Certified biobanking at the University of Szeged (BBMRI-Hungary, Szeged)

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USZ Biobank, University of Szeged, Szeged

INTRODUCTION - GLOBAL HEALTH TREND

World Health Organization

2019 - the start of the 13th General Framework Programme.
+1 billion people enjoy access to universal health coverage,
+1 billion people protected by health emergencies (insured care)
+1 billion people enjoy improved health care and well-being.

INTRODUCTION - GLOBAL HEALTH TREND

World Health Organization

Developing patient-centred care
Harmonisation , standardisation
Vertical and horizontal consolidation
Personalised medicine
Smart healthcare (Smart drugs, implants and medical devices)
Networking

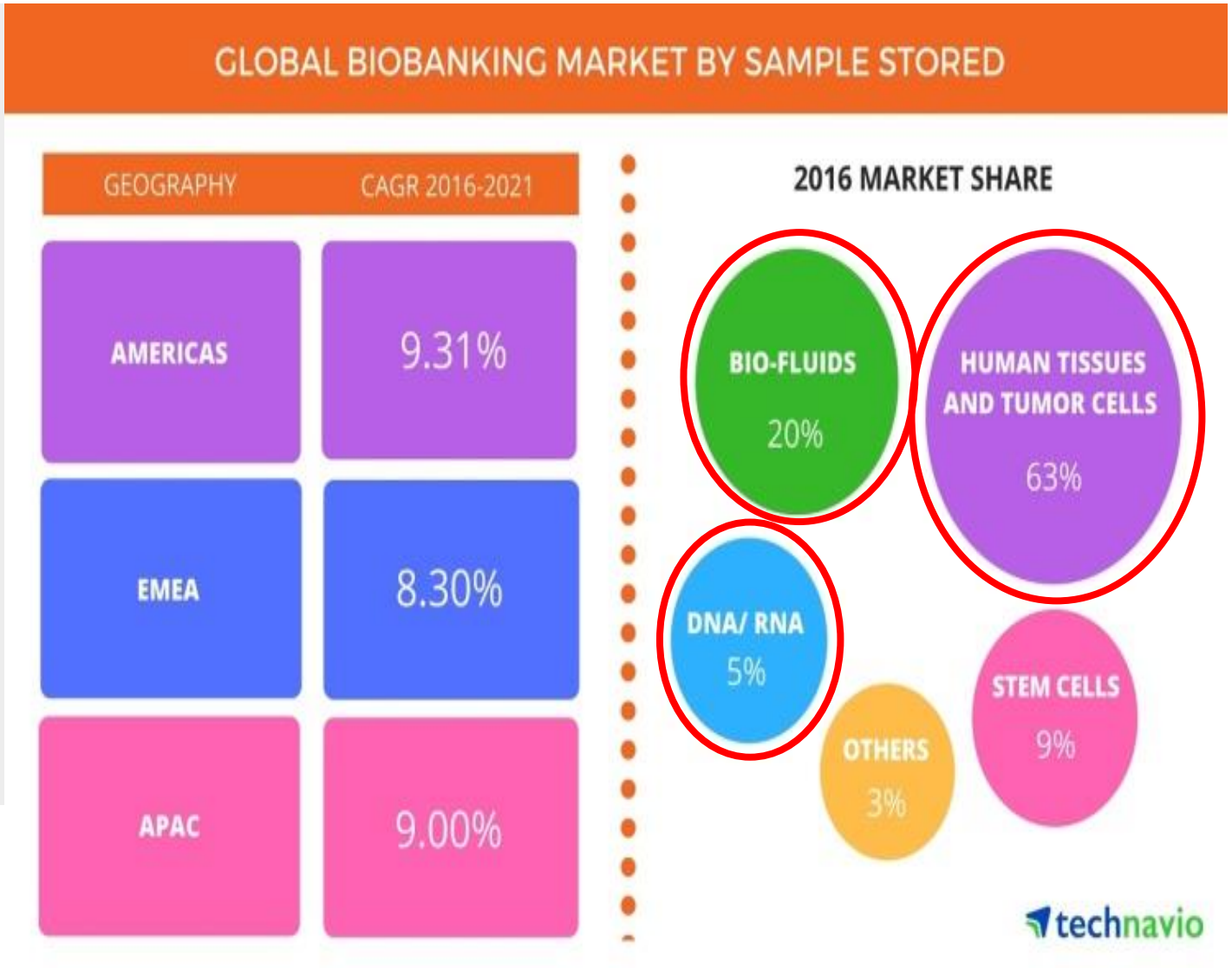
Increasing cost efficiency
Reducing healthcare expenditure
Increasing efficiency, effectiveness
Localisation (resources, skills, technology)

BIOBANKS

Biobanks are used for various applications, such as clinical research, life science and medical research and regenerative medicine.

