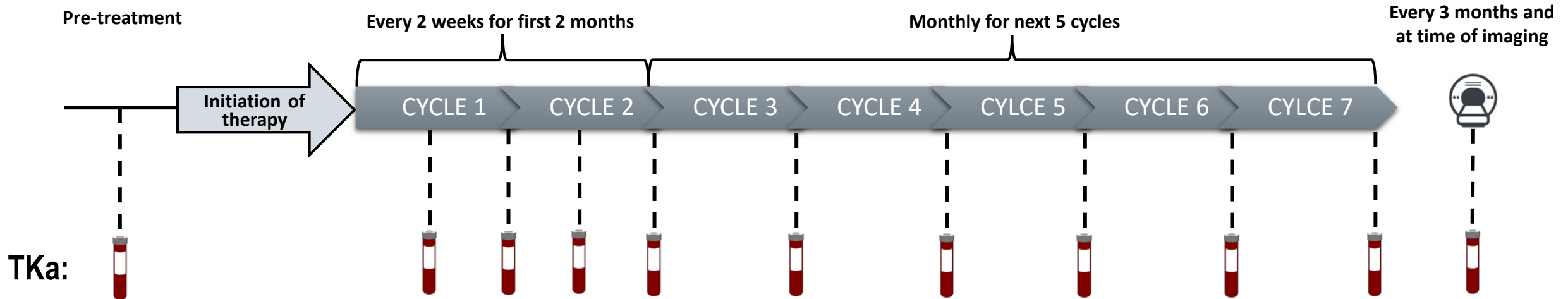


# TK-IMPACT Study (currently enrolling)

BI+VICA



- ❑ First study in the US where DiviTum®TKa is being used by oncologists in “real-time”

