



Polyclone
Bioservices Pvt Ltd

Indo German Partnering Models for Effective Molecular Assay Design & Validation

Fourth Hanseatic India Colloquium, Hamburg, Oct 2009

Sanjay Bettadpura, Chief Business Officer

Outline

- About Polyclone
- Challenges in assay design & validation
- Indo-German models to address the challenges
- Case studies
- Summary



Polyclone
Bioservices Pvt Ltd



About Us



Polyclone
Bioservices Pvt Ltd

Focus

Focus

Cancer and Infectious disease target & biomarker discovery and validation

Approach

Synergistic combination of *in vitro* and *in silico* techniques

Expertise

Molecular & cell biology, genomics, proteomics and bioinformatics

Model

- Fee for service
- Collaborative research



Background

Inception

- Founded in 2005 in Bangalore, India
- By life science & business professionals with more than a decade of experience in global biotech industry
- Lab incubated at University in Northern Karnataka

Team

- Molecular biologists, cell biologists, bioinformaticians and IT Specialists
- Expertise in lab and *in silico* aspects of qPCR, microarray, RNAi, miRNA, MS based genotyping & ribonomics
- More than 100 person years of combined experience inclusive of advisors



Scientific advisory board

**Biomarkers &
Mol. Diagnostics**

Dr. Amal Mukhopadhyay, Founder and Director, ELGA Biotech, Hamburg, Germany; Representative of Hamburg (HWF) for India Life Sciences

**qPCR/
Gene Expression**

Dr. Mikael Kubista, CEO, Founder, TATAA Biocenter, Sweden, Global pioneer in qPCR technology

**Metabolic
pathway profiling**

Dr. Sanjay Swarup, HoD. of Bio. Sci. NUS, Singapore; Areas of expertise include pathway profiling and vaccine development



