



WROCLAW  
MEDICAL  
UNIVERSITY



# Wroclaw Medical University Biobank- case study

Agnieszka Matera-Witkiewicz

25/10/2022

Biobanking workshop: Increase awareness of ISO 20387 standard for biobanking in Ireland



# Samples and data resources

## SAMPLES

serum, plasma  
cell pellet  
whole blood  
whole blood & RNA stabilizer  
RNA  
DNA  
Urine, urine supernatant  
faeces  
native saliva  
saliva & DNA stabilizer  
nasal swab  
breast milk  
Solid tissues (brain and spinal tumors)  
cerebrospinal fluid  
cerebrospinal fluid supernatant

## DATA

medical records  
physiological/biochemical parameters  
images  
treatment protocols  
clinical symptoms  
surveys data: nutrition, lifestyle, sociological, medicines, sport activity...

# STRATEGY

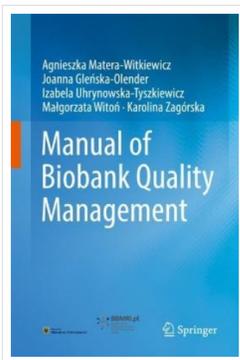


lehmanns  
media

alle Medien ▾

Titel, Autor, Stichwort, ISBN

Bücher eBooks Hörbücher Zeitschriften / Datenbanken B2B-Services Medshop

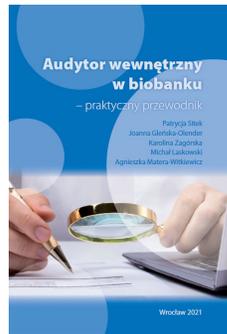


## Manual of Biobank Quality Management

Agnieszka Matera-Witkiewicz, Joanna Gleńska-Olender, Izabela Uhrynowska-Tyszkiewicz, Małgorzata Witoń, Karolina Zagórska, Katarzyna Ferdyn, Michał Laskowski, Patrycja Sitek, Błażej Marciniak, Jakub Pawlikowskimehr, Dominik Strapagiel (Autoren)

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## Internal Auditor in Biobank-a practical guide

## Audit Programme in PBN



## Trainings Workshops (QSPB implementation)

## Doc Templates: procedures, instructions, forms...

BBMRI.pl: Preparation of QM biobanking standards for scientific purposes; implementation of common solutions

## Quality Standards for Polish Biobanks

## Auditor Manual Handbook-checklist for audits

Standardy jakości dla biobanków polskich v. 1.00

Standardy jakości dla biobanków polskich v. 2.00

pod redakcją Agnieszki Matera-Witkiewicz Joanny Gleńskiej-Olender Karoliny Zagórskiej Izabeli Uhrynowskiej-Tyszkiewicz Małgorzaty Witoń

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MEDICAL  
RESEARCH  
AGENCY

OUR MISSION

*Through research to health*



AAA



PL



News Calls for proposals Polish Clinical Trials Network Recruitment of external experts About us



**Through research to health**

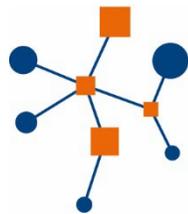
*From 2022 all noncommercial clinical trials sponsored by  
Medical Research Agency **must perform biobanking** and it must be done  
according to the **Quality Standards for Polish Biobanks v.2.00***

**Standardy jakości**  
dla biobanków polskich  
v. 2.00

pod redakcją  
Agnieszki Matera-Witkiewicz  
Joanny Gleńskiej-Olender  
Karoliny Zagórskiej  
Izabeli Uhrynowskiej-Tyszkiewicz  
Małgorzaty Witoń

Agnieszka Matera-Witkiewicz  
Joanna Gleńska-Olender  
Izabela Uhrynowska-Tyszkiewicz  
Małgorzata Witoń · Karolina Zagórska