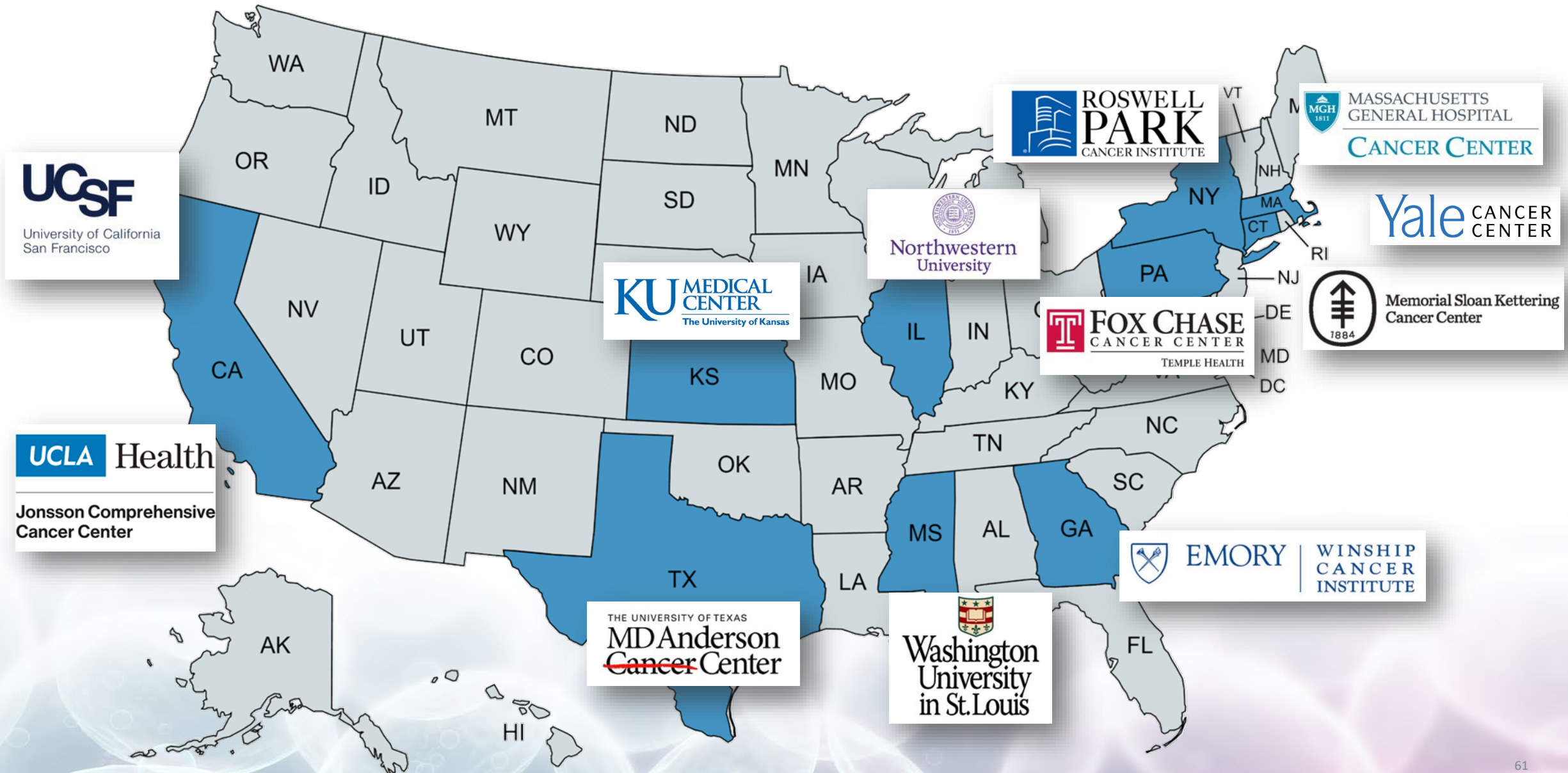


- ❑ Metastatic HR+ breast cancer patients prescribed any FDA approved CDK4/6 inhibitor with any approved endocrine therapy
- ❑ Oncologists will receive patient TKa measurements in real time and be able to make treatment decisions based on the TKa data



# Scientific Advisory Boards (USA)

BI+VICA



## Advisory Board Feedback

- Positive reaction to the new TKa data in CDK4/6 inhibitor treated patients and potential clinical utilities
  - “Ideas are on target”
  - “Biovica has the right focus”
  - “Game changing”
  - “Potential is huge”
- New opportunities identified
- New collaborations being discussed/evaluated

## Exciting New Utility for DiviTum®TKa

- New data has revealed a novel use for DiviTum®TKa
- New patent has been filed
- TKa values would identify patients who are likely to respond to a specific class of cancer therapy
- Very large market
- Addresses an unmet need





# 2022 ASCO<sup>®</sup>

## ANNUAL MEETING

- DiviTum<sup>®</sup>TKa and ctDNA data comparison from BioltaLEE trial
- Oral presentation will highlight key similarities and differences

### ABSTRACTS & PRESENTATIONS

2022 ASCO Annual Meeting - Clinical Science Symposium - June 6<sup>th</sup> 6:18PM EDT



**First Author:**  
Grazia Arpino

**Circulating tumor DNA (ctDNA) and serum thymidine kinase 1 activity (TKa) matched dynamics in patients (pts) with hormone receptor-positive (HR+), human epidermal growth factor 2-negative (HER2-) advanced breast cancer...**



A background image showing a microscopic view of cells, likely cancer cells, with a blue and purple color palette. The cells are clustered and have a textured, granular appearance.

# BIOVICA

Treatment Decisions With Greater Confidence  
Pharma Collaborations  
Henrik Winther

# Agenda

1. Biovica's Pharma-collaboration Strategy
2. Current Status of our Pharma-collaborations
3. Financial Impact and Expectations  
- for the Biovica/Pharma-collaborations



## About the Presenter

### Henrik Winther, DVM, PhD

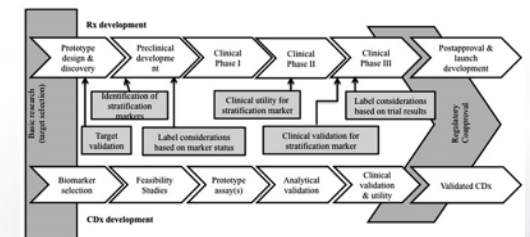
- SVP Business Development & Pharma Collaborations
- 20+ years in the in vitro diagnostic (IVD) society bringing **biomarker assays** into the **clinical routine market** and with managing roles within R&D and BD.
- Special passion and general manager roles within the **Companion Diagnostic (CDx)** field and **collaborations with Pharma**.
- Design responsible for the first global market CDx assay (HercepTest™)
- Responsible for the **development, registration and commercialization** of the Keytruda and Opdivo CDx's (one true CDx and one Complementary Diagnostics)





