

The SPIDIA logo features a dark blue background with a series of green diagonal lines on the left side. The word "SPIDIA" is written in white, uppercase letters to the right of the lines.

SPIDIA



# CEN and ISO Standards for Pre-analytics

Joint Meeting of BBMRI.at and BBMRI-ERIC National Nodes

Obergurgl, March 13<sup>th</sup> 2015

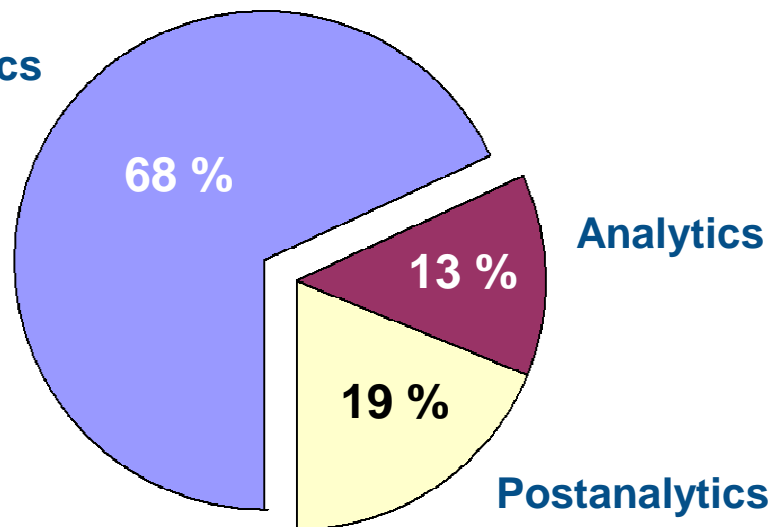
Dr. Uwe Oelmüller  
QIAGEN GmbH

# Pre-Analytical Errors Impacting Diagnostic Results

“Preanalytical errors still account for nearly 60%-70% of all problems occurring in laboratory diagnostics, most of them attributable to mishandling procedures during collection, handling, preparing or storing the specimens”.

Lippi G. *et al.*. Preanalytical quality improvement: from dream to reality. *Clin Chem Lab Med.* 2011 Jul; 49(7):1113-26. Epub 2011 Apr 25.

## Preanalytics

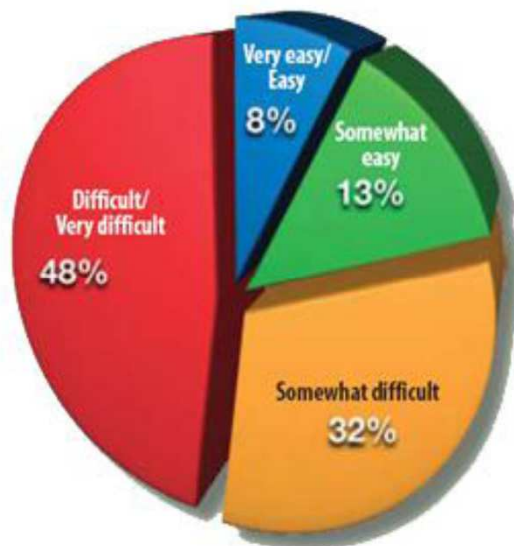


Costs of ~ 347,000 € / year in an average German hospital caused by pre-analytical errors

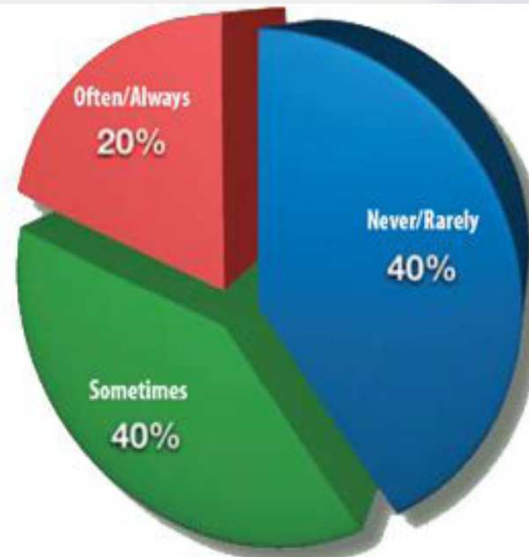
Frost & Sullivan 2011 on behalf of BD

# Access to Good Quality Biospecimens A Critical Key Step in Biomedical Research

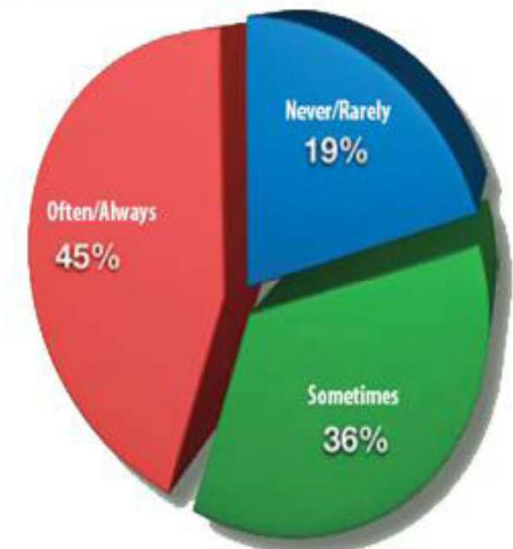
**Ease of Acquiring the  
Quality of Biospecimens**