**Manual of  
Biobank Quality  
Management**



# BBMRI.pl

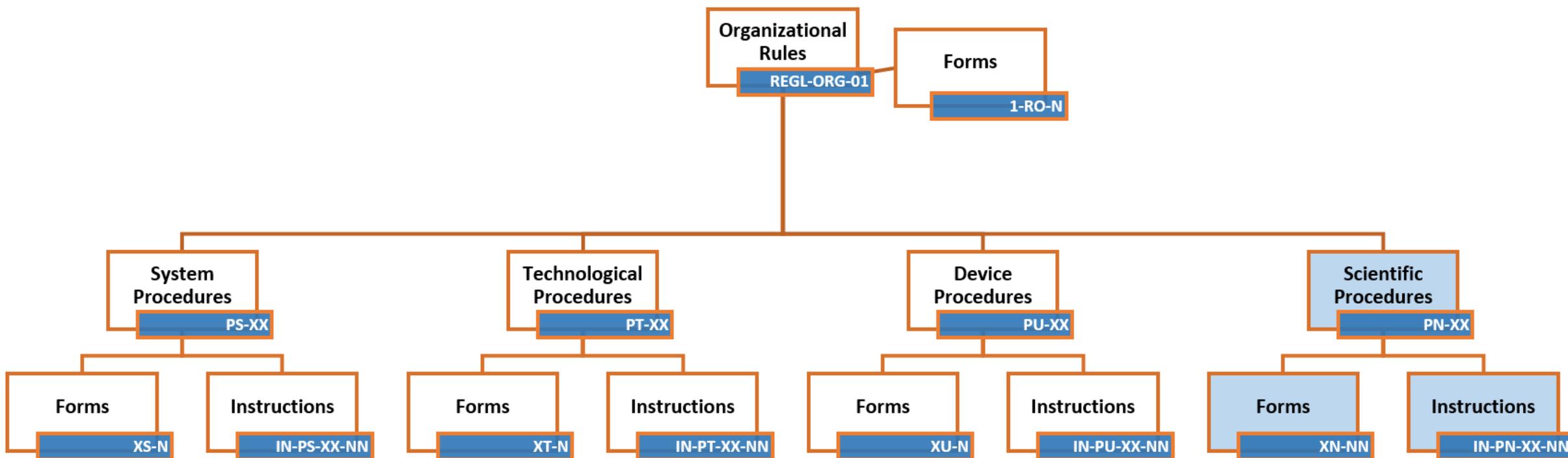
Biobanking and  
BioMolecular resources  
Research Infrastructure  
Poland

**BBMRI.pl/Quality TASK: Preparation  
of QM biobanking standards  
for scientific purposes; implementation  
of common solutions**

## QMS creation

Aug

2017





## QMS creation

Aug

Dec

2017

Integrated  
WMU Biobank  
establishment

Zarządzenie nr 127/XV R/2017  
Rektora Uniwersytetu Medycznego we Wrocławiu  
z dnia 15 grudnia 2017 r.

w sprawie utworzenia Biobanku Uniwersytetu Medycznego we Wrocławiu na  
Wydziale Farmaceutycznym z Oddziałem Analityki Medycznej oraz zmian  
w wykazie jednostek organizacyjnych Uniwersytetu Medycznego we Wrocławiu

Na podstawie art. 66 ustawy z dnia 27 lipca 2005 r. Prawo o szkolnictwie wyższym (t.j. Dz. U. 2017, poz. 2183 ze zm.) oraz § 13 ust. 4 i 5 Statutu Uczelni (t.j. uchwała nr 1774 Senatu UMW z dnia 31 maja 2017 r.) zarządza się, co następuje:

### § 1

1. Z dniem 15 grudnia 2017 r. na Wydziale Farmaceutycznym z Oddziałem Analityki Medycznej w strukturze Pracowni Przesiewowych Testów Aktywności Biologicznej i Gromadzenia Materiału Biologicznego tworzy się jednostkę, o której mowa w § 12 ust. 2 statutu Uczelni, tj.  
**Biobank Uniwersytetu Medycznego we Wrocławiu (skrótowa nazwa: Biobank UMW)**
2. Nazwa w języku angielskim:  
**Wrocław Medical University Biobank (skrótowa nazwa: WMU Biobank)**

### § 2

1. Po utworzeniu Biobanku Uniwersytetu Medycznego we Wrocławiu struktura jednostki jest następująca:  
Pracownia Przesiewowych Testów Aktywności Biologicznej i Gromadzenia Materiału Biologicznego, w skład której wchodzi jednostka, o której mowa w § 12 ust. 12 Statutu Uczelni, tj.:
  - 1) Biobank Uniwersytetu Medycznego we Wrocławiu (skrótowa nazwa Biobank UMW).