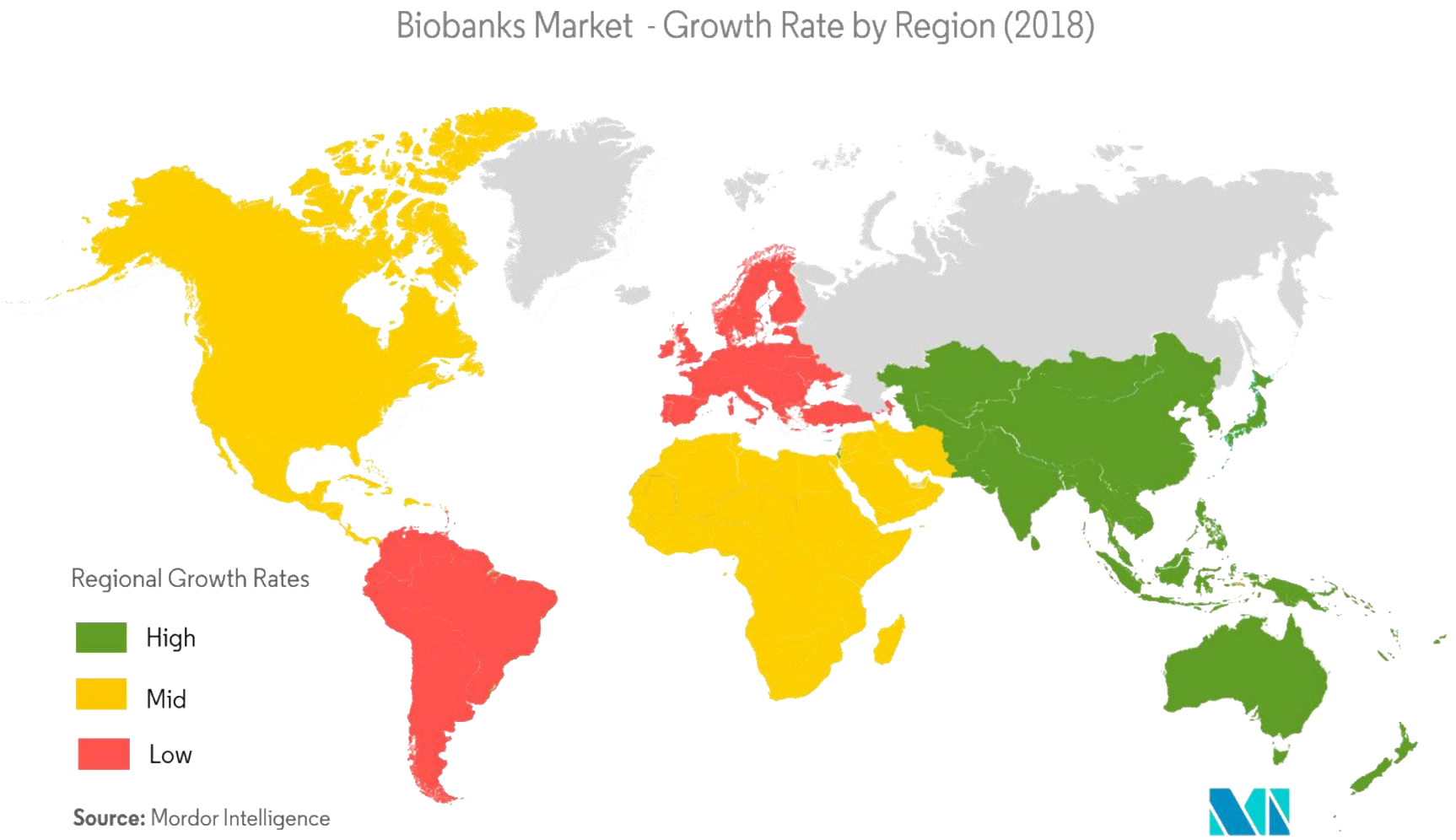
Of these, clinical research accounts for the largest share, 49.2% in 2018.
This is due to the growth in clinical research to determine the safety and efficacy of drugs, diagnostic tools and products worldwide.

The fastest growing sector is regenerative medicine.



BIOBANKS

- **Markets related to biobanking activities worth USD 1.8 billion**
- **Around 100 million registered samples are placed in biobanks worldwide every year.**



QUALITY MANAGEMENT SYSTEMS
2008 - 2019

QUALITY MANAGEMENT SYSTEMS FOR BIOBANKING ACTIVITIES

Problem: highly diversified activities!

Quality management systems/Standards

ISO 11737-1:2006
ISO/CD 11737-1
ISO 11737-1:2006/Cor 1:2007
ISO/NP 11737-2
ISO 11737-2:2009
ISO 7713:1985
ISO 12771:1997
ISO 12772:1997
ISO 13130:2011
ISO 13132:2011
ISO 15189:2012
ISO 15190:2003
ISO/TS 17518:2015
ISO/TS 17822-1:2014
ISO/DTS 20658
ISO/TS 22367:2008
ISO/TS 22367:2008/Cor:2009
ISO/TR 22869:2005 implementation of ISO 15189: 2003
ISO 22870:2006
ISO/FDIS 22870
ISO 24998:2008
ISO 13079:2011
ISO 15193:2009
ISO 15194:2009
ISO 15197:2013
ISO 15198:2004
ISO 16256:2012
ISO 17511:2003
ISO/NP 17511
ISO 18113-1:2009
ISO 18113-2:2009
ISO 18113-3:2009
ISO 18113-4:2009
ISO 18113-5:2009

GMP, GLP, GDP, GCP

GDPR,
ISO 15190

MEES

ISO/CD 15195
ISO 15195:2003
ISO 18385:2016
ISO 11607-1:2006
ISO/NP 11607-1
ISO 11607-1:2006/Amd 1:2014
ISO 11607-2:2006
ISO/NP 11607-2
ISO 11607-2:2006/Amd 1:2014
ISO 11238:2012
ISO/NP 11238
ISO 13274:2013
ISO 13274:2013/Cor 1:2014
ISO 16103:2005
ISO 16495:2013
ISO 16883:2007
ISO/IEC TR 24714-1:2008
ISO/IEC Guide 2:2004
ISO/IEC TR 19764:2005
ISO Guide 73:2009
ISO/IEC Guide 59:1994
ISO 11737-1:2006
ISO/CD 11737-1
ISO 11737-1:2006/Cor 1:2007
ISO/NP 11737-2
ISO 11737-2:2009
ISO/CD 20186-3

ISO/CD 20186-1
ISO/CD 20186-2
ISO/CD 10993-5
ISO 10993-6:2007
ISO 10993-12:2012
ISO 13022:2012
ISO 22442-1:2015
ISO 22442-2:2015
ISO 22442-3:2007
ISO/TR 22442-4:2010
ISO 23640:2011
ISO 29701:2010
ISO/CD 10993-1
ISO 18153:2003
ISO 19001:2013
ISO/DIS 20166-1
ISO/DIS 20166-2
ISO/DIS 20166-3
ISO/DIS 20184-1
ISO/DIS 20184-2
ISO/TC 276
ISO 17025:2005
ISO 14001
ISO/IEC 27001
ISO 50001
ISO 9001

