



The Mark of
Individualized Medicine

Overcoming a Global Sample Collection Challenge

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Monogram Company Background

- Founded November 1995 in South San Francisco, CA
- ~350 employees
- 80,000 sq ft facility
- CLIA/CAP credited lab
- ~100,000 tests annually
- State-of-the-art high-throughput reference laboratory
- Science-driven organization with patented technologies in HIV and Oncology



Monogram Mission Statement

Our mission is to improve healthcare by advancing individualized medicine through the discovery and commercialization of innovative products to guide and improve the treatment of HIV, cancer and other serious diseases.

The Right Treatment for the Right Patient at the Right Time

Products

HIV-Virology

- Patient Resistance Testing

GeneSeq™
HIV DRUG RESISTANCE ASSAY

PhenoSENSE ENTRY
HIV DRUG RESISTANCE ASSAY

PhenoSENSE GT™
REPLICATION CAPACITY
COMBINATION HIV DRUG RESISTANCE ASSAY

- Patient Selection Testing

trofile™
CO-RECEPTOR TROPISM ASSAY

Oncology

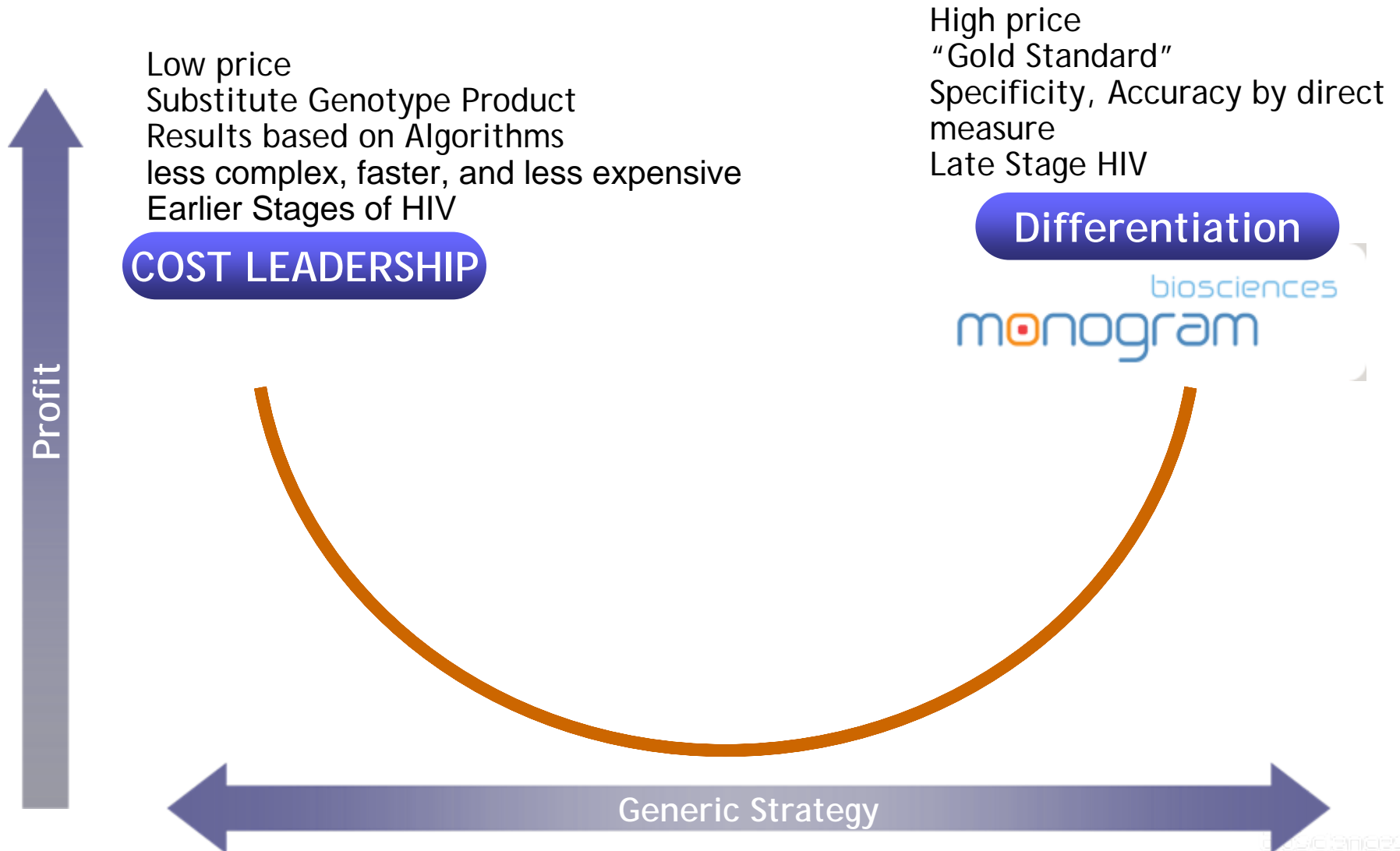
- Selection testing

VeraTag™
TECHNOLOGY

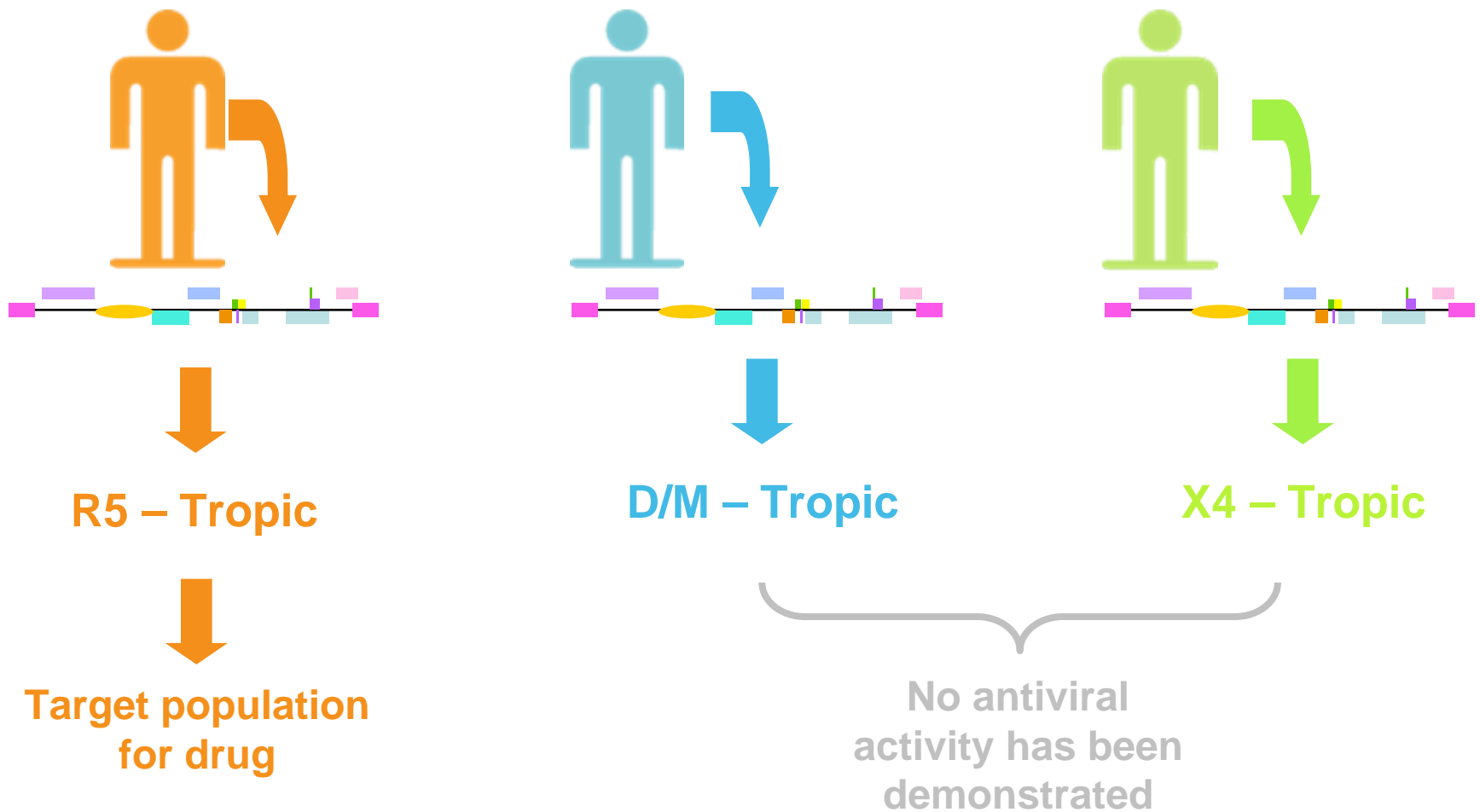
HERmark™
BREAST CANCER ASSAY



HIV Products-Positioning



Trofile as a screening tool prior to CCR5 antagonist use



Trofile™ Results: R5

- Results provided by V-Link web-portal accessed by clinicians.