### § 3

1. Cel i zakres działalności Biobanku Uniwersytetu Medycznego we Wrocławiu, zwanego dalej „Biobankiem” obejmuje:
  - 1) Zapewnienie poprawy dostępności materiału biologicznego o wysokim standardzie, dla jednostek funkcjonujących w obrębie Uniwersytetu Medycznego we Wrocławiu,



## QMS creation

**Aug****2017****Dec**

**Integrated  
WMU Biobank  
establishment**

**Sep****2018**

KOMISJA BIOETYCZNA  
przy  
Uniwersytecie Medycznym  
we Wrocławiu  
ul. Pasteura 1; 50-367 WROCLAW

### OPINIA KOMISJI BIOETYCZNEJ Nr KB – 541/2018

Komisja Bioetyczna przy Uniwersytecie Medycznym we Wrocławiu, powołana zarządzeniem Rektora Uniwersytetu Medycznego we Wrocławiu nr 133/XV R/2017 z dnia 21 grudnia 2017 r. oraz działająca w trybie przewidzianym rozporządzeniem Ministra Zdrowia i Opieki Społecznej z dnia 11 maja 1999 r. (Dz.U. nr 47, poz. 480) na podstawie ustawy o zawodzie lekarza z dnia 5 grudnia 1996 r. (Dz.U. nr 28 z 1997 r. poz. 152 z późniejszymi zmianami ) w składzie:

## BIOETHICAL COMMITTEE OPINION

**Biobanking for scientific, R&D and  
educational purposes**

„Prowadzenie działalności w zakresie biobankowania materiału biologicznego do celów naukowo-badawczych, rozwojowych i/lub dydaktycznych w Biobanku Uniwersytetu Medycznego we Wrocławiu”



## Bioethical Committee opinion

## QMS creation

Aug

2017

Dec

Integrated  
WMU Biobank  
establishment

Sep

2018

Apr

2019

ISO 9001  
certification

bsi.



## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Wroclaw Medical University  
Faculty of Pharmacy with Division of  
Laboratory Diagnostics  
Screening Laboratory of Biological  
Activity Test and Collection of Biological Material  
Wroclaw Medical University Biobank  
Borowska St. 211A, 50556 Wroclaw  
Poland

Holds Certificate No:

**FS 708094**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Biobanking of biological material for scientific, educational, research and development purposes.

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2019-04-02

Effective Date: 2019-04-02

Latest Revision Date: 2019-04-02

Expiry Date: 2022-04-01

Page: 1 of 1



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**Bioethical  
Committee  
opinion**

**QMS creation**

**Aug**

**2017**

**Dec**

**Integrated  
WMU Biobank  
establishment**

**Sep**

**2018**

**Apr**

**2019**

**ISO 9001  
certification**

**Dec**

**Biobanking agreement  
Hospital – University**



Bioethical  
Committee  
opinion

BBMRI.pl  
Q-mark

QMS creation

Aug

Dec

Sep

Apr

Dec

Jan

2017

2018

2019

2020

Integrated  
WMU Biobank  
establishment

ISO 9001  
certification

Biobanking  
agreement  
Hospital – University

**Standardy jakości**  
dla biobanków polskich  
v. 2.00

pod redakcją  
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Karoliny Zagórskiej  
Izabeli Uhrynowskiej-Tyszkiewicz  
Małgorzaty Witon

Bioethical  
Committee  
opinion

BBMRI.pl  
Q-mark

QMS creation



Home - News & Events Overview - First biobank quality mark in the BBMRI-ERIC Directory according to ISO 20387

Wroclaw Medical University Biobank

ISO-9001:2015 ✓

BBMRI audited ISO 20387:2018 ✓

**Collection types:** Population-based, Sample collection, Cross-sectional, Hospital, Disease specific, Cohort, Longitudinal

**Juridical person:** Wroclaw Medical University

**FIRST BIOBANK QUALITY MARK  
IN THE BBMRI-ERIC DIRECTORY  
ACCORDING TO ISO 20387**

# Certificate of Registration

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## FIRST BIOBANK QUALITY MARK IN THE BBMRI-ERIC DIRECTORY ACCORDING TO ISO 20387

It is truly a success for the BBMRI-ERIC network of biobanks. Our first biobank – Wroclaw Medical University Biobank (WMU Biobank) made a great effort to integrate the international standard for biobanks – ISO 20387:2018 – into their work processes. The standard implementation phase was started in 2019 and, in the next step, also led to the desire to have this performance confirmed by a peer review audit.

On behalf of BBMRI-ERIC, two independent certified and biobank-experienced auditors (Prof. Dominik Strapagiel and Sylwia Dobrowolska) embarked on a 2-day on-site audit on behalf of BBMRI-ERIC. By strictly adhering to COVID-19 security and hygiene measures, both auditors carried out a full review of the biobank documents and assessed their accordance to the requirements of the biobank standard. The lead auditor Prof. Strapagiel, submitted a standardized report and checklist to BBMRI-ERIC, confirming that the biobank adopted a management system based on the requirements and principles of ISO 203287:2018 and is working according to this standard. The Quality mark is now visible in the [BBMRI-ERIC Directory](#).