ISO/TS 14071:2014 Additional requirements and guidelines to ISO 14044:2006
ISO/TR 14047:2012 examples on how to apply ISO 14044
ISO/TS 16775:2014 guidance on the application of ISO 11607-1 and ISO 11607-2
ISO/PRF TR 14073 examples on how to apply ISO 14046
ISO/AWI 16106 guidelines for the application of ISO 9001
ISO 16106:2006 guidelines for the application of ISO 9001

ISO 20387 GENERAL OPERATION OF BIOBANKS

INTERNATIONAL STANDARD

ISO 20387

First edition
2018-08

Biotechnology — Biobanking — General requirements for biobanking

Biotechnologie — «Biobanking» — Exigences générales relatives au «biobanking»

SZTE – BIOBANK

It has been operating since 2011 (11 sites), in 2021 with 19 institutes.
Total number of reportable samples: 60,567 (based on the Genetics Act 2008, 31 December 2019)
Total number of samples: about 1.5 million
Number of publications in the last 5 years: 38
PhD students currently: 37 people, last 5 years defended: 51 people
Number of projects: 45

RESEARCH

I. Department of Internal Medicine,
Hungarian Pancreatic Working Group Pancreas Registry
Institute of Medical Microbiology and Immunobiology
Department of Dermatology and Allergology Biobank
Clinic of Rheumatology
Institute of Pharmacology
Psychiatric Clinic
Clinic of Neurology
Southern Great Plain Neurobiological Knowledge Center

TUMOR (ONCOLOGY)

Department of Dermatology and Allergology Tumorbank
Institute of Pathology Tumorbank

DIAGNOSTICS

Genetics and Metabolism Laboratory
Institute of Medical Genetics
Institute of Laboratory Medicine
Clinical Microbiology and Diagnostics

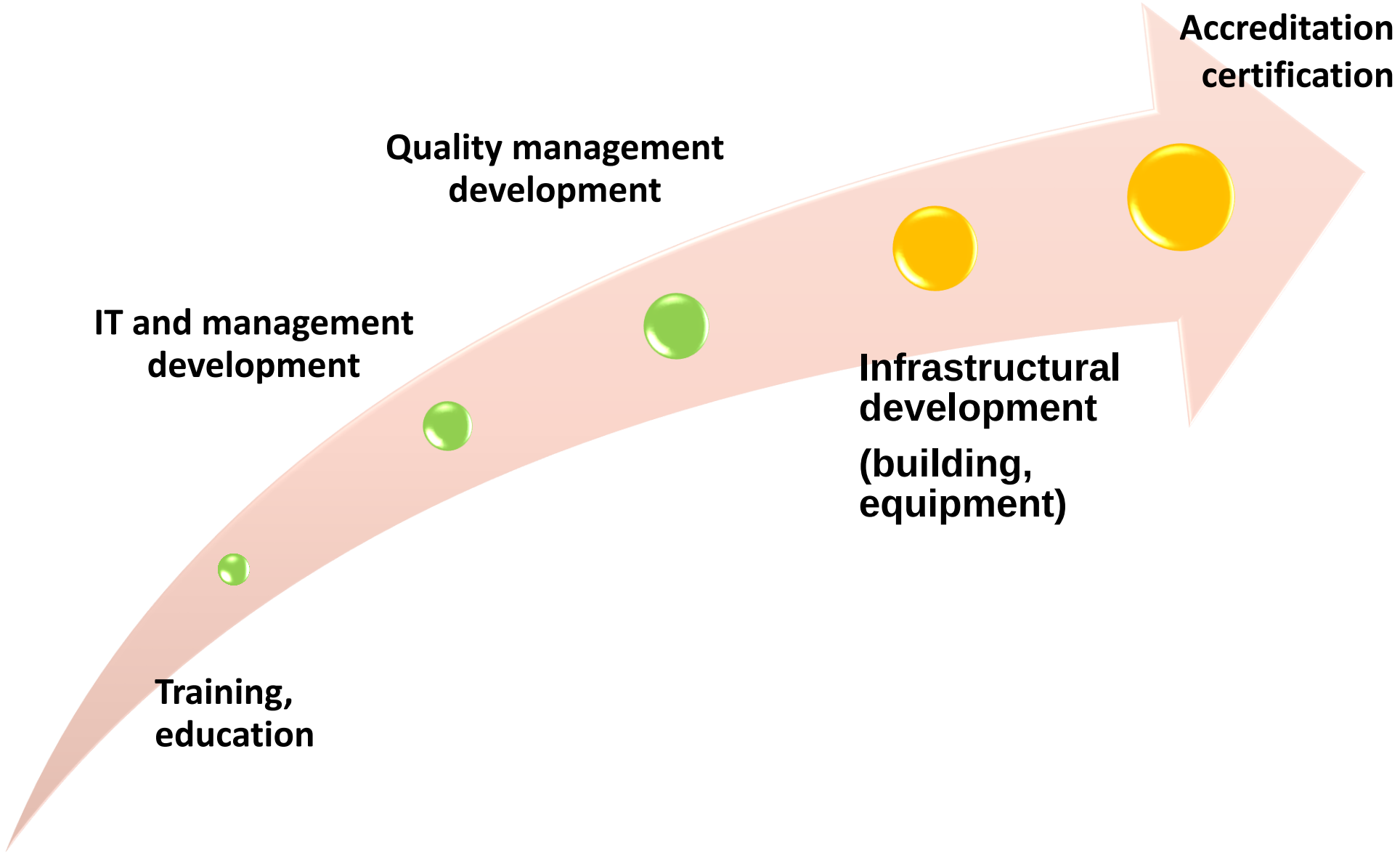
TRANSPLANTATION

Ophthalmology
II. s. Clinic of Internal Medicine and Cardiology Center
Hematology Transplant Department