Polyclone
Bioservices Pvt Ltd

Partners



Kamatak Cancer Therapy and
Research Institute, India

Hubli, India
Cancer patient
samples & data



Berlin, Germany
Multi-individual arrays for
agri-biomarker studies



Dortmund, Germany
Microarray and liquid-
handling technologies



Gothenburg, Sweden
Multi-dimensional gene
expression data analysis



Albany, USA
RIP-CHiP and Cancer
Genomics

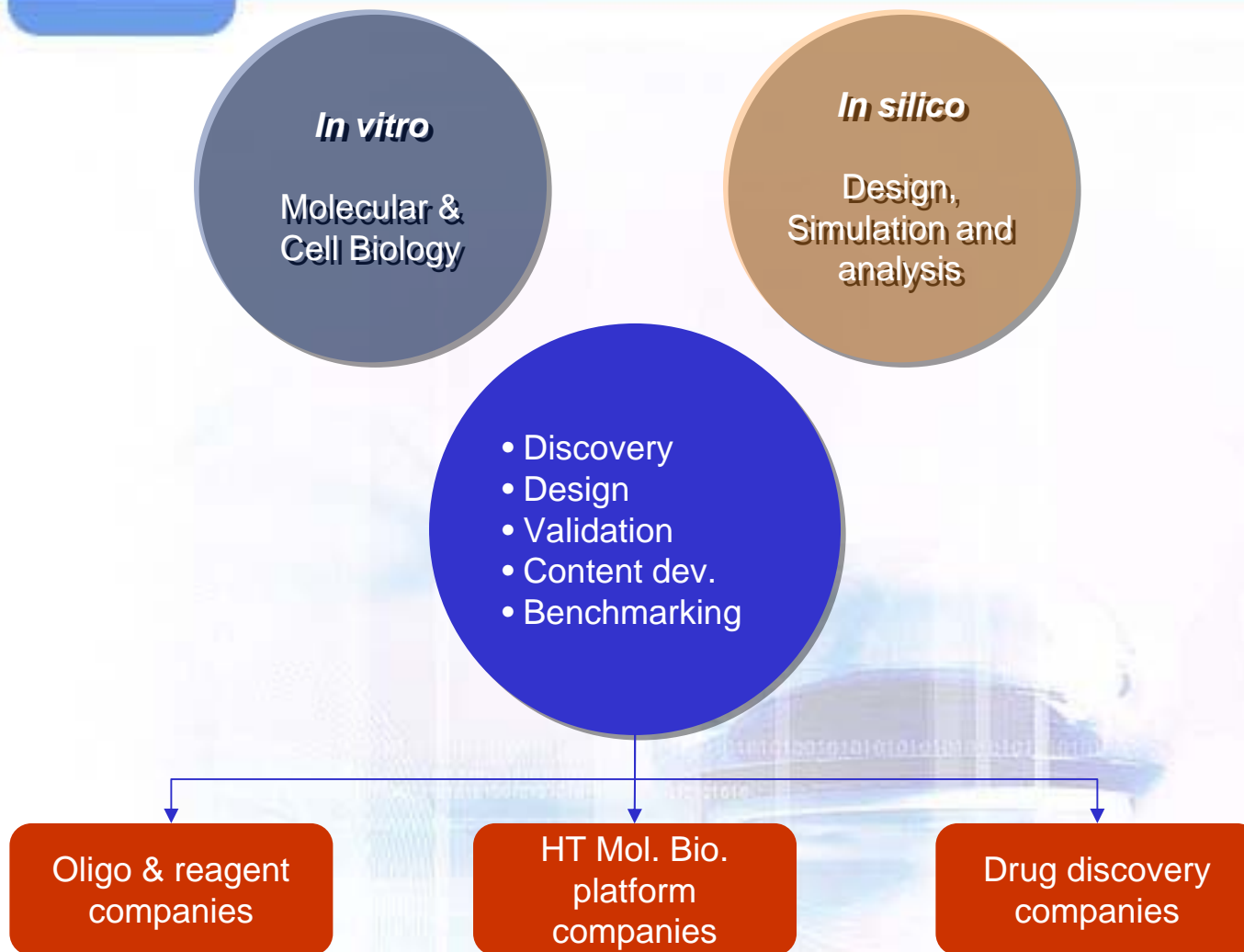


Hamburg, Germany
Scientific & German
business advisors

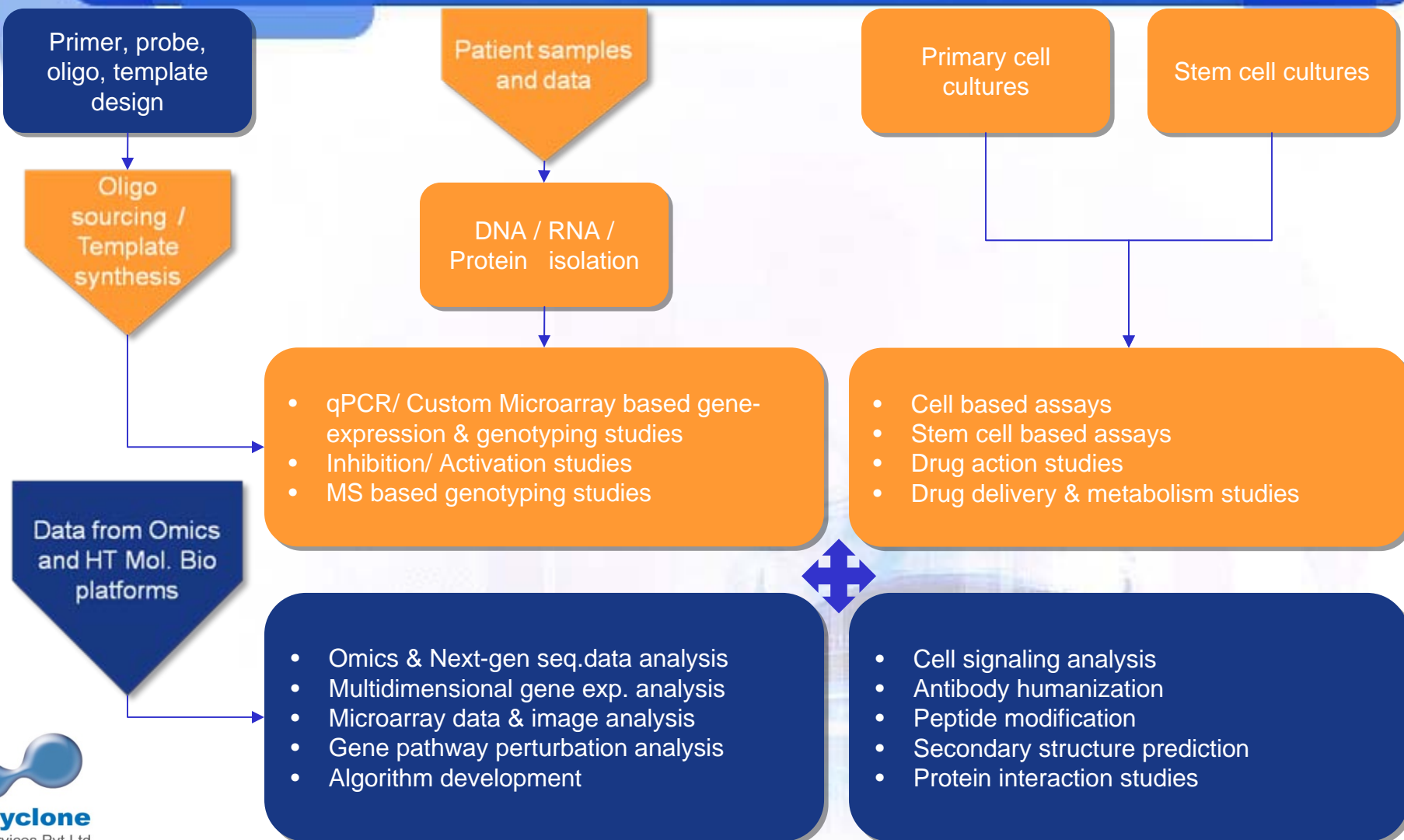


Polyclone
Bioservices Pvt Ltd

Service portfolio & Customer profile



Assay design & validation capabilities



Customers

For the last 3 years we have been enabling European & US biotech companies in their ***molecular & cell biology, genomics, proteomics and bioinformatics*** goals and helping them beat their budget and timeline challenges. Some of these companies include:



eppendorf



scienion
ENABLING LIFE SCIENCE



ALTONA
BIOTEC



Eurogentec
Experience true partnership



PHILIPS
sense and simplicity



WaferGen
Biosystems



COMBIMATRIX



BIOSYNTHESIS