“This is really a great achievement by the head of the WMU Biobank, Dr. Agnieszka Matera-Witkiewicz, and her competent team. I would not be surprised if the WMU-Biobank submit an application for accreditation by the Polish Accreditation Center (PCA) in the near future,” said BBMRI-ERIC Head of Quality Management Andrea Wutte. “This is the right way to prove that biobanks are competent partners in biomedical research. Biobanks protect and manage, so to speak, the legacy of all donors: their valuable samples and data. One thing is crystal clear: these donors want to support biomedical research with the highest quality standards, in order to use their samples and data for the health and well-being of mankind. Now, in this pandemic, we are faced with the gravity of this responsibility.”

Wroclaw Medical University Biobank (WMU Biobank) was established in 2017 as a key project listed within three scientific strategic activities proposed for the Polish University in 2016-2020: Translational Medicine/Integrated Biobank; Healthy Aging; and Clinical Epidemiology.

WMU Biobank was created to ensure the enhancement of biological material availability not only for internal cooperation but also for external partners, where the highest quality standards will be accomplished.

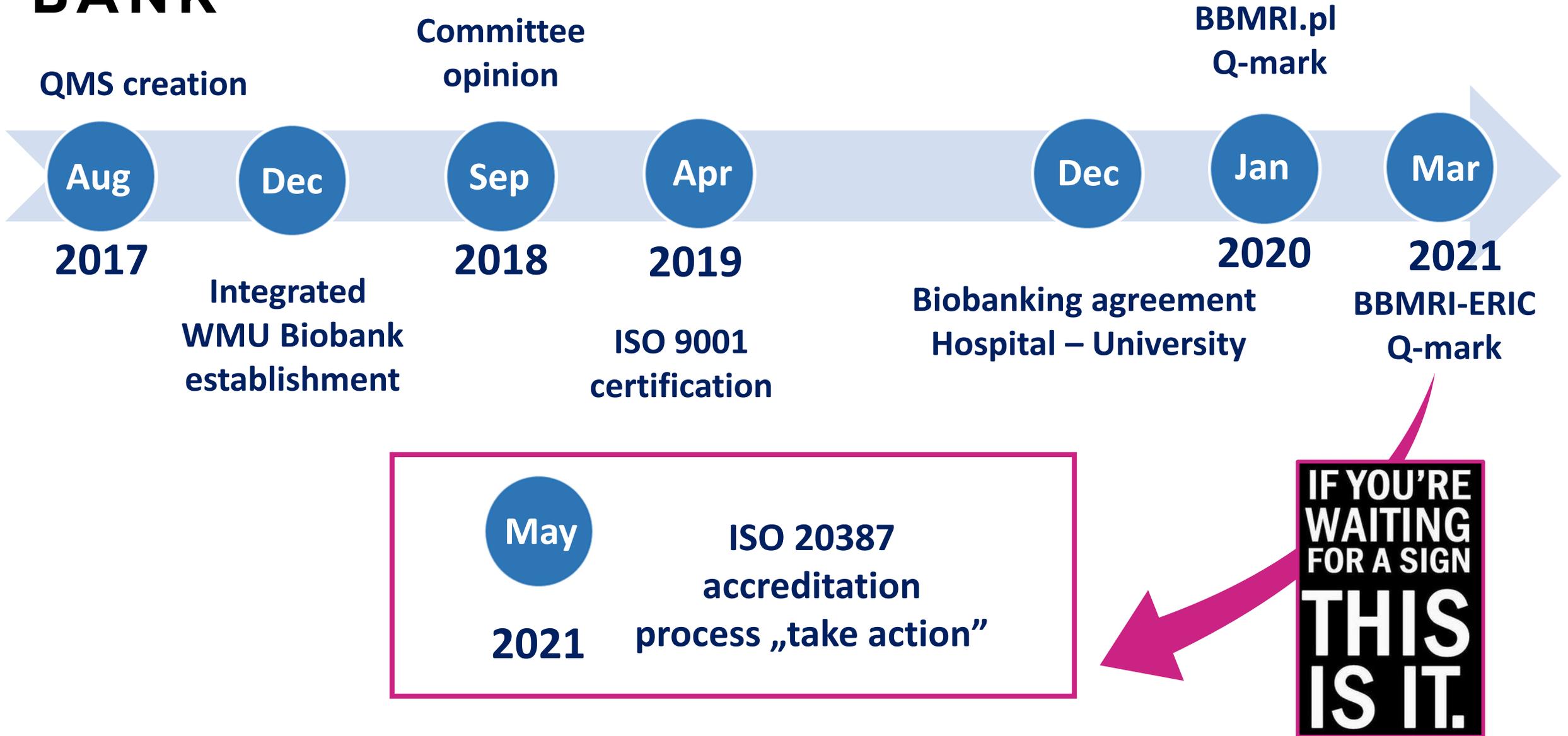
“This is a huge success and a great step forward for all biobanks as well as for our Quality Management Team. The onsite audit taken at Wroclaw Biobank on behalf of BBMRI-ERIC is hopefully the first in a long series. This experience should encourage other biobanks to do the same!” said Agnieszka Matera-Witkiewicz.