# Biovica's Two-Staged Companion Diagnostic (CDx) and Monitoring Diagnostic (MDx) Strategy

- Stage 1:
  - ***Building Trust:*** The Biovica CDx/MDx business operates as a FFS\* R&D partner to Oncology Pharma, offering DiviTum®TKa as a RUO collaborative tool for pre-clinical and phase I/II pharma studies during Rx development.
    - Primary collaborators: US and EU Oncology Pharma companies developing next generation CDK inhibitors. Focus is TIER 1 & 2 Pharma.
- Stage 2:
  - ***True CDx/MDx Development:*** Biovica CDx/MDx FFS offerings include true CDx/MDx product development, registration and commercialization for Oncology Pharma based on DiviTum®TKa technology(ies).



\*FFS: Fee For Service



# Types of Pharma Services/Collaborations

## Currently: Research Use Only (RUO)

- Planning/guidance of TKa testing in pharma studies/trials
- Actual TKa testing of pharma samples
  - Biovica Labs (Uppsala & San Diego)
  - Mayo Clinic ICC
  - UCR Uppsala
- Evaluation of TKa test results related to outcome data

## Next step: IVD

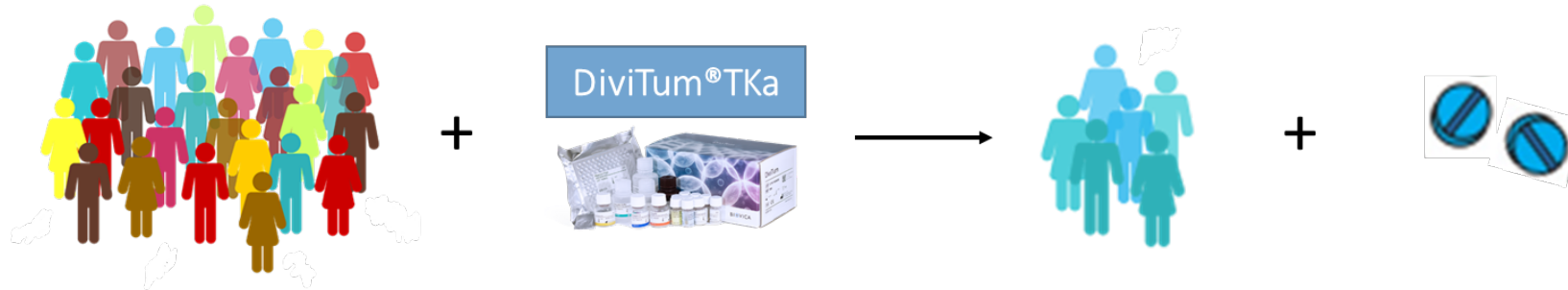
- Development, registration & commercialization of monitoring predictive TKa assays (CDx's<sup>1</sup>/MDx's<sup>2</sup>) for IVD use

<sup>1</sup>CDx : Companion Diagnostics    <sup>2</sup>MDx: Monitoring Diagnostics



# TKa Has Demonstrated Convincing Clinical Data as a CDx/MDx-Tool

TKa for **upfront** selection of patients for a specific treatment



References

**SWOG**  
Clin Cancer Res  
(2021) 27 (22):  
6115–6123.

TKa for **early on-treatment** monitoring and selection of patients for a specific treatment