INC
SYNTHESIS THROUGH INGENUITY

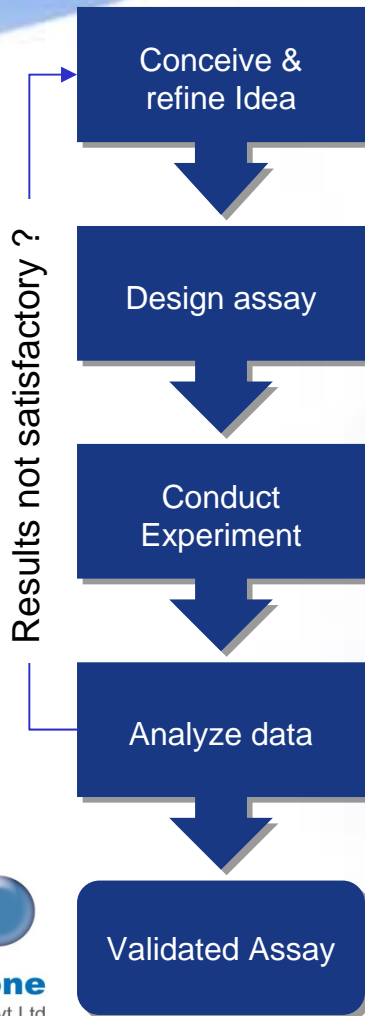


Polyclone
Bioservices Pvt Ltd



Challenges in Assay design & validation

The Assay Design & Validation Process



Challenges

Relevance of assay

- Population specific or 'universal' e.g. Specific to German / Indian races or global outlook?
- Usage of end product – e.g. decentralized or centralized tests in case of diagnostics ?
- Costs to the end customer – price sensitivity of target customer groups

Technology selection & design

- Surge in HT technologies - Which technology ? Does it provide validated content?
- Stringency of primer/ probe/ template design
- IP rights concerns (Specific sequences/ primers patented)

Access to samples & resources

- Non-availability of significant size of affected populations in specific regions
- Lack of climate/ environmental/ life-style and other epigenetic factors
- Availability of relevant technologies & human resources

Data size & disparity

- Huge amounts of data generated by HT Platforms
- Multiple sources of data & multiple data formats to be integrated & mined



