Standardization and Improvement of Generic Preanalytical Tools and Procedures for In Vitro Diagnostics
- EU Project SPIDIA -

3rd Annual BRN Symposium
Bethesda, March 25th 2010

Dr. Uwe Oelmueller
QIAGEN GmbH (Coordinator)

Agenda

- Preanalytical Workflow Challenges
- SPIDIA Project Project History
- Project Goals and Structure
- Status

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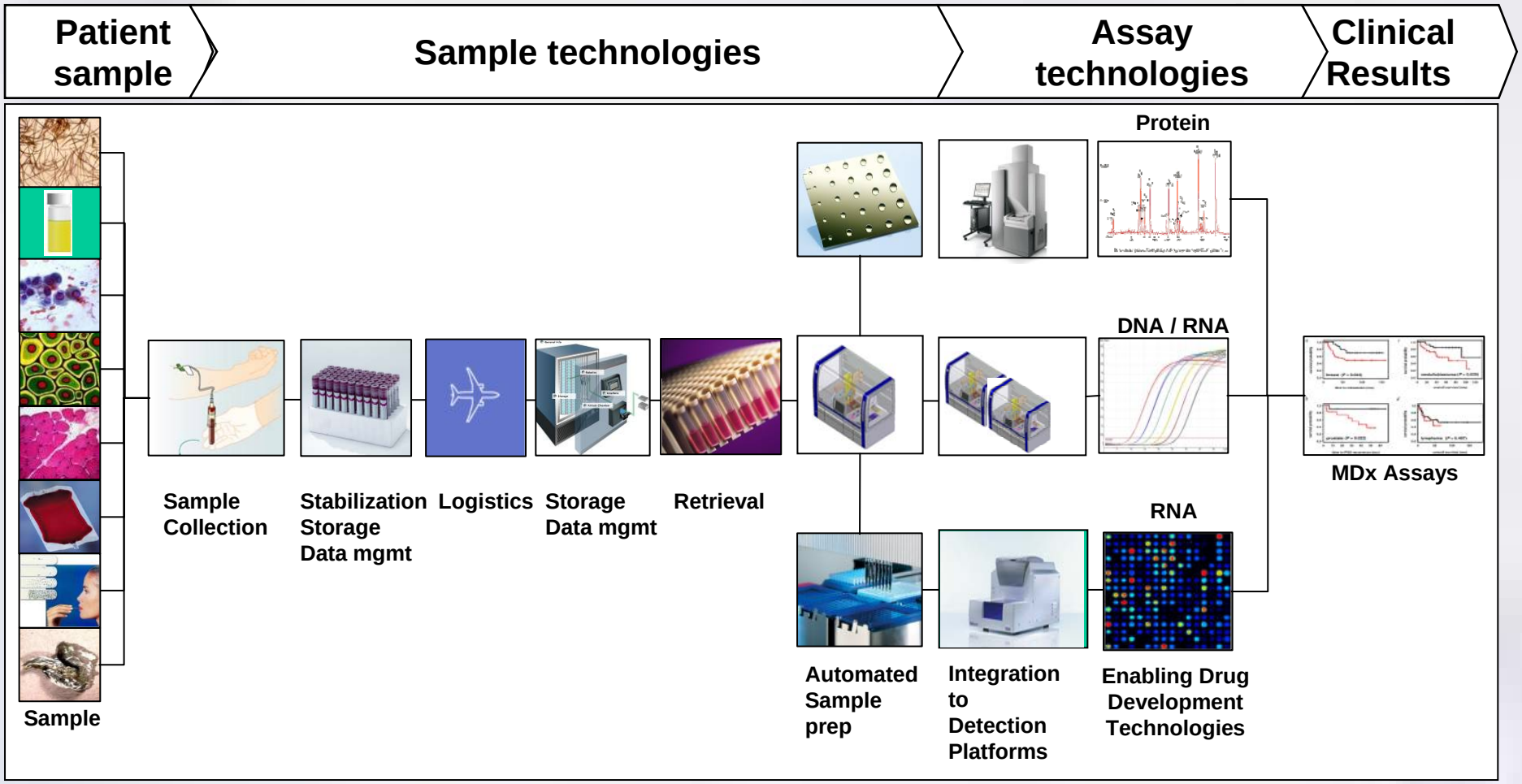
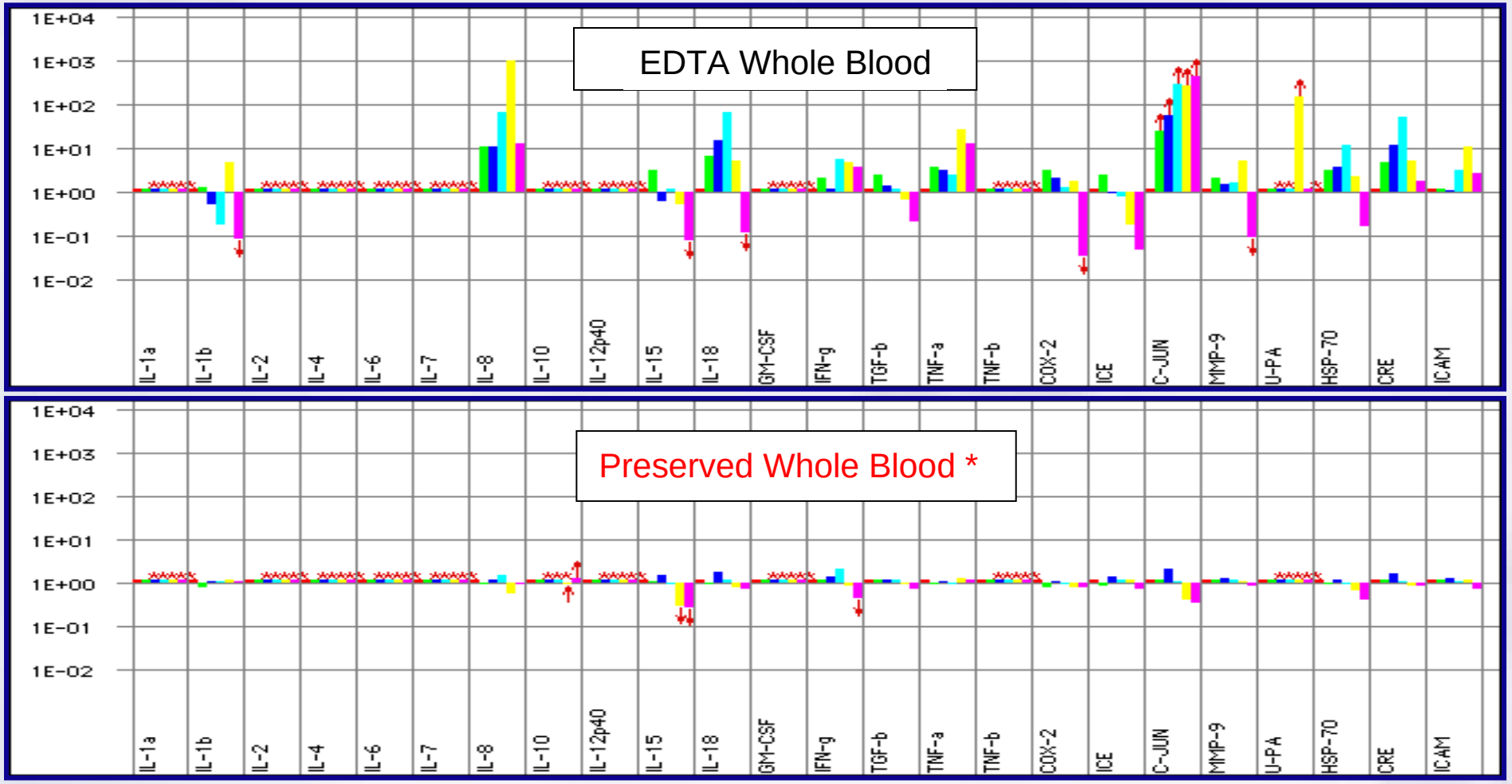
From Patient Samples to Clinical Result



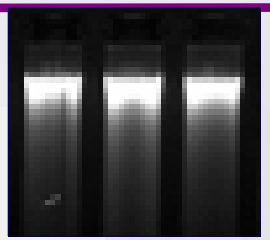
Ex Vivo Changes in the Whole Blood RNA Profil