**BiolaLee**  
ESMO 2021  
ASCO 2022  
**PYTHIA**  
Eur J Cancer  
(2022), volume 8,  
164: 39-51

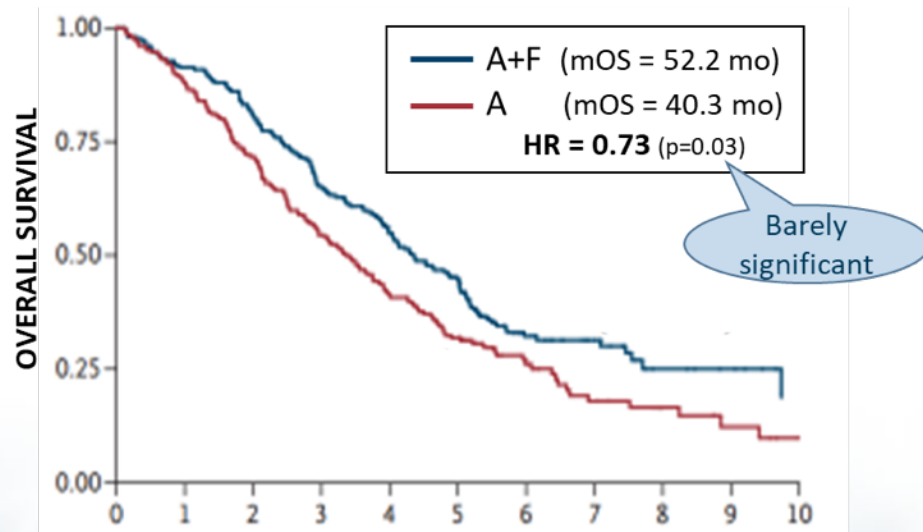
TKa for **on-treatment** monitoring of continued response to specific drug



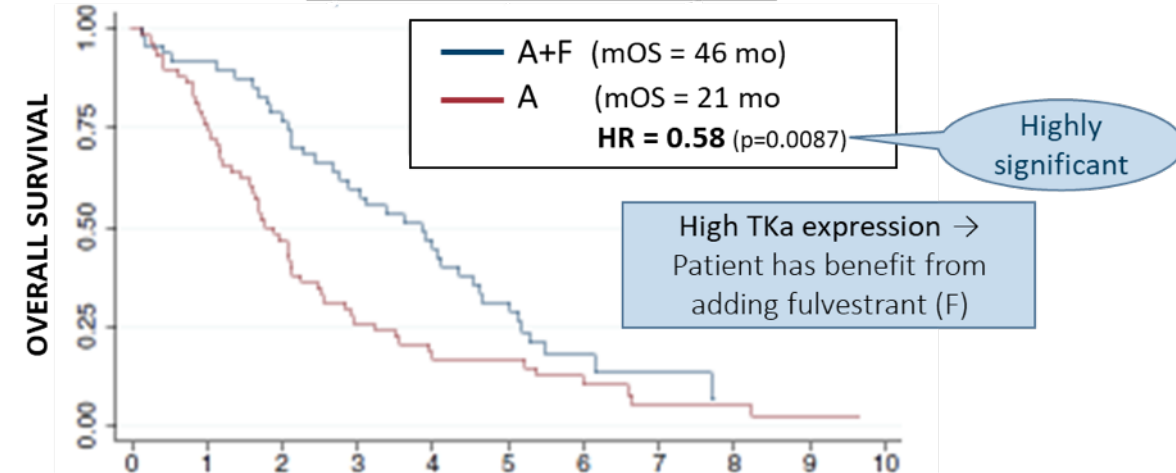
**PALBO-DOSING**  
npj Breast Cancer  
(2022), volume 8,  
Article number: 35