Overcoming the challenges through Indo-German collaborations

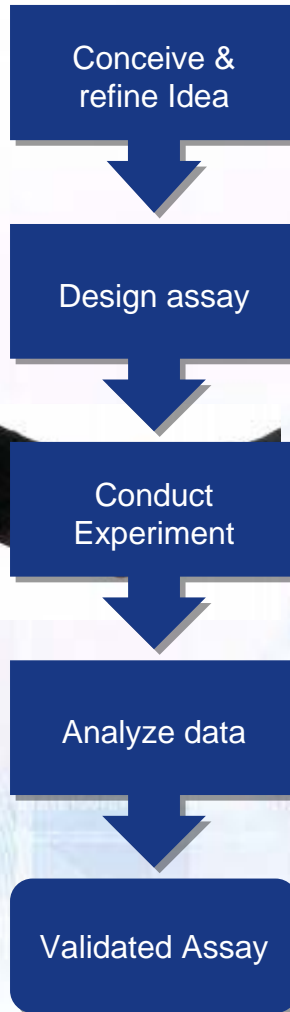


Polyclone
Bioservices Pvt Ltd

Leveraging on mutual strengths



- Global leader in discovery research
- Ideas & innovation for transformational assays
- Strong patent portfolio
- Automation & Engineering expertise for development of new platforms
- Access to cutting edge HT technologies
- Ability to fund investments
- Simulation and cluster computing expertise
- Developed domestic market & gateway to European & World markets



- Leader in adapting technology to mass and price sensitive markets
- Favorable track record in IPR since joining the WTO regime
- Bioinformatics & in silico expertise for accurate assay design
- Wide gene pool diversity to determine assay specificity
- Diverse climate conditions & changing lifestyles for epigenetic studies
- Proven data analysis, mathematics & statistical strengths
- Strong emerging domestic market & gateway to South Asian and other developing markets