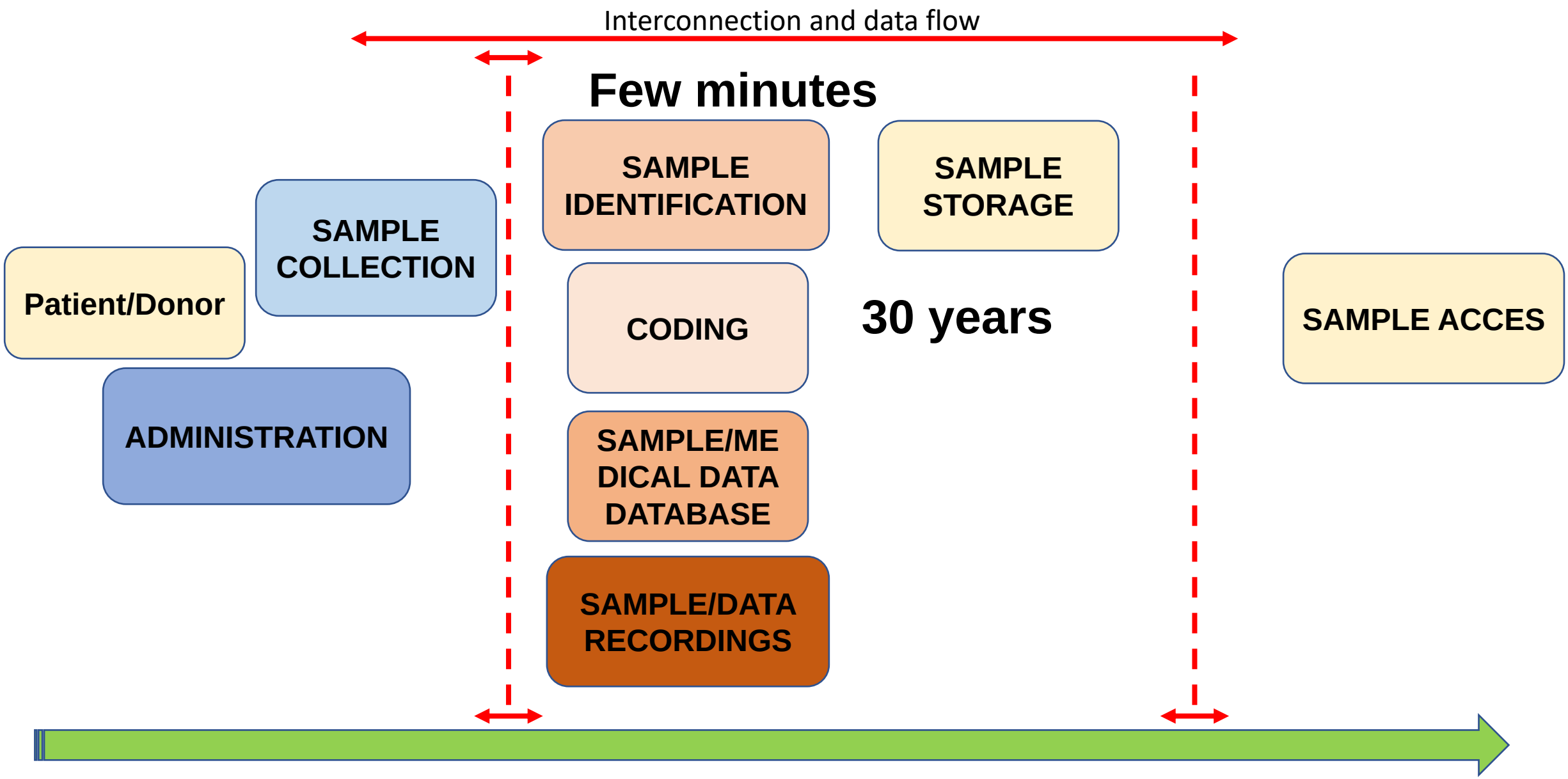
IVF

Department of Obstetrics and Gynecology, Andrology

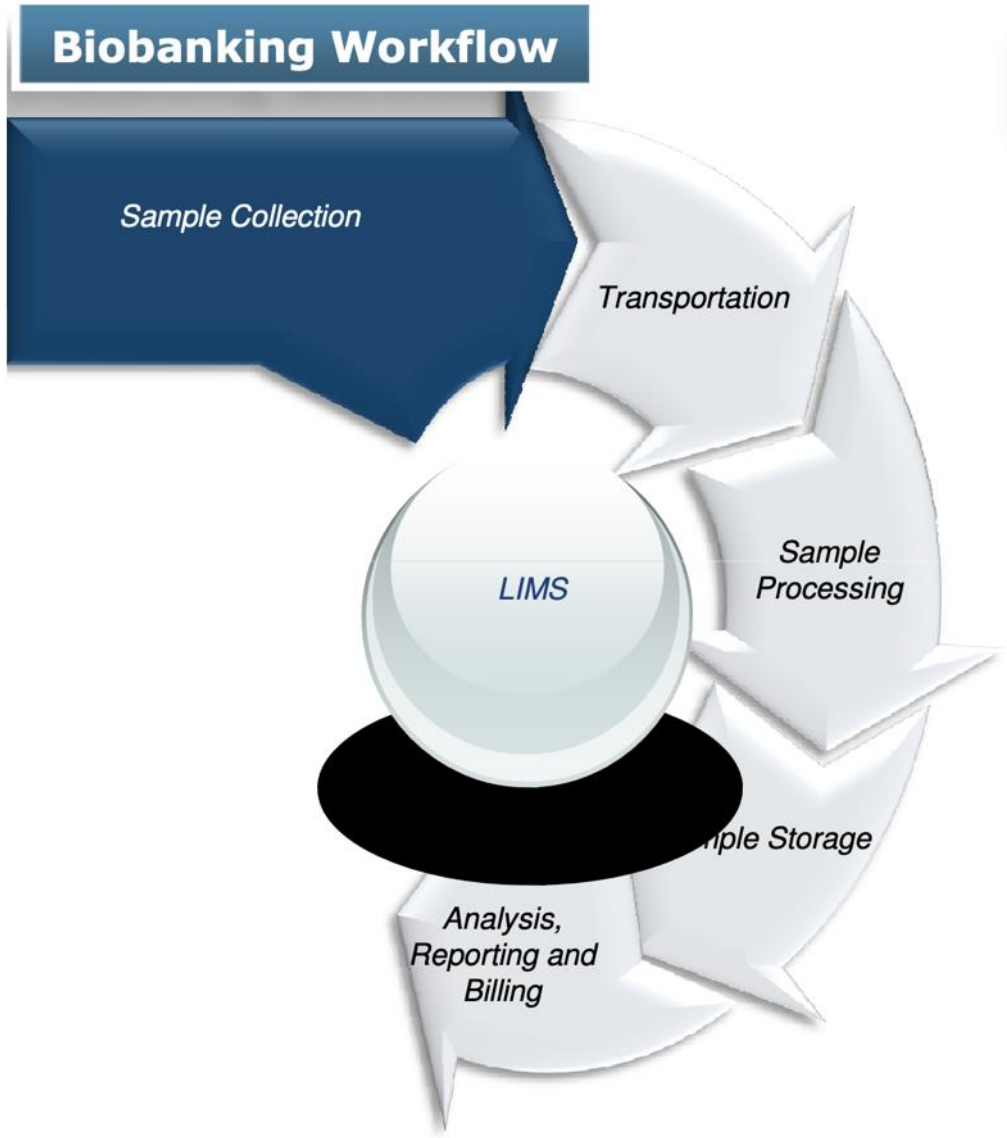