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**First Biobank in Poland with ISO 9001:2015 certificate in the scope of *biobanking* for scientific, R&D and educational purposes**

**Poland as a first country in BBMRI-ERIC with Q-mark proving ISO 20387:2018 compliance**



**IF YOU'RE  
WAITING  
FOR A SIGN  
THIS  
IS IT.**

## Accreditation requirements:

- ✓ PN-EN ISO 20387:2021-01
- ✓ DA-05 *Proficiency testing participation Policy (ILAC P9)*
- ✓ DA-06 *Traceability of measurement results Policy (ILACP10)*

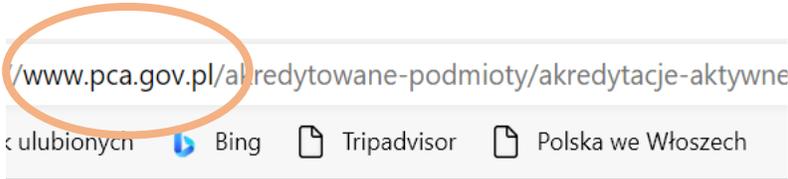
## After accreditation:

- ✓ DA-02 Rules of PCA accreditation symbols usage
  - use of PCA accreditation symbols in terms of communication



BB XXX

# ***SCOPE: Biobanking of human biological material as well as related information and data***



AKREDYTOWANE

Strona główna | Akredytowane podmioty | Akredytacje aktywne | Biobanki

### Akredytacje aktywne

- Laboratoria badawcze
- Laboratoria medyczne
- Laboratoria wzorcujące
- Jednostki certyfikujące systemy
- Jednostki certyfikujące wyroby
- Jednostki certyfikujące osoby
- Jednostki inspekcyjne
- Organizatorzy badań biegłości
- Producenci materiałów odniesienia
- Weryfikatorzy EMAS

### Biobanki



Akredytacja: BB 001  
Data ważności akredytacji: 25-09-2026  
Akredytacja od: 26-09-2022

#### Dane organizacji:

Uniwersytet Medyczny im. Piastów Śląskich we Wrocławiu  
ul. Wybrzeże L. Pasteura 1; 50-367 Wrocław

#### Zakres skrócony:

Biobankowanie ludzkiego materiału biologicznego i związanych z nim informacji i danych; Biobanking of human biological material as well as related information and data

Biological material	Storage conditions
peripheral blood	-65°C to -86°C
urine	-65°C to -86°C & -20°C to -30°C
faeces	-65°C to -86°C
saliva	-65°C to -86°C & 15°C to 30°C
nasal swab	-65°C to -86°C
human milk	-65°C to -86°C
tissues	-65°C to -86°C
cerebro-spinal fluid	-65°C to -86°C

2021

Application

2022

2nd assesment  
(on-site 4 auditors)  
1NC, 5 Observations

May

Nov

Dec

Mar

??????