trofile™
CO-RECEPTOR TROPISM ASSAY
biosciences

monogram

Patrick Joseph, MD, Medical Director - 345 Oyster Point Blvd
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Patient Initials:	DOB	Patient ID	Gender	Monogram Accession # 06-100010
Date Collected	Date Received	Date Reported	Mode	Report Status
Investigator				Specimen ID
Comments:				

Troptotype Result

R5

D/M

X4

Virus uses CCR5 co-receptors to enter the CD4+ cell.

R5

Activity of
CCR5 antagonist
anticipated?

YES
 NO

ABOUT TROPISM

WHAT IS TROFILE™?

Trofile is a CLIA-validated*, cell-based approach to determine an individual's HIV co-receptor tropism (or "troptotype"™). Co-receptor tropism is defined as an interaction of a virus with a specific co-receptor on the target cell. To gain entry to the CD4+ cell (host), HIV must bind to the cell surface CD4 receptor and to one of two chemokine co-receptors (CCR5 or CXCR4) also present on the cell surface.

TROFILE VIRAL CLASSIFICATION

CCR5 (R5) Virus = Virus uses CCR5 chemokine co-receptor to enter the CD4+ cell.

DUAL/MIXED (D/M) Virus = Dual-tropic viruses can use either the CXCR4 or CCR5 co-receptors to enter the CD4+ cell. Mixed-tropic is a mixed population of both CCR5 and CXCR4 tropic viruses.

CXCR4 (X4) Virus = Virus uses CXCR4 chemokine co-receptor to enter the CD4+ cell.

Non-reportable = Your patient's troptotype could not be determined by the Trofile assay. Common causes of failure of the assay are viral load <1,000 copies/mL, reduced viral fitness, or compromised sample collection/handling.

CO-RECEPTOR ANTAGONISTS

A new class of drugs – co-receptor antagonists – provides a novel mechanism to inhibit the HIV viral replication cycle. These drugs work by binding to a specific chemokine receptor (CCR5 or CXCR4) and block the virus' ability to bind these co-receptors and initiate its entry into the host cell. Trofile can help determine whether a CCR5 antagonist or a CXCR4 antagonist may be an appropriate drug for your patient. Several clinical trials on CCR5 antagonists have demonstrated the positive and negative predictive value of Trofile in clinical settings.

Monogram Trofile assay

Personalized Medicine in Action

- May 2006: Monogram went into contract with a large pharmaceutical company in a non-exclusive 3-year collaboration to make Monogram's HIV Co-Receptor Tropism Assay available for patient use on a global basis.
- **Landmark HIV Partnership**
 - First HIV diagnostic/drug combination
 - Monogram's Trofile Assay is the **only clinically proven** way to identify patients
 - Trofile has been used in all CCR5 trials to date
 - Global recognition of Trofile technology
 - U.S. - Monogram retains all rights
 - Ex-U.S. - Monogram provides Trofile in all countries where large pharma's drug is available