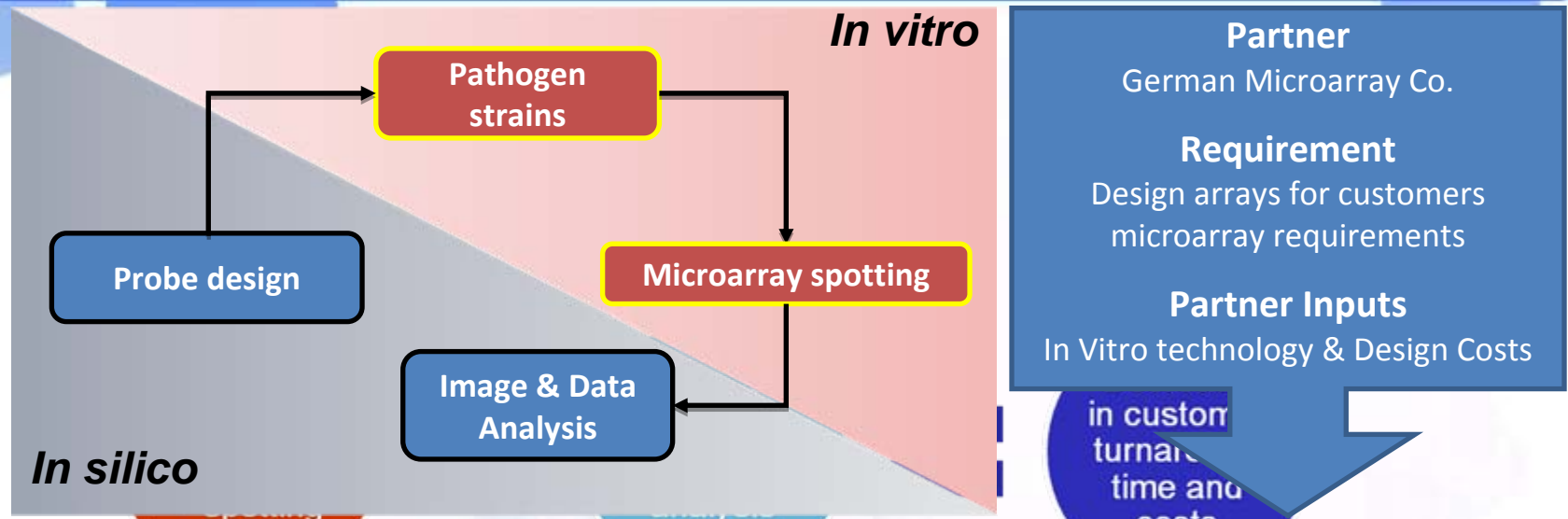


Case studies



Polyclone
Bioservices Pvt Ltd

Case study 1: Microarray design

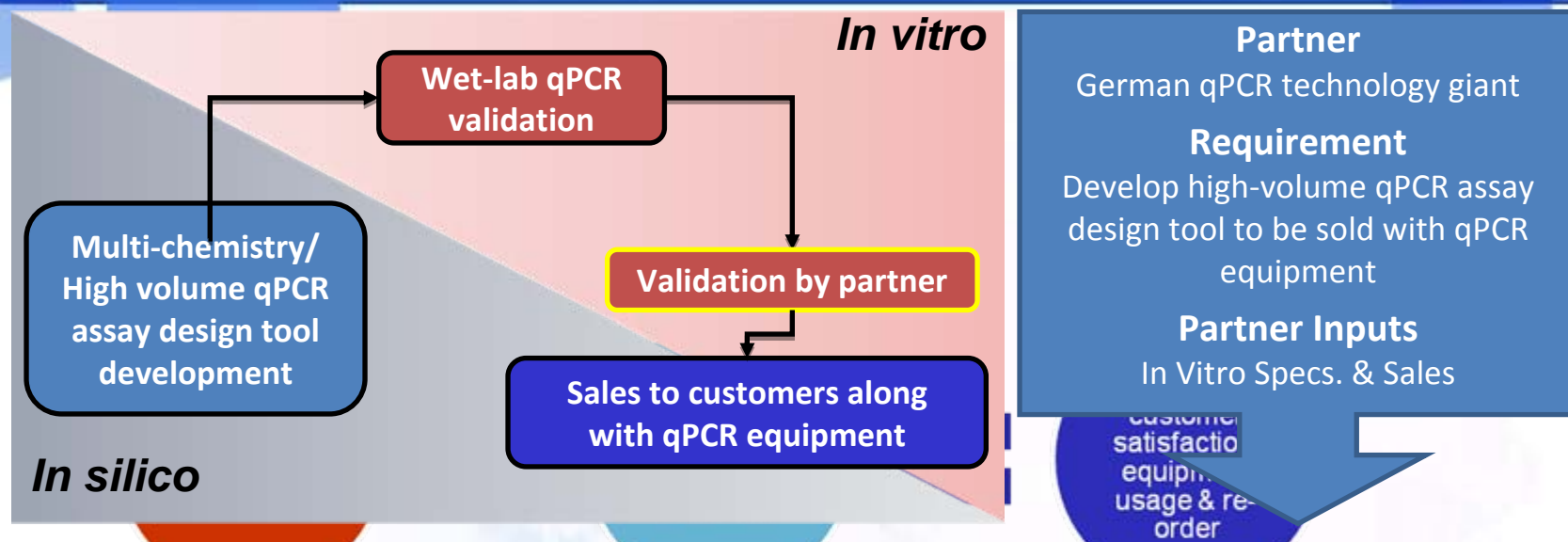


Objective	Challenge	Polyclone Inputs
Unique Probe Design	Strain specific, microarray based identification	<i>In silico</i> design using proprietary tools
Test Sensitivity	Low sensitivity of traditional methods for strain identification	Molecular assays (microarray based assay) provide improved sensitivity
Cost and management	Continuous and disparate requirements from customers for array design	High throughput automated process with low error rate for probe design & data analysis

Key Benefit: An automated quality probe design for customer's microarray needs validated in the wet-lab