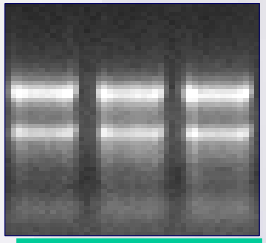
* PAXgene Blood RNA System

Rainen et al.. Clin.Chem. 2002, 48(11):1883-90

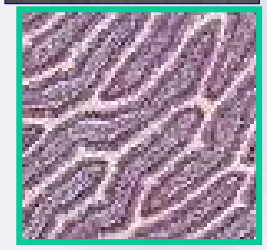
Biomolecules and Morphology: Challenge for Tissue Samples



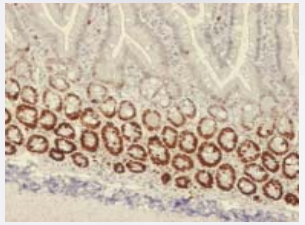
DNA



RNA, miRNA

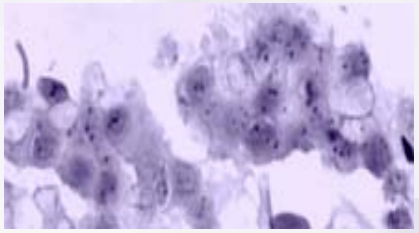


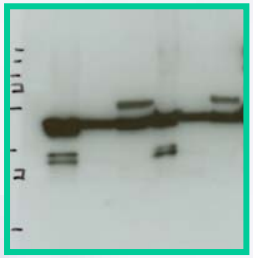
Histomorphology



Immunohistochemistry

In situ Hybridization





Western Blot Analysis

Diagnostic Preanalytical Workflow – What is missing?

- Knowledge if and how biomolecule profiles change during the process
  - Nucleic acids, proteins, metabolites
  - New sub-classes as ncRNA etc.
  - Each molecule or molecule complex can be different
  - Individual patient samples can change differently
- Can the individual diagnostic assays tolerate the changes?
  - Intended use, claims, clinical utility
- Technologies that prevent biomolecule profile changes
- Standardization & guidelines

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Project History

EC FP7-HEALTH-2007-B

Call June 2007 - Funding Scheme: Collaborative Project

"Standardisation and improvements of pre-analytical procedures for *in vitro* diagnostics"

Provide pan-European ***quality assurance schemes*** and ***guidelines*** for pre-analytical procedures such as sample ***collection, handling, transportation, processing and storing*** of clinical samples. ***Tissue samples***, ***blood samples*** and perhaps ***other specimens*** should be considered.

Project History & Facts

June 2007	EC Call publication
Sept. 2007	SPIDIA Grant Proposal
March 2008	SPIDIA favourably evaluated
October 2008	Kick Off Meeting
Consortium	7 public research organizations 8 companies 1 standards organization (CEN)
Coordinator	QIAGEN GmbH
Budget	13 Mio €
EC Contribution	9 Mio €
Duration	4 years
Web page	www.spidia.eu

Consortium Members

- QIAGEN GmbH - Coordinator
- Medical University of Graz *(Prof. Kurt Zatloukal)*
- University of Florence *(Prof. Mario Pazzagli)*
- University of Florence
- TATAA Biocenter
- PreAnalytiX GmbH
- DIAGENIC ASA
- Aros Applied Biotechnology
- Dako Denmark
- ACIES
- Biotechnology Inst. of Czech Academy of Science
- European Committee for Standardization (CEN)
- ImmunID Technologies
- Erasmus Medical Center Rotterdam
- Technical University Munich
- Fondazione IRCCS Istituto Nazionale dei Tumori

Scientific Advisory Board

- *Prof. François Rousseau* (Univ. Laval, Quebec. CanGeneTest Network)
- *Dr. Roberta M. Madej* (CLSI)

Project Ethics Committee

- *Dr. Anne Cambon-Thomsen* (CNRS, INSERM, Tolouse, France)
- *Dr. Ruth Chadwick* (ESRC Centre, Cardiff University, UK)