trofile[™]
CO-RECEPTOR TROPISM ASSAY



Trofile's role

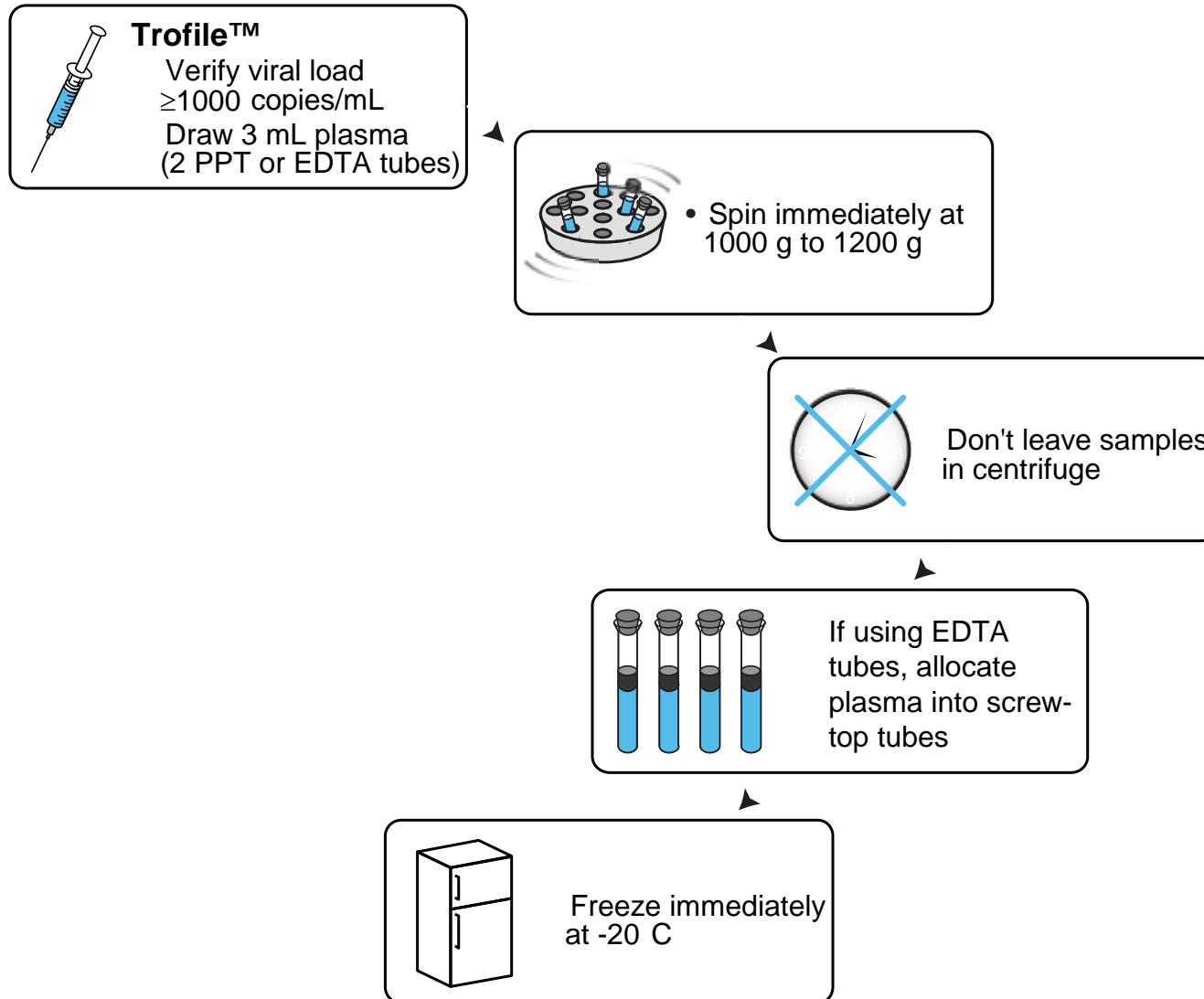
- *Wall Street Journal - February 28, 2007*
- For the clinical trials, South San Francisco-based Monogram Biosciences tested potential patients to determine which portal HIV used to enter the cell. Only patients whose HIV entered through CCR5 were admitted to the trial. In a first for AIDS drugs, FDA approval might require doctors to ship samples to Monogram's headquarters for testing before prescribing the treatment.
- ***"This is going to be a logistical nightmare," said Dr. Deeks.***

The Challenge

To provide a commercial solution for a companion diagnostic in a “clinical trials-centric” world.