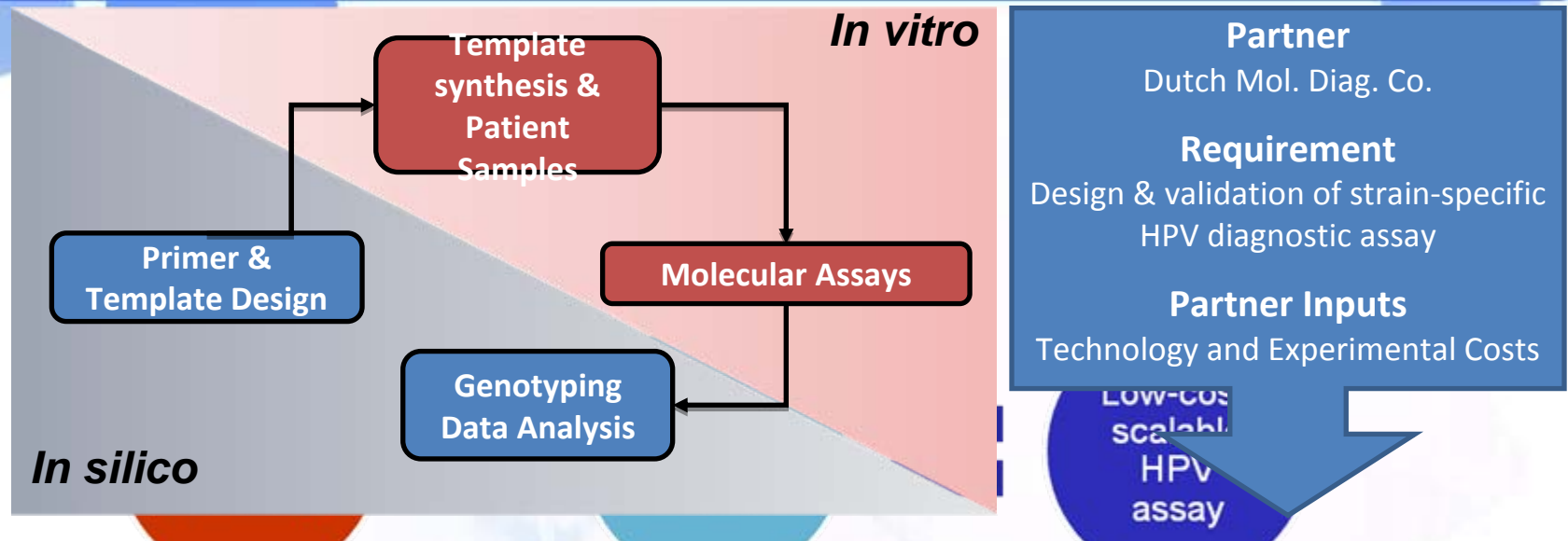
Case study 2: qPCR assay design tool



Objective	Challenge	Polyclone Inputs
Facilitate customers with high volume & accurate qPCR assay design tool	To support multiple chemistries, customizability and tweaked to partner's equipment	Developed first of its kind qPCR assay design tool and validated results in the wet-lab
Cost and management	Continuous and disparate requirements from customers for qPCR assay	High throughput automated process with low error rate for primer design

Key Benefit: Facilitated the optimal usage of partner's equipment by customers, increasing customer-satisfaction and retention.

Case Study 3: HPV assay design & validation



Objective	Challenge	Polyclone Inputs
Validation of biomarkers	Had to be specificity to Indian Population	<i>In silico</i> design of primers & probes specific to 20 Indian strains;
Increased test sensitivity	To develop quantitative, accurate and low-priced assay	qPCR based molecular assays designed to provide improved sensitivity . Validated on Indian donors.
Cost and management	Labour intensive, expensive process Scale disadvantages	High throughput molecular assay to make it automated and cost-efficient

Key Benefit: A robust, qualitative, low cost, multiplatform diagnostic assay

Other European Experiences

- In Silico antibody humanization for Hamburg based drug discovery start-up
- Agricultural bio-marker research collaboration with Array-On of Berlin/ University of Frankfurt
- Transfection reagent benchmarking study through cell-biology approach for Belgian reagents company
- Development of heat-map and dendrogram modules for Swedish gene expression software company



Summary

- India and Germany have always shared an intellectually stimulating relationship from the times of Hegel, Marx/ Rabindranath Tagore, Subash Chandra Bose
- Knowledge and technology based collaboration key to leverage German innovation and Indian ingenuity
- Together we can break the shackles of the global economic crisis and take advantage of our domestic and neighborhood markets





Polyclone
Bioservices Pvt Ltd

Thank you

www.polyclonebio.com

Sanjay.b@polyclonebio.com

Europe:

Innovendia Consulting

Dr. Michael Steinwand
Bartholomäus-Moser-Weg 4
D-88696 Owingen, Germany
Tel: +49 7551 83 84 11
Fax: 49 7551 83 84 12

USA:

New Trail Consulting
781, San Carlos Ave
Mountain View
California, 94043
Tel: +1-650-996-4951

India:

437, 40th Cross, 5th Block,
Jayanagar
Bangalore – 560041
Tel : +91-80-26638766
Fax : +91-80-42198340

www.polyclonebio.com