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SPIDIA

Main Goals

- Pan-european quality assurance schemes and guidelines for the pre-analytical process: blood, tissue – RNA, DNA, Proteins
- New tools & technologies that integrate and standardize pre-analytical steps: blood, tissue, non- / less invasive samples
- Identification of Biomarkers for monitoring changes in clinical samples: RNA, DNA, Proteins, Metabolites
- Training and dissemination of results
- Cooperation with international organizations

Project Structure

Guidelines Standards

Tissue

Blood

Testing
- RNA, DNA
- Proteins
- Cytology, IHC, ISH
- Metabolites

Identification of Quality Markers

QA Schemes Guidelines

Tool Developments

Tissue

Blood

Plasma

Non-Invasive

Tools Standardization

Test in Dx Marker Discovery

Colon Cancer

Neuro-degenerative Diseases

Metabolism

Tools Standardization

Implementation Dissemination

Training Programs

Hospitals

Labs

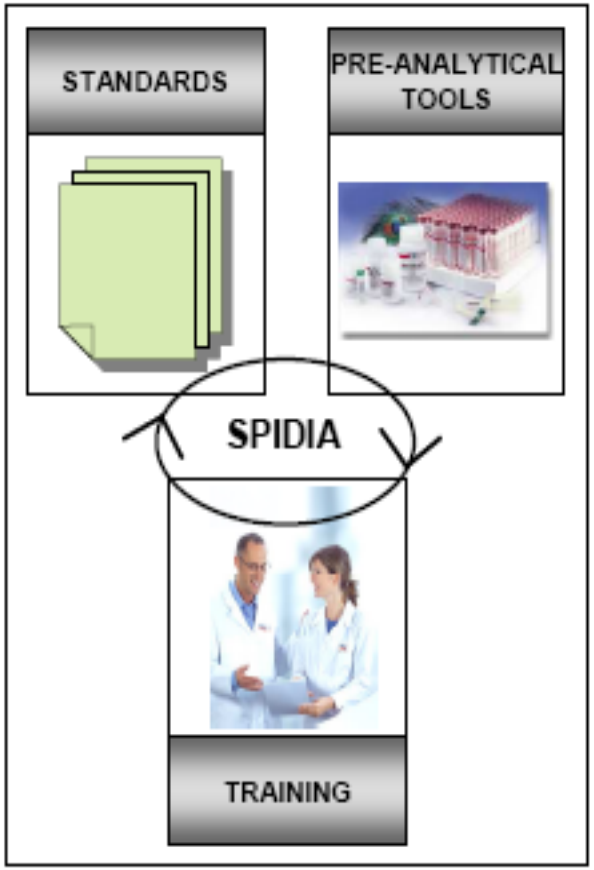
International co-operations (CLSI, EFCC, NCI/OBBR)

Scientific Advisory Board - Non EU

Club of Interest

Impacts

SPIDIA KEY OBJECTIVES



General Public

Evidence-based guidelines

Know-how and tools for pre-analytical phase combining classical and molecular diagnostics

Reliable, early diagnosis of disease

Less-invasive, blood based diagnoses of cancers, AD

Mother's blood-based diagnosis for foetal disease

✓Standards Bodies

✓Patient Groups

✓Medical profession
- •Pathologists
- •Clinicians
- •Nurses

Early treatment

Higher quality of life

Fewer false positives or negatives

Peace of mind

Research Community

✓Universities

✓Research Institutes

Diagnostic tool and assay developers

✓Pharmaceutical Companies

Springboard for molecular diagnostic studies

Improved Reproducibility

Pre-analytical tools that are the pre-requisite for valid biomarker discovery

Increased share in the $21 billion *in vitro* diagnostic market

Strengthening of the European Research Area

Increased trade

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Status of SPIDIA‘s Work
Newsletter 1 / 2010

- New tissue stabilization & collection technology
  - RNA/DNA, Proteins, morphology, antigenicity, (> 2.000 human samples)
  - > 1.500 compounds & combinations screened
- New tissue sample laboratory tracking system
- Biomolecule profile changes studies in tissues
- New stabilization technologies screenings (blood, less invasive samples)
- New automated workflow for RNA, ncRNA isolation from stabilized blood samples
- Blood ring trials with 320 participants (RNA, DNA, fcNA)
- Pre-analytical workflow QA biomarker discovery programs running
- Dissemination activities