UNIVERSITY OF SZEGED - BIOBANK DEVELOPMENT PLAN



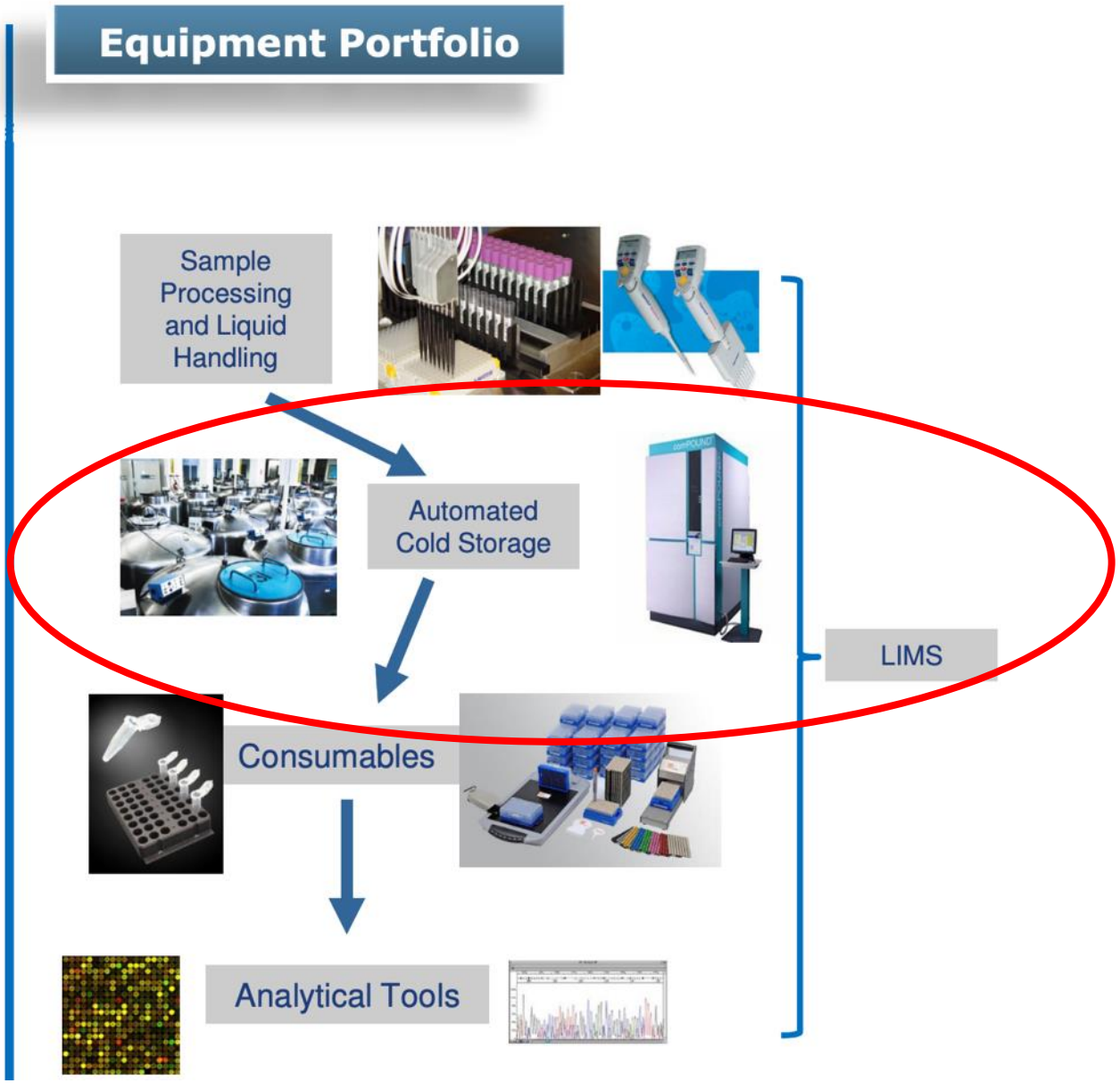
BIOBANK: VALUE IS THE SAMPLE (AND DATA)