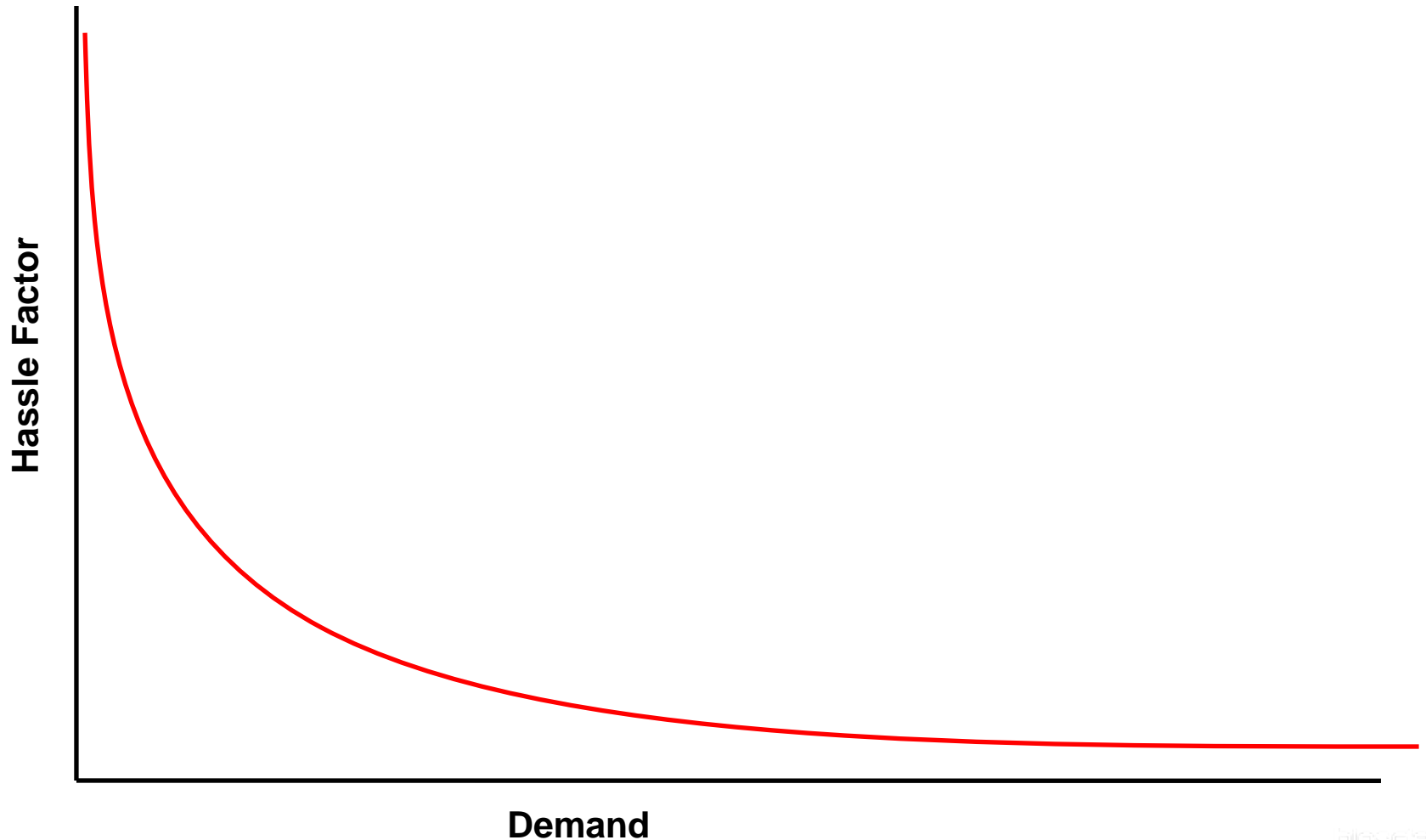
- First HIV assay co-marketed with a pharmaceutical for the global market.
- Differentiations
 - No protocols
 - No investigators
 - No sponsors
 - No length of study
- **Key issues**
 - Key Opinion Leader acceptance.
 - Building a positive patient and physician perception.
 - **Ease of use**
 - **Quality**
 - **Cost**
 - **Reasonable TAT**