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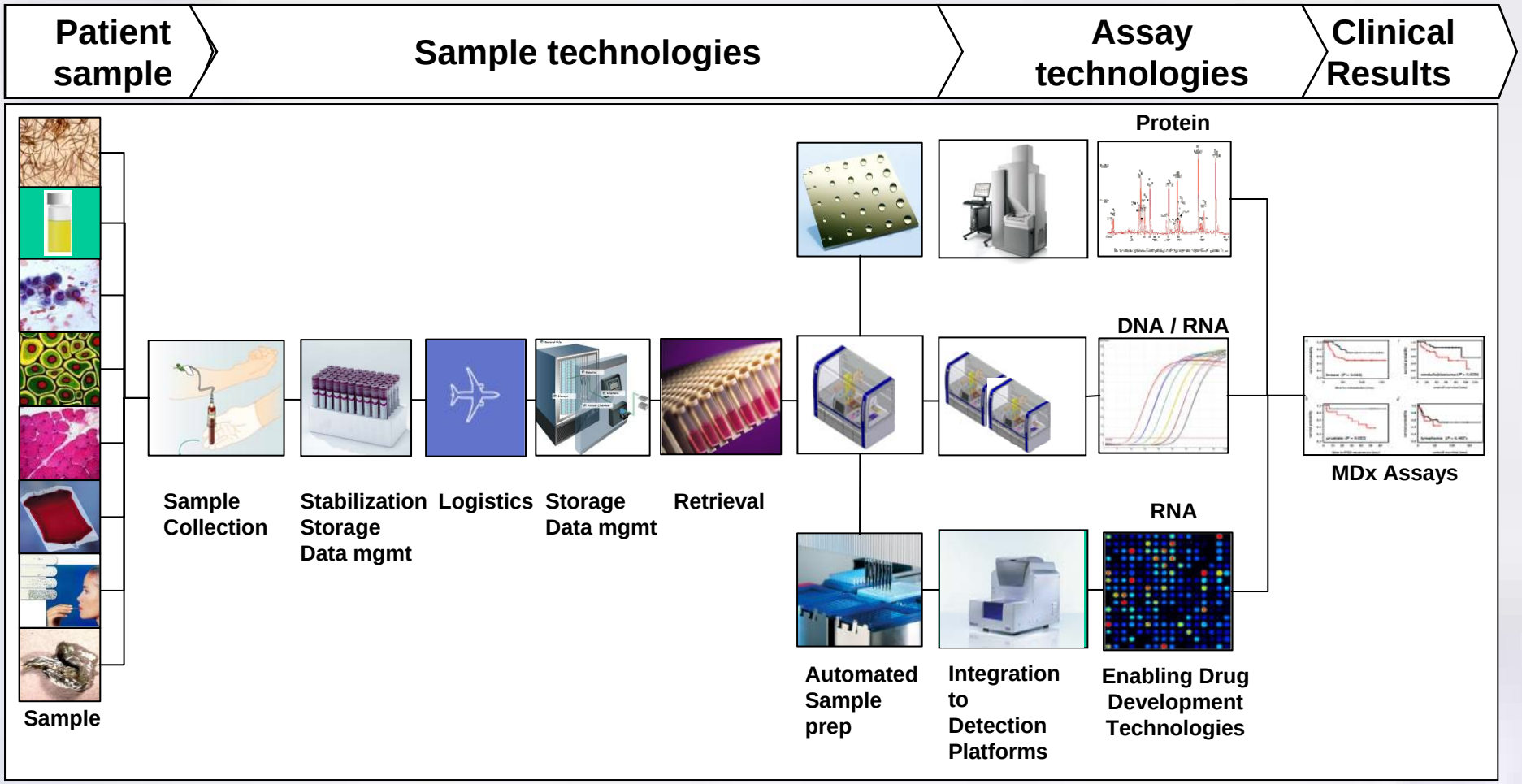

SPIDIA

Thank you!

Questions ?