# SWOG Results: DiviTum®TKa Can Predict/Select Which Patients Will Benefit From Combination Therapy

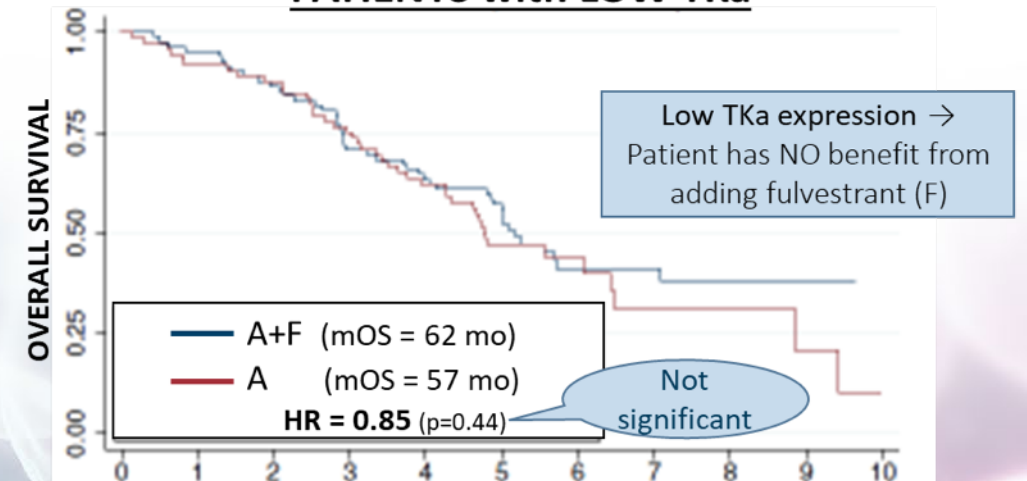
## ALL PATIENTS (Without TKa as a selection biomarker)



## PATIENTS with HIGH TKa

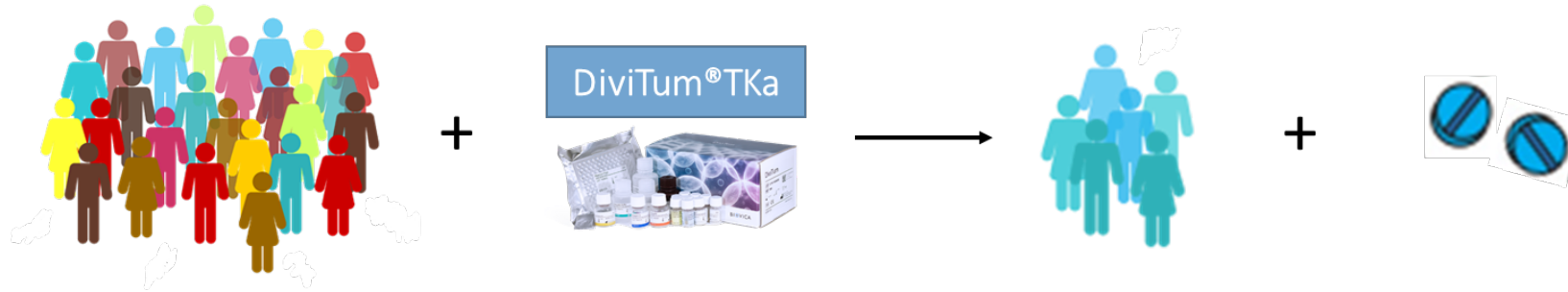


## PATIENTS with LOW TKa



# TKa Has Demonstrated Convincing Clinical Data as a CDx/MDx-Tool

TKa for **upfront** selection of patients for a specific treatment



References

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TKa for **on-treatment** monitoring of continued response to specific drug



**PALBO-DOSING**  
npj Breast Cancer  
(2022), volume 8,  
Article number: 35



# Pharma Have Identified TKa as a Highly Relevant Tool for the Development of Cell Proliferation Inhibitor Drugs

Pharma-partner	Indication(s)	Drug (Rx)	Rx Study Phase	Agreement
1. TIER-2 <sup>2</sup> pharma (EU)	mBC (HR+, HER2÷). Patients resistant to CDK4/6i treatment.	CDK-inhibitor.	Phase IIa. Phase IIb. FDA fast track designation.	TESA <sup>3</sup>
2. TIER-2 <sup>2</sup> pharma (US)	mBC (HR+)	CDK-inhibitor	Phase I/II. Dose-escalation.	TESA <sup>3</sup> → MSA <sup>4</sup>
3. TIER-2 <sup>2</sup> pharma (US)	mBC and other solid tumors	CDK-inhibitor	Phase I	MSA <sup>4</sup>
4. TIER-2 <sup>2</sup> pharma (US)	Solid tumors	CDK-inhibitor	Phase I	RSA <sup>5</sup> /MSA <sup>4</sup>
5. TIER-2 <sup>2</sup> pharma (US)	Solid tumors	Rx's targeting key drivers of cancer cell growth	Phase I	KSA <sup>6</sup> →
6. TIER-1 <sup>1</sup> pharma (EU/US)	Breast, prostate and ovarian cancers	CDK-inhibitor	Phase I	KSA <sup>6</sup>
7. TIER-2 <sup>2</sup> pharma (US)	mBC (HR+), other solid tumors	CDK-inhibitor	Phase I/IIa	KSA <sup>6</sup>