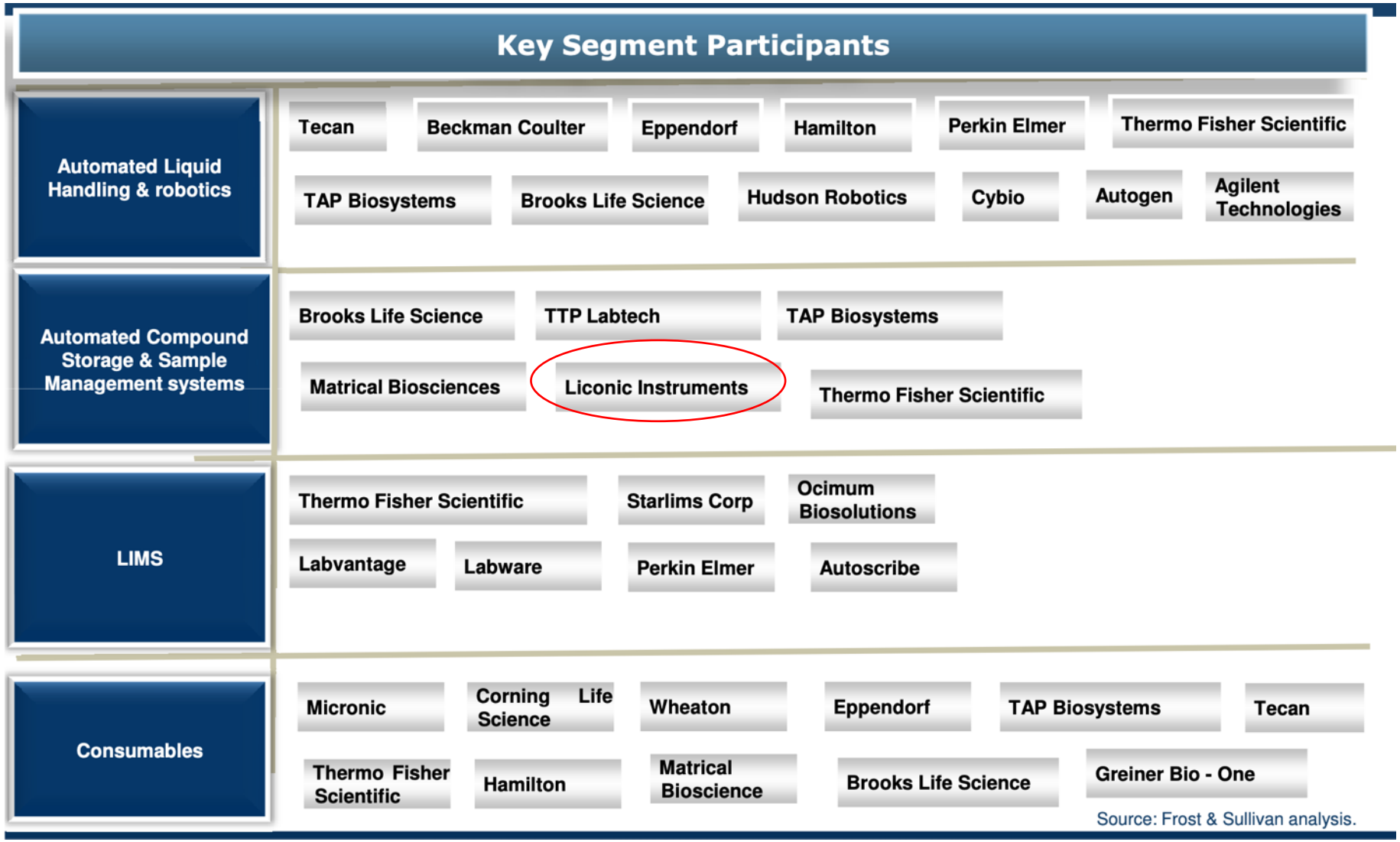
"AUTOMATED BIOBANKING - THE NEXT BIG LEAP FOR BIOBANKS"



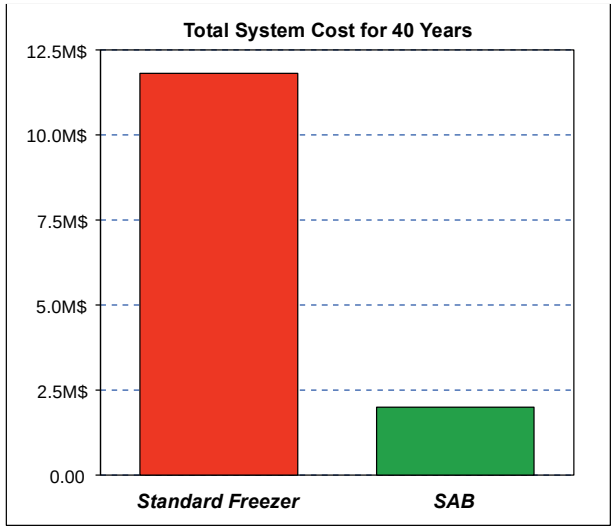
Source: Frost & Sullivan analysis.



