

The SPIDIA logo features a dark blue background with several parallel, slanted green lines on the left side. The word "SPIDIA" is written in white, uppercase, sans-serif font to the right of these lines.

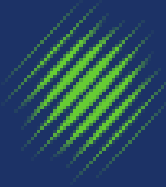
SPIDIA



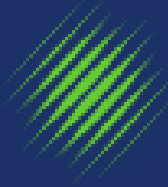
# **Standardization and Improvement of Generic Preanalytical Tools and Procedures for In Vitro Diagnostics - EU Project SPIDIA -**

3<sup>rd</sup> Annual BRN Symposium  
Bethesda, March 25<sup>th</sup> 2010

Dr. Uwe Oelmueller  
QIAGEN GmbH (Coordinator)

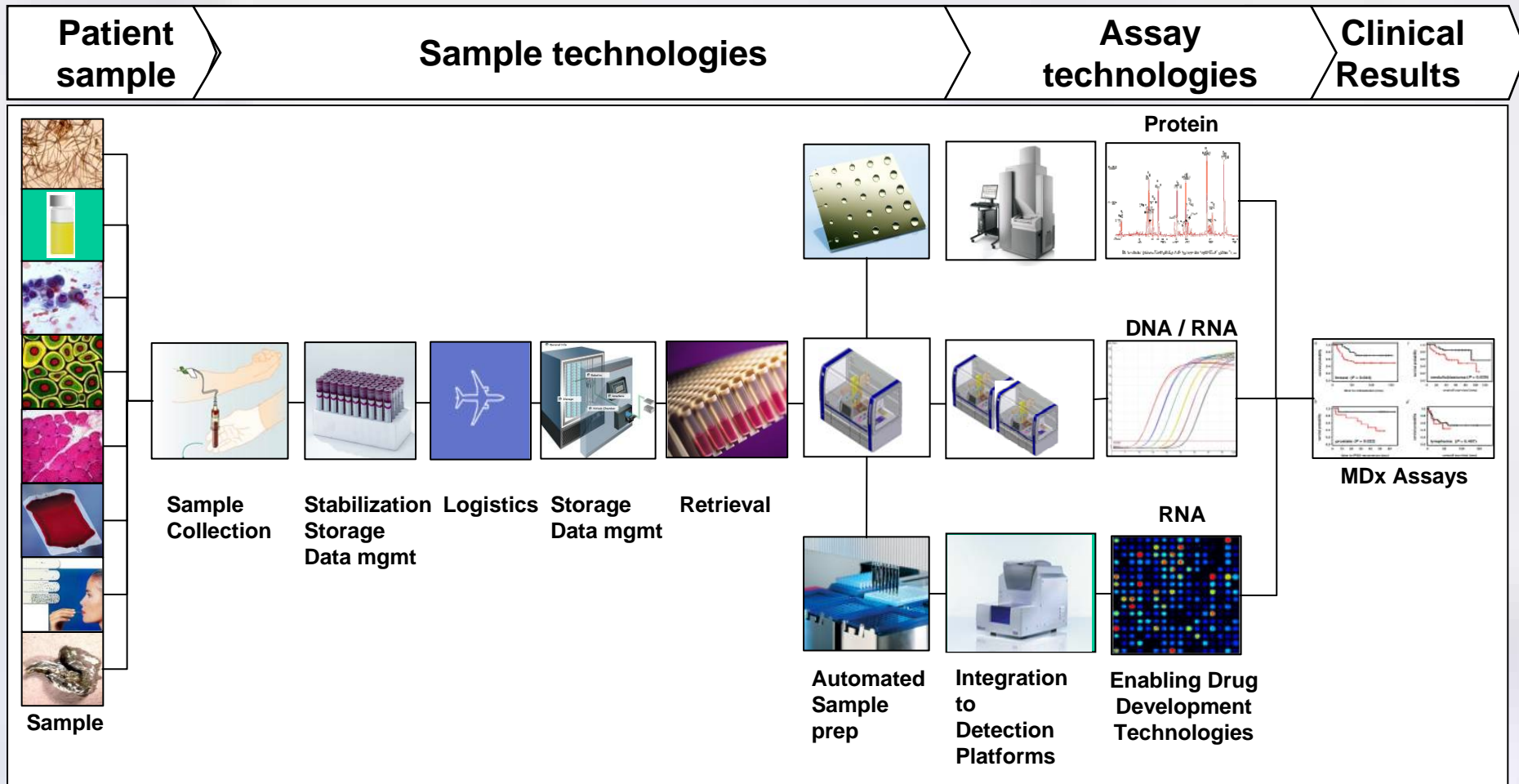


- Preanalytical Workflow Challenges
- SPIDIA Project Project History
- Project Goals and Structure
- Status