<sup>1</sup>TIER-1: Large-sized Pharma; <sup>2</sup>TIER-2: Mid-sized Pharma

<sup>3</sup>TESA: technical Evaluation Service Agreement; <sup>4</sup>MSA: Master Service Agreement; <sup>5</sup>RSA: Research Service Agreement; <sup>6</sup>KSA: Kit Supply Agreement

# Timeline Considerations for the Biovica/Pharma Business Development

## Plan/Expectations

- 3 TESA's
- 1 MSA discussion initiated
- 3 Mid-sized pharma companies
- 3 projects initiated

- 6 TESA's
- 4 MSA signed
- 2 Large pharma companies
- 6 Mid-sized pharma companies
- 10 projects initiated

FY 2021/2022

FY 2022/2023

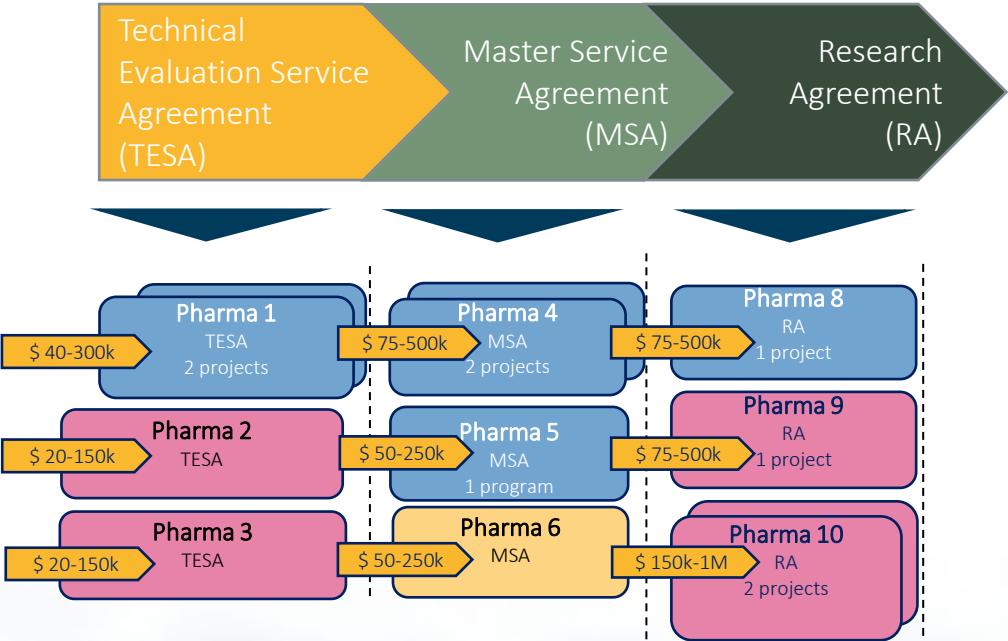
- 2 TESA's
- 3 MSA's signed
- 1 Large-sized pharma company
- 6 Mid-sized pharma companies
- 6 projects initiated

*"We are almost a year ahead of our expectations –TKa has become a very attractive biomarker to pharma"*

## Current Situation

# CDx/MDx Revenue Potential By Strategy

## Stage 1: FFS R & D Collaborations



## Stage 2: True CDx/MDx Development



Stage 2 POTENTIAL	New CDx Products	IU Expansion of Existing CDx
FFS REVENUE (PER INDICATION)	\$4.5 – 8M	\$1.2 – 3M
PRODUCT SALES REVENUE (YEARLY)	\$8-40M (per product)	\$2-6M (per expansion)
TIME TO LAUNCH	3.5 – 6 YEARS	1-2 YEARS

YEARLY REVENUE  
POTENTIAL  
(PER CDx)