**Question Their Data  
Because of the  
Quality of Biospecimens**



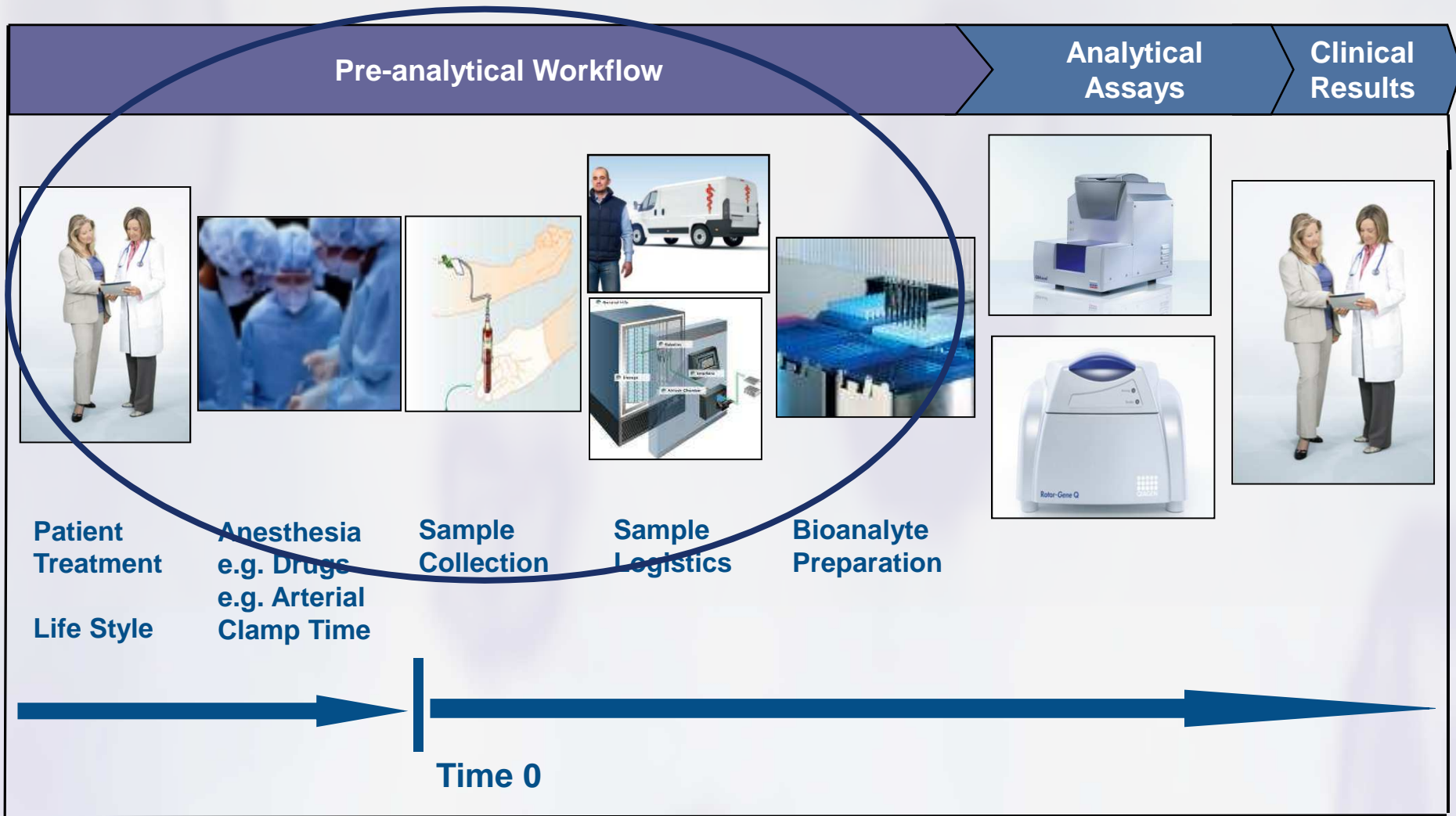
**Limit Research Scope of  
Work Due to the Shortage of  
Quality Biospecimens**