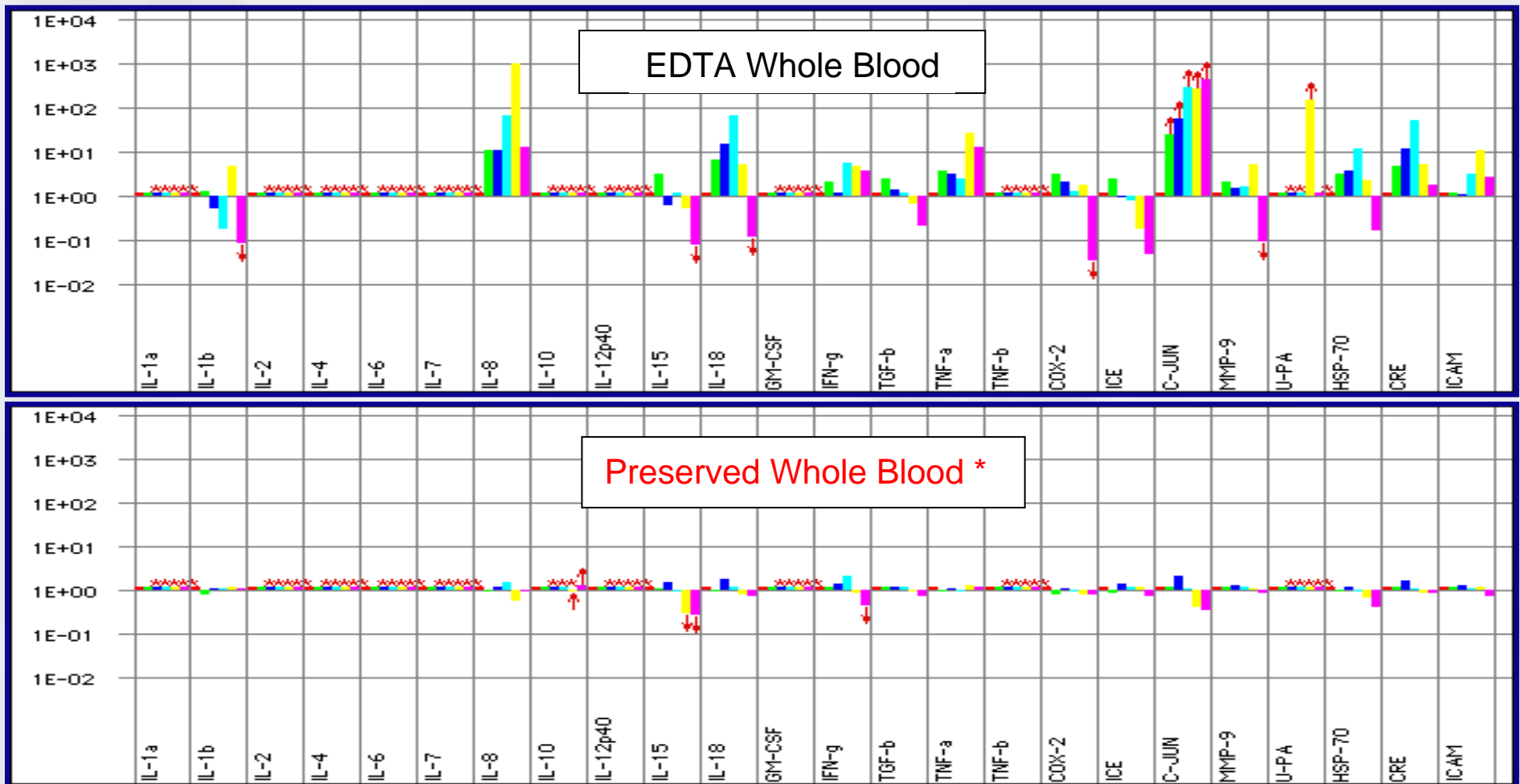


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# From Patient Samples to Clinical Result