Preparing the Sample for Testing

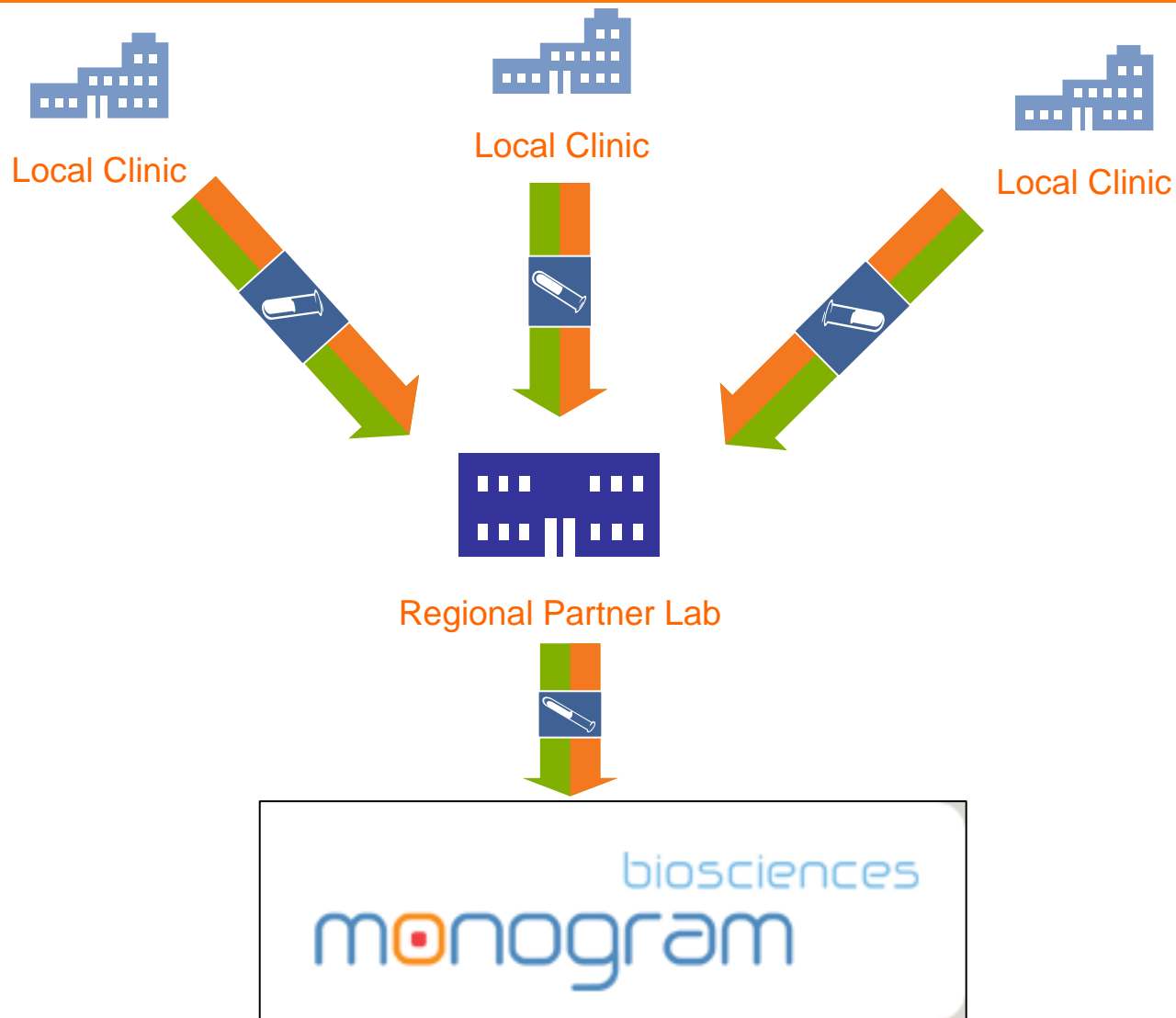


Hassle factor demand curve

- Demand vs Hassle Factor



Simple consolidation model



Selection criteria

- **Criteria:**

- **Accessibility**: Do they have the assets and resources in the target market?
- **Capability**: Can they meet our SOP for maintaining sample quality/TAT?
 - Biological services
 - Dry ice sourcing
 - Specific MGRM/Trofile operations (paperwork, packaging, “swap”)
- **Cost**: Which Logistics provider can provide the above services at the appropriate cost?