INFRASTRUCTURE DEVELOPMENT
MARKET PLAYERS



SAMPLE STORAGE - 40 YEARS



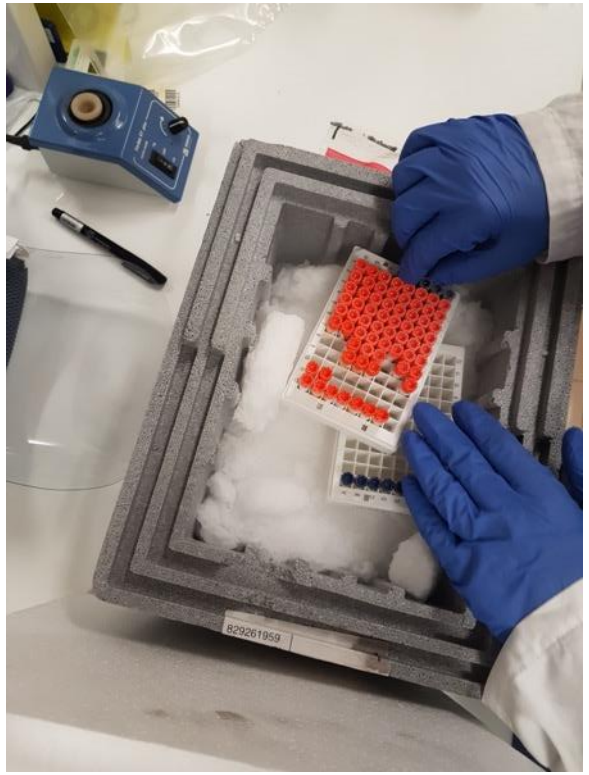
Calibrated sensors

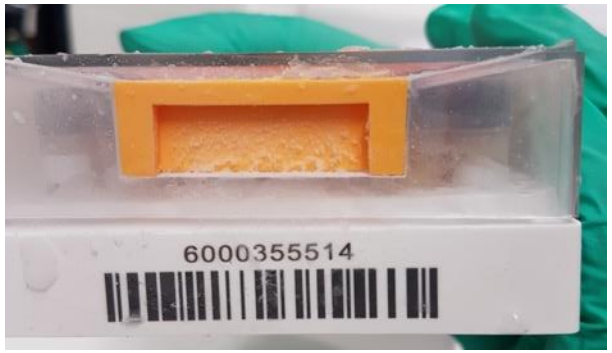
-80C to operate
15sec data transmission

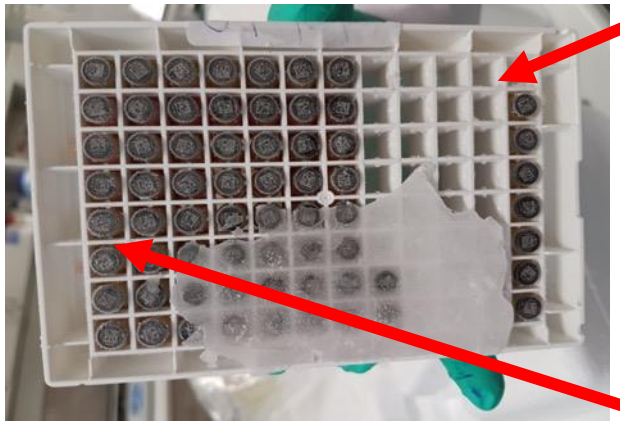
Security systems
Theoretically it never stop

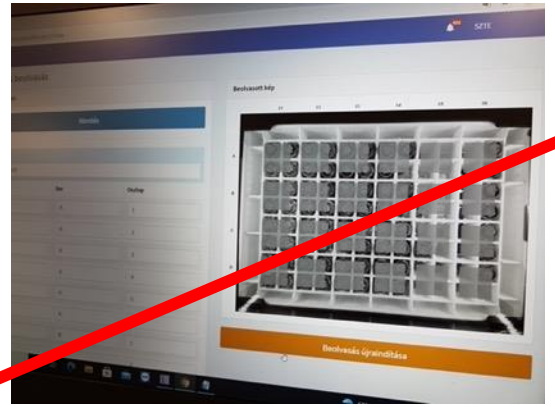
BiO.Li.X! SAB-Series examples			SAB46k0-ULT		SAB98k0-ULT		SAB220k5-ULT	
Labware	Plate height	Pitch	Levels	Samples	Levels	Samples	Levels	Samples
FluidX 0.3 ml Screw Cap	19.1 mm	25 mm	50	4'147'200	78	8'626'176	78	19'408'896
Micronic 0.5 ml Screw Cap	28.5 mm	35 mm	36	2'985'984	56	6'193'152	56	13'934'592
LVL LX1000	45.6 mm	52 mm	24	1'990'656	37	4'091'904	37	9'206'784
Thermo Matrix 1.0ml Screw Cap	54.6 mm	61 mm	20	1'658'880	32	3'538'944	32	7'962'624
Greiner Bio One 2 ml	48.0 mm	54 mm	23	953'856	36	1'990'656	36	4'478'976

SAMPLE IDENTIFICATION – BASE REQUIREMENT FOR ROBOTISATION





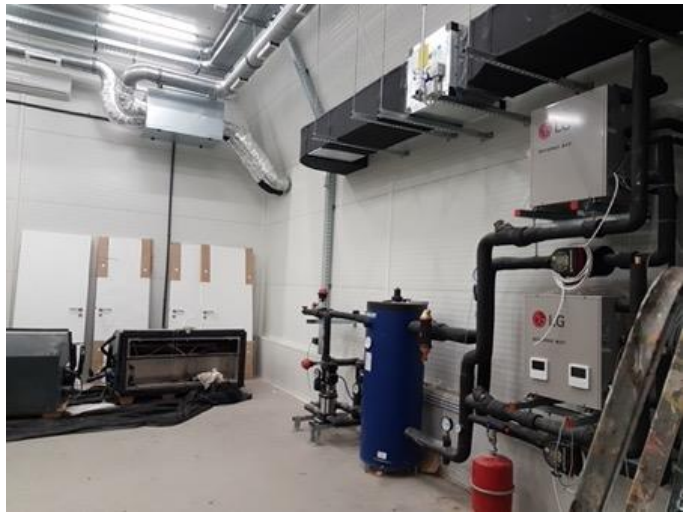




NO TWO TUBES WITH THE SAME BARCODE OCCURS

INFRASTRUCTURE

More than 10 biobankin freezer in the new building (ca 30 at the USZ)



BSL-2 Laboratory

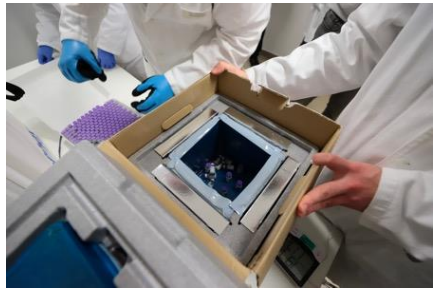
Liconic system (from donation by Spartacus Cancer Fnt)

Micronic and Thermo 2D barcode system

LIMS (under development)

RedCap

Building management systems



SAMPLE STORAGE - REPOSITORY IDENTIFICATION

SAMPLE STORAGE

The Spartacus Cancer Foundation donation to the University of Szeged 2019.