# Ex Vivo Changes in the Whole Blood RNA Profil

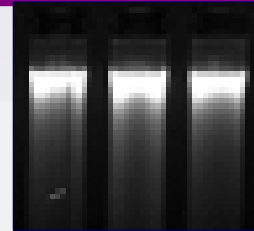
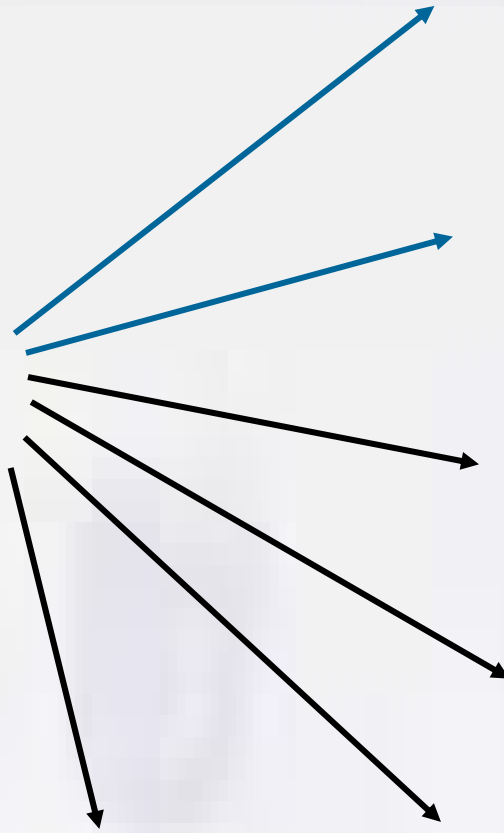
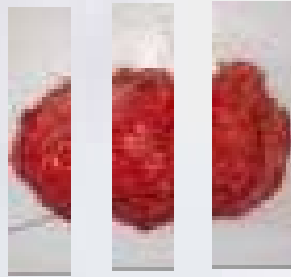


\* PAXgene Blood RNA System

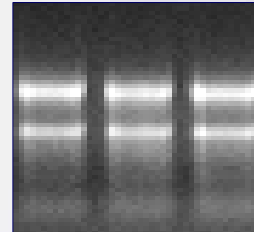
Rainen et al.. Clin.Chem. 2002, 48(11):1883-90



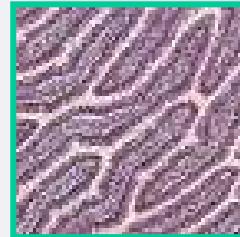
# Biomolecules and Morphology: Challenge for Tissue Samples



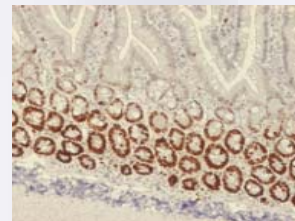
DNA



RNA, miRNA

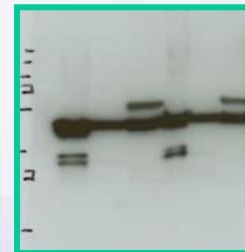
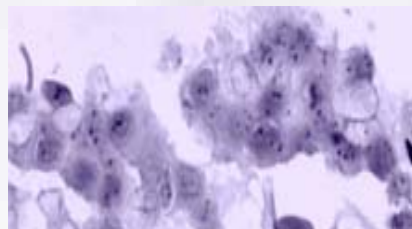


Histomorphology



Immunohistochemistry

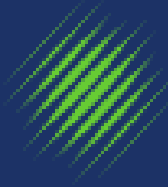
*In situ* Hybridization



Western Blot Analysis

# Diagnostic Preanalytical Workflow – What is missing?

- Knowledge of 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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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](http://www.spidia.eu)

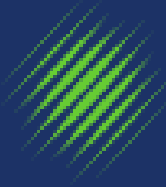
- QIAGEN GmbH - Coordinator
- Medical University of Graz (*Prof. Kurt Zatloukal*)
- University of Florence (*Prof. Mario Pazzagli*)
- University of Florence
- TATAA Biocenter
- PreAnalytiX GmbH
- DIAGENIC ASA
- Aros Applied Biotechnology
- Dako Denmark
- ACIES
- Biotechnology Inst. of Czech Academy of 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, Toulouse, France)
- *Dr. Ruth Chadwick* (ESRC Centre, Cardiff University, UK)