\$50-100  
million

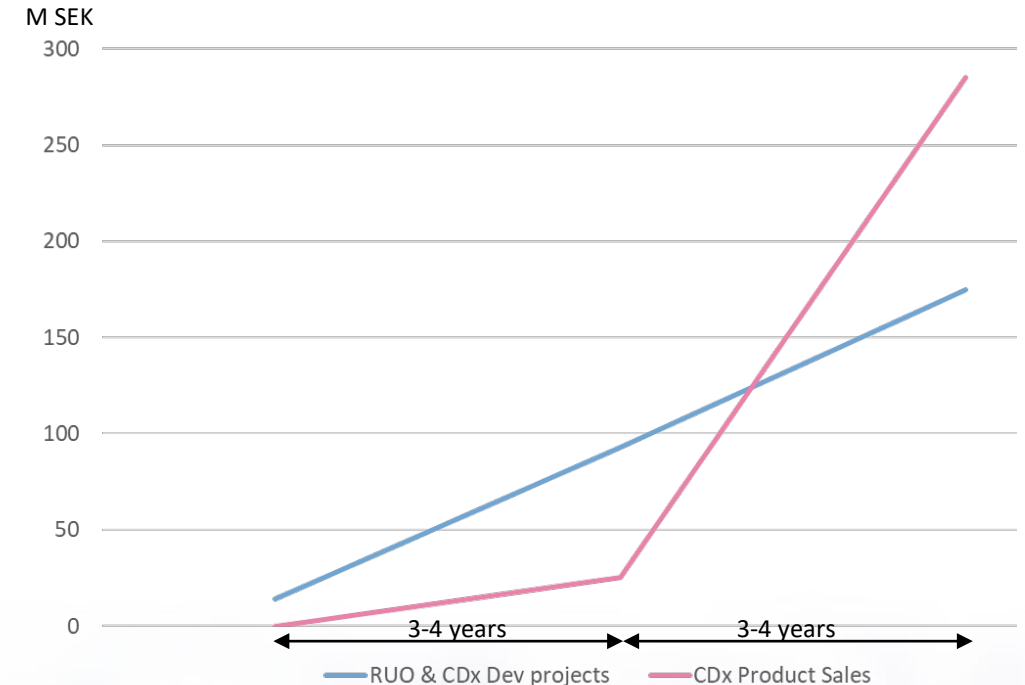
# Product Sales Occurring During Stage 2 Will Significantly Increase the CDx Revenue

## Key Assumptions

- ~10% RUO projects turn into CDx products
- ~20-30% of CDx projects turn into CDx products
- ~4Y for CDx product development
- ~1,5 Y for Add-on indications

## Business Model

- RUO & CDx Dev projects
  - Fee-for-Service (FFS) with ~50% GM's
- CDx Product Sales with ~80-90% GM



- RUO revenue in 6-8Y's: ≥50MSEK
- First CDx-product launched in 4-6Y's
- Potential CDx Business revenue at ≥500 MSEK in 8-10 years



The background of the slide features three distinct clusters of cells, likely representing tumor spheroids or organoids, rendered in a light, semi-transparent style against a dark blue gradient background. One cluster is positioned in the upper right, another in the lower right, and a third in the lower left.

# BIOVICA

Treatment Decisions With Greater Confidence  
Summary & Milestones  
Anders Rylander

# Summary & Milestones

- DiviTum®TKa addresses an important clinical unmet need within metastatic cancer.
- DiviTum®TKa comes with strong clinical data
- DiviTum®TKa is supported by cancer KOL's and scientific collaborators globally, constituting a strong foundation for the commercialization process.

## Upcoming milestones:

- 510(k) clearance
- US launch after 510(k) clearance
- European launch after launch in US





The background of the slide features three distinct clusters of cells, likely representing tumor spheroids or organoids, set against a soft-focus gradient of blue and purple. The clusters are composed of numerous small, rounded cells with visible nuclei, some showing more complex internal structures. They are positioned in the upper right, lower left, and lower right areas of the frame.

# BIOVICA

Treatment Decisions With Greater Confidence

Q&A

Charlotte Stjerngren

Thank You!