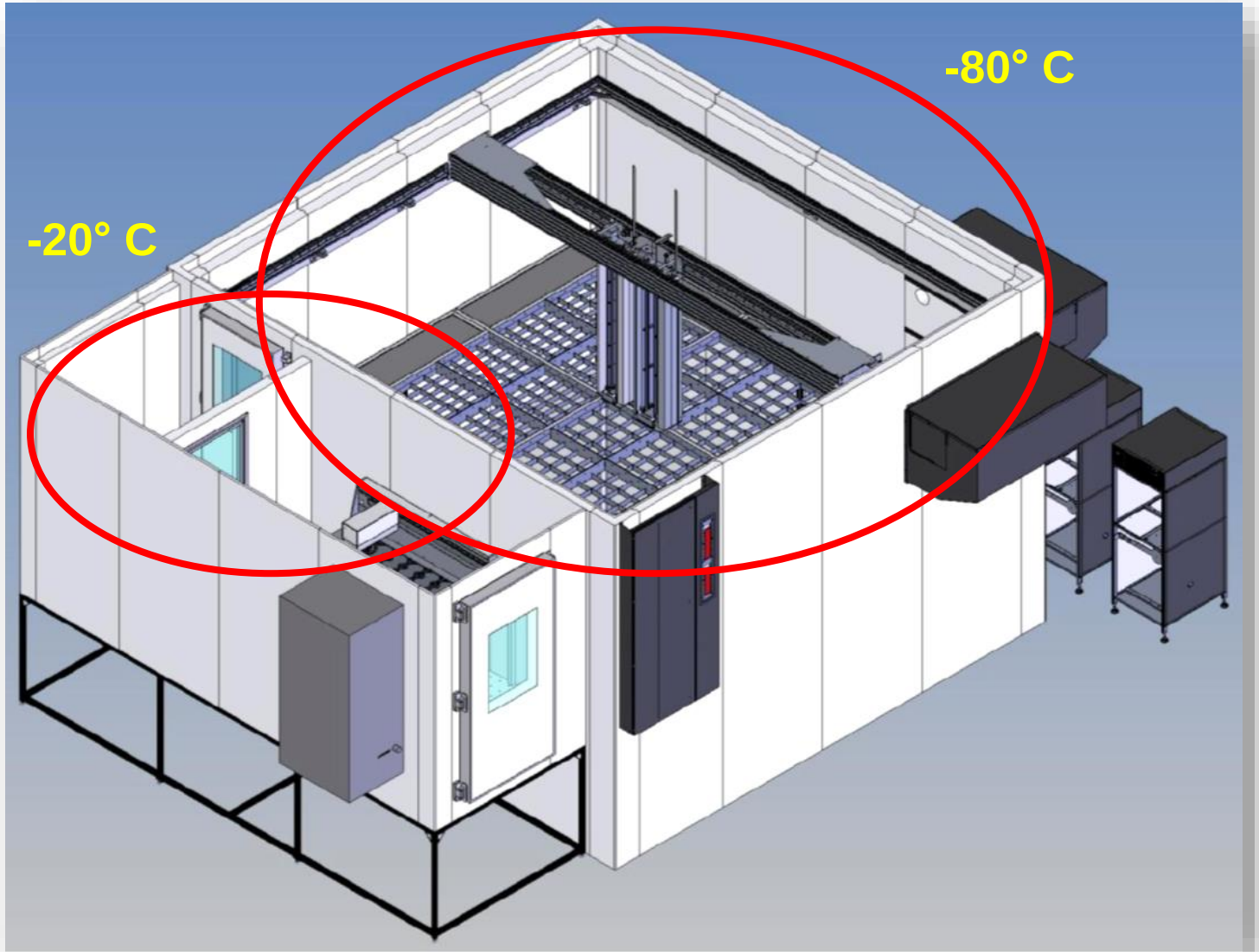
Storage of about 2 million samples

SAMPLE STORAGE - 40 YEARS

-80°C in the storage compartment, -20°C in the multifunction peripheral interface unit.

The storage section consists of a grid of independent cells.
These cells are in turn filled by vertical shelving cassettes or racks. The sample racks are retrieved by a rack handler, running in an X-Y plane on top of a -20°C storage compartment.

The rack handler operates at -20°C. All moving parts that set any system component in motion are located in the safety of the -20°C area.



ROBOTIZATION / AUTOMATION

ROBOTIZATION / AUTOMATION

It does not exempt you from QA and QM:

- sensors
- calibration
- continuous maintenance: at -80°C
- software validation (critical!)

requires special infrastructure

More procedures, more administration and more work

EMT Zrt.

TANÚSÍTVÁNY

Tanúsítjuk, hogy a

Szegedi Tudományegyetem IKIKK Biobank

6725 Szeged, Semmelweis u. 8.

megfelel a Biotechnológia. Biobank-tevékenység. A biobank-tevékenységre vonatkozó általános követelmények című

MSZ EN ISO 20387:2018

szabvány követelményeinek, a következő alkalmazási területeken:

Biobanki tevékenység (gyűjtés, tárolás)

A tanúsítvány száma: 700-2272
Dátum: 2022.08.04
Érvényes: 2025.08.04

Budaörs, 2022.08.04

Bujtás Gyula
vezérigazgató

<u>INCREASED SECURITY, FAST AND MASS STORAGE</u>

<u>AN IDENTIFIER IS SAVED ONLY ONCE IN THE SYSTEM</u>

THANK YOU FOR YOUR ATTENTION

Katalin Boldog

Anett Dancs

Révészné Zsuzsanna Tóth

Gábor Markovits

Prof. Dr. Márta Széll