Selection criteria - Europe

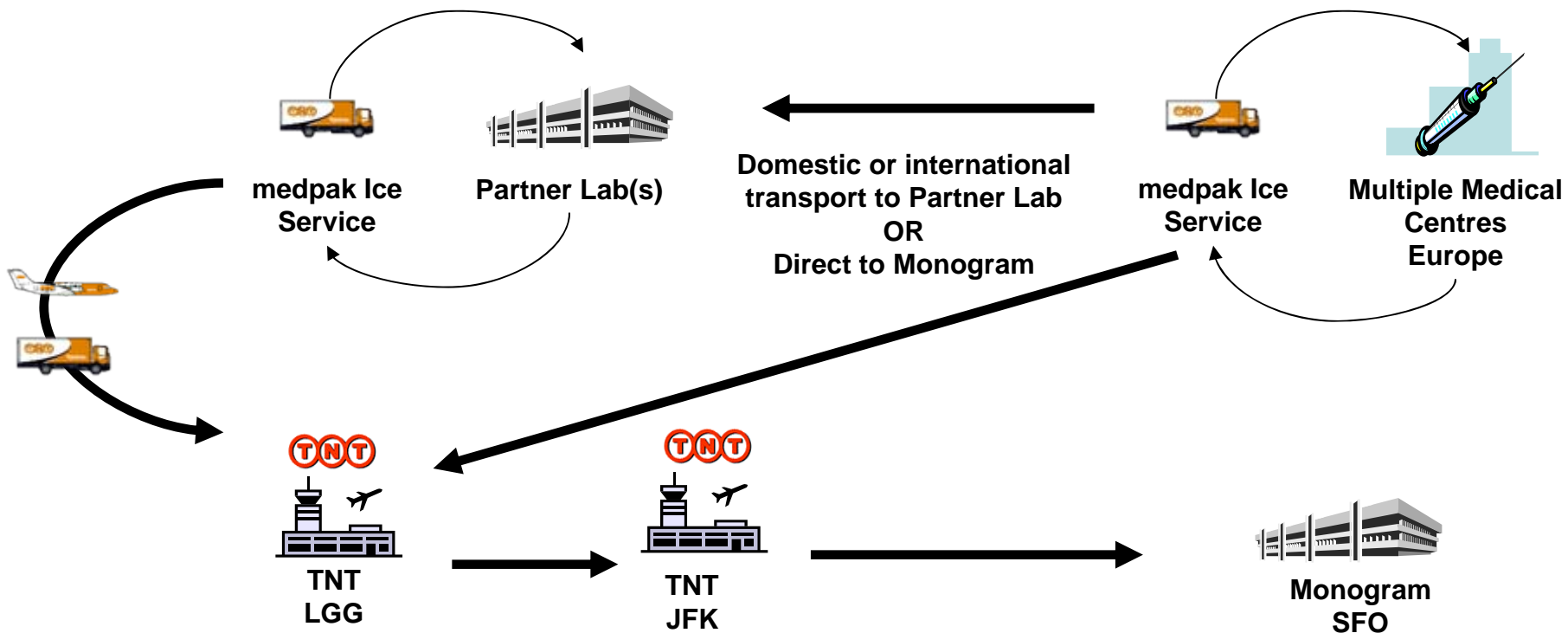
- **We decided to address Europe as a whole. To work toward a integrated Logistics vendor solution.**
- **Operational factors include:**
 - **Projected regional sample consolidation.**
 - **Ease of management of a single Logistics Partner.**
 - **Bundled contract leads to better pricing.**
- **Using the important criteria below and focusing on EU regional expertise, the following items were considered when choosing a Logistics Partner.**
 - **Price**
 - **Quality**
 - **TAT**
 - **Capability**
 - **Communication**



Meeting the challenge

- How does a company such as TNT meet the challenge?
 - Global Express Transport operator with the leading position in Europe
 - 150,000 employees
 - 230 million consignments annually
 - Extensive air and road networks
 - 64 countries, network covering 200 countries
 - 46 planes, 26,610 vehicles
 - A large organization, still small enough to be flexible to our customers' requirements
 - Special Services
 - Industry specific focused
 - More than 1 million clinical samples transported annually
 - Understanding our intrinsic role = consequence of failure as opposed purely to A to B transport