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## 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

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

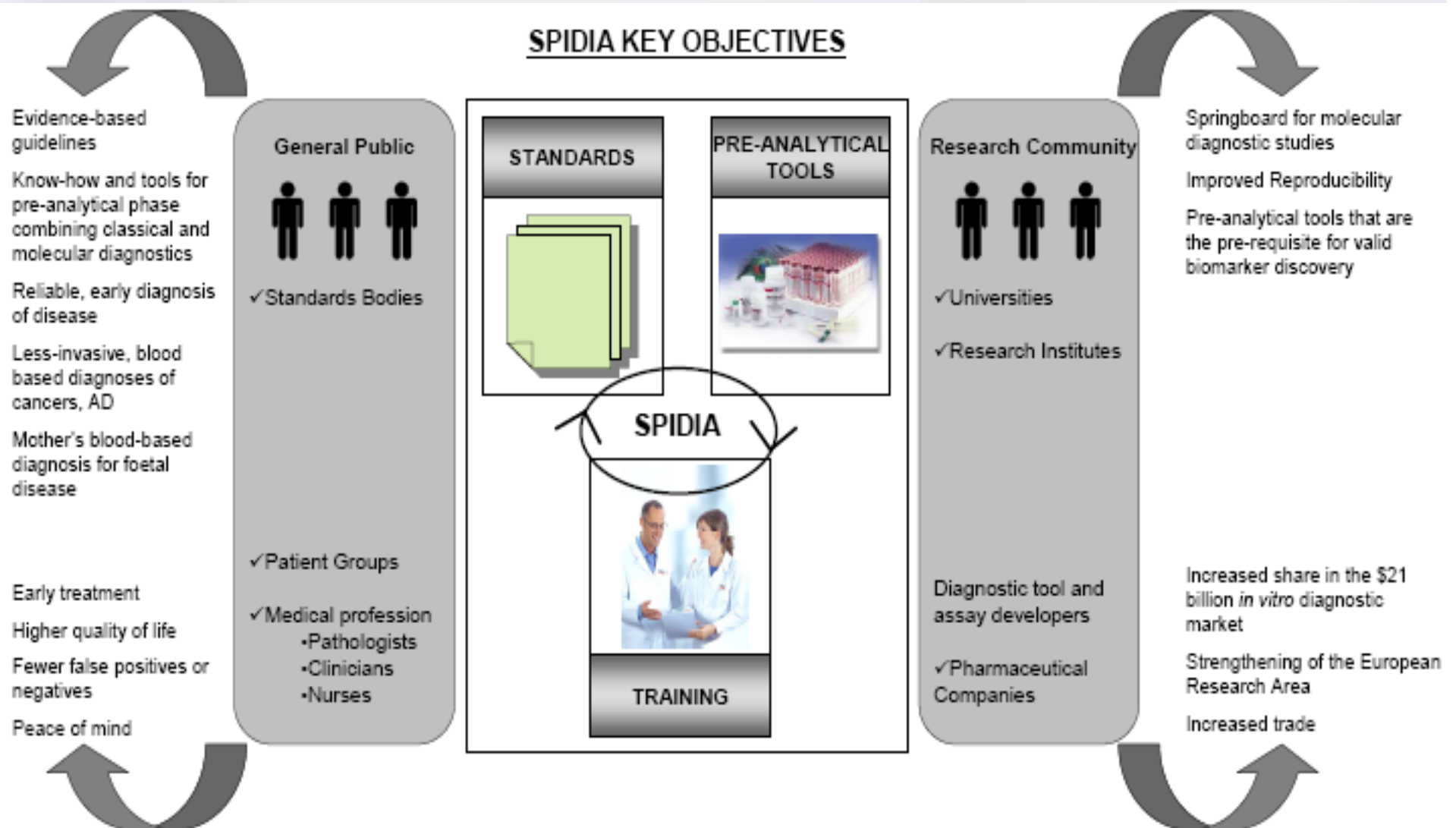
Implementation  
Dissemination

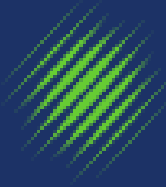
Training Programs  
Hospitals  
Labs

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

Scientific Advisory  
Board - Non EU


Club of Interest



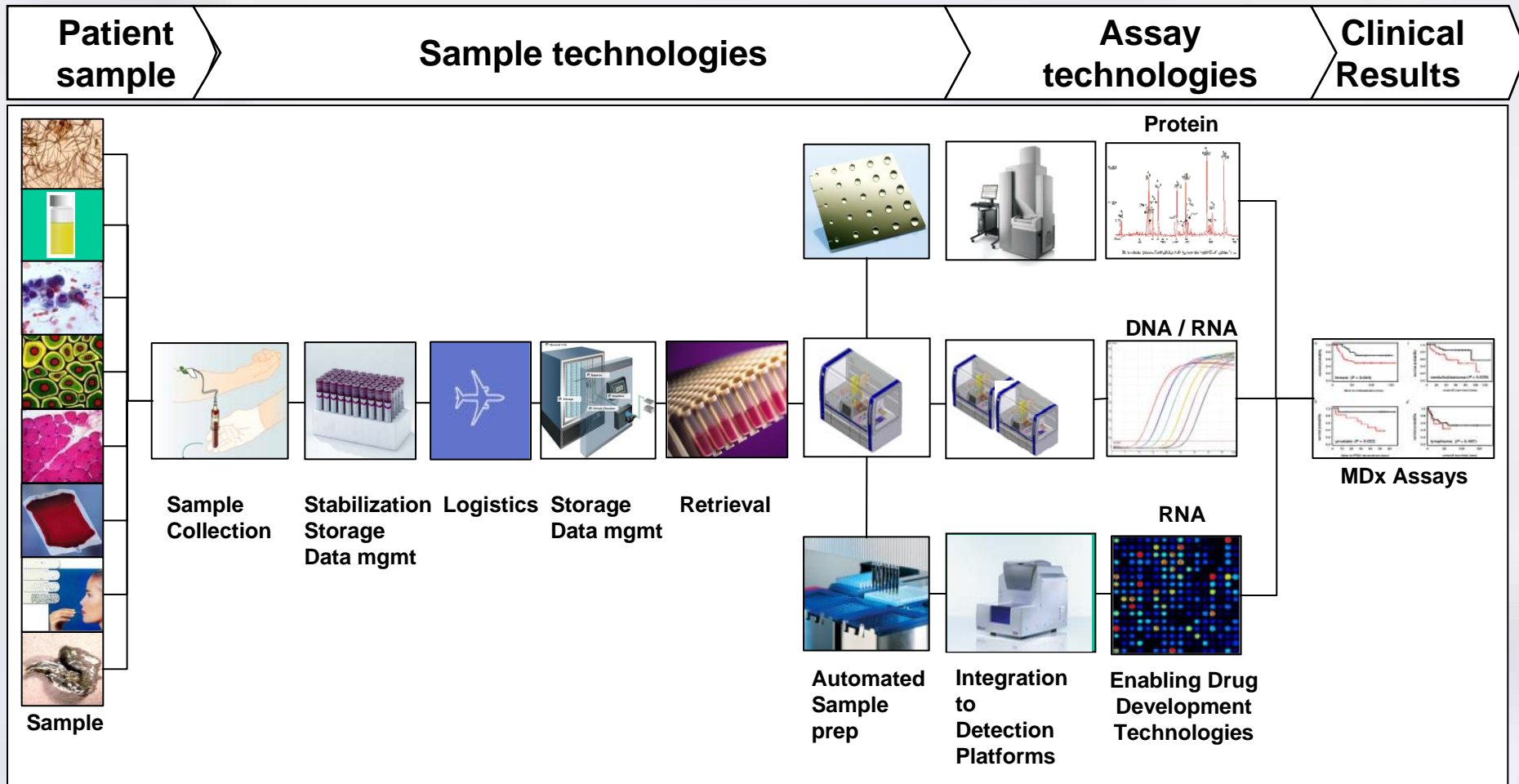


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- New tissue stabilization & collection technology
  - RNA/DNA, Proteins, morphology, antigenicity, (> 2.000 human samples)
  - > 1.500 compounds & combinations screened
- New tissue sample laboratory tracking system
- Biomolecule profile changes studies 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

# From Patient Samples to Clinical Result



SPIDIA

Thank you!

*Questions ?*