Source: Office of Biorepositories and Biospecimen Research, 2009 <http://biospecimens.cancer.gov/cahub/>

Keynote Presentation Dr. George Poste - Annual Biospecimen Research Network (BRN) Symposium  
Bethesda, MD 28 March 2011

## Sample-to-Insight Workflows From Patients' Samples to Clinical Results



- **New technologies** for securing high quality samples
- **International Standards** on pre-analytical workflows



### Traditional Role of Standards

- Source of technical know-how
- Trade facilitation and opening of markets
- Providing a scientific basis for legislation in the health, safety and environment sectors

### Valued-added role for research and innovation

- Speeding up innovation by providing the requisite knowledge base (technology transfer)
- New ideas, technologies and products need standardization to get into the marketplace and to be successful



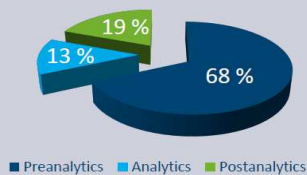


- 2014: 8 new projects for ISO Standards approved in ISO/TC 212 „Clinical laboratory testing and in vitro diagnostic test systems”

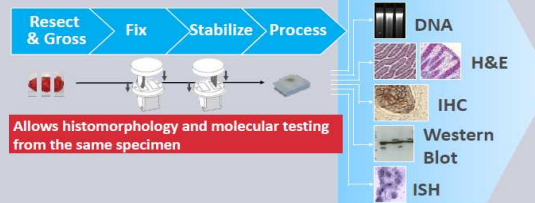


- 2015: 9 CEN Technical Specifications to be published
- 2013: 9 new projects approved in CEN/TC 140 „In vitro diagnostic medical devices“
- 2010: Start of standardization work

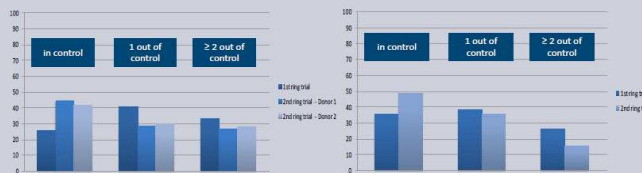
### 1. Problem - Errors in Diagnostics



### 2. Technical Solutions



### 3. Ring-Trials – Blood RNA (l.) and DNA (r.)



European Conference. Standards: Your Innovation Bridge. Brussels (2014). SPIDIA Booth.



### **European Standard – EN**

*Goal: Development of normative specifications reflecting the current state of technology*

### **European Technical Specification – CEN/TS**

*Goal: Specifications which aid market development and growth*



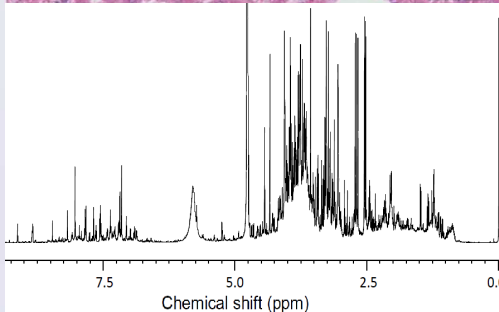
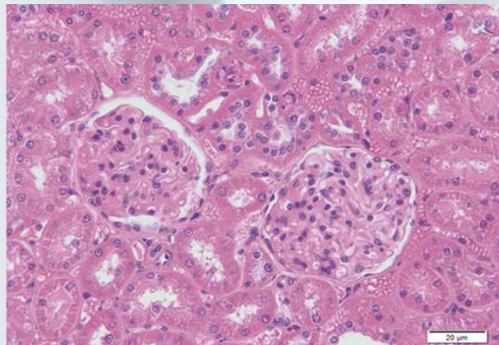
### **European Technical Report – CEN/TR**

*Goal: Specifications of a recommendatory and explanatory nature*

### **CEN Workshop Agreement – CWA**

*Goal: Special specifications developed with the rapid consensus of expert stakeholders*





- Pre-analytical phase: covers all steps from the clinicians requests to the beginning of the analytical examination
  
- Molecular *in-vitro* diagnostic examinations - Specifications for pre-examination processes for
  - blood — Cellular RNA
  - blood — Genomic DNA
  - blood — Circulating cell free DNA
  
  - FFPE tissue — DNA
  - FFPE tissue — RNA
  - FFPE tissue — Proteins
  - frozen tissue — RNA
  - frozen tissue — Proteins
  
  - metabolomics in urine, serum and plasma



## ■ Biobanks

- Source for high quality samples

## ■ Biomedical & Translational Research

- Academia
- Pharma industry
- Diagnostic Industry

## ■ Diagnostics

- High sample quality is the safe way
- Analytical assay might tolerate lower quality or not ⇒ Validation studies

### The Ice Cube Tray Model