Logistics model overview



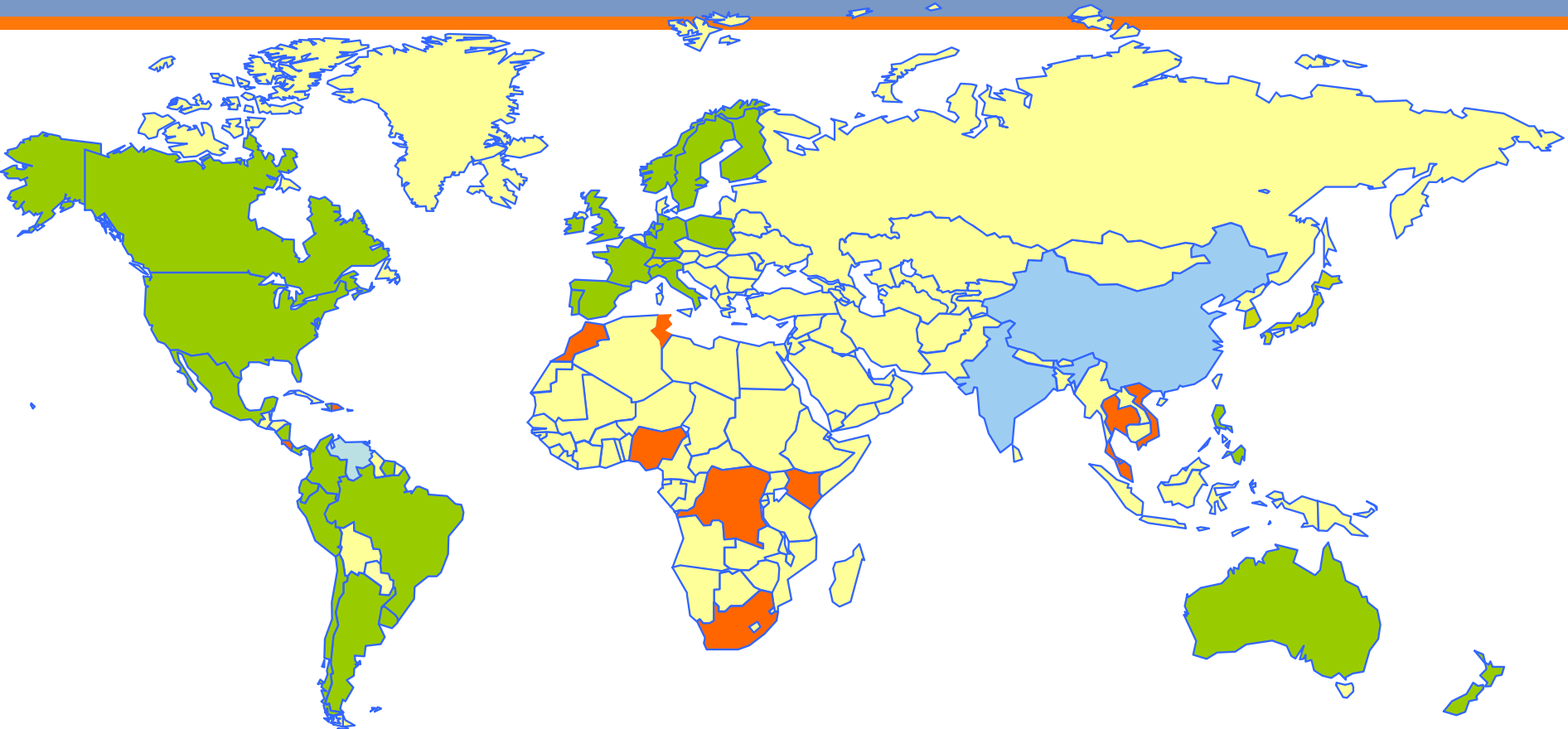
"This is going to be a logistical nightmare," said Dr. Deeks




Correctly tailored logistics add simplicity, efficiency and improved cost control – say TNT

Making it work

- What really makes it work?
 - Collaborative approach between customer and supplier
 - Dedicated customer service for Healthcare
 - Skills, resources and experience in the “clinical trials centric world”
 - Understanding requirements and having the flexibility to make adjustments
 - Order placement
 - Implementation process
 - High level of communication
 - Understanding our role, obligations and consequences
 - Patients
 - Perception
 - Effect on demand
 - Dedication to making it happen every time

Current Trofile Markets



Fully operational	
Beginning 2009	
Beyond 2009	

Current Trofile availability

EU	Americas	AFME	Asia
UK	Canada	n/a	Australia
Ireland	Brazil		New Zealand
France	Argentina		S. Korea
Spain	Chile'		Taiwan
Germany	Uruguay		Japan
Italy	Colombia		Philippines
Portugal	Peru		
Greece	Costa Rica		
Austria	Dominican Republic		
Switzerland			
Finland			
Sweden			
Norway			
Lithuania			
Czech Republic			
Slovakia			