Processes  
improvement

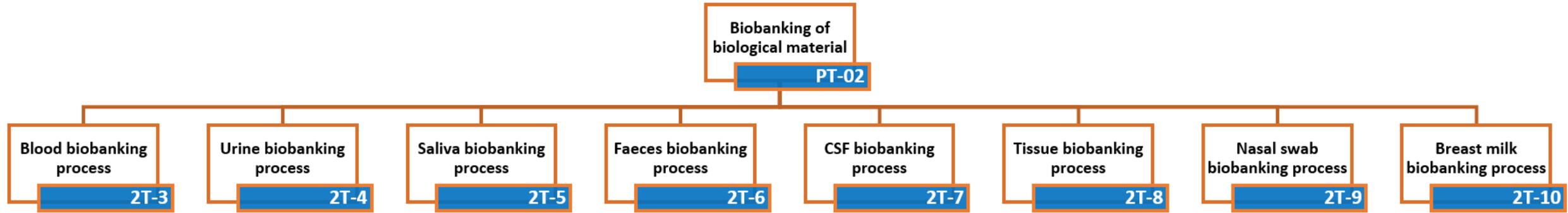
1st assesment  
(remote 4 auditors)



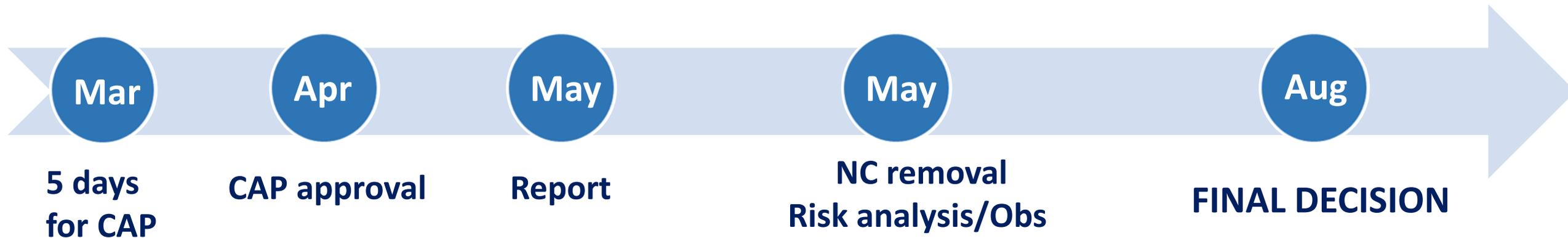
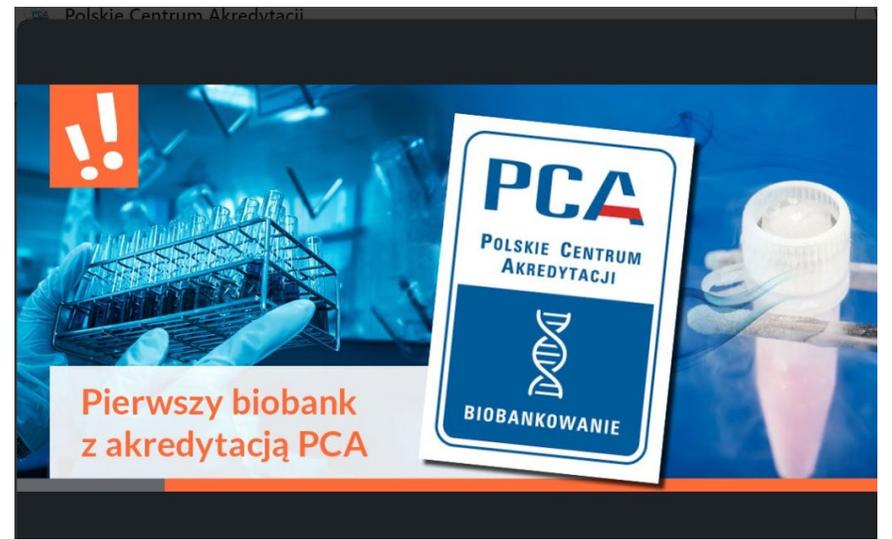
PS-10 Hiring employees and their qualifications		
Copy 1 of 1 ver. 1.08 PS-10	QMS Procedure <b>Hiring employees and their qualifications</b>	Valid from: _____ Withdrawn on: _____
Made by	Accepted by	Accepted by

*„The Biobank has not provided evidence of the competence of the staff involved in the activities of the Biobank in relation to the education, training, skills and/or experience identified in relation to the assigned tasks and activities” \*\*\**

*\*\*\* three separate docs: responsibilities and authorities; dedicated personal duties, employment requirements*



- a **detailed biobanking scheme** for each biological material
- ISO 20387 particular **conformity declaration** (processes, material, data etc)
- exclusion Hospital Clinics from the **list of providers**
- **report form the distribution** (use only the normative vocabulary)
- **internal audit plan/** need to address the reason and effect when audit is shifted



**288 DAYS**



## CONCLUDING REMARKS FROM ISO 20387 ACCREDITATION

- lack of experience in **biobank auditing**, audit proces based on experience from **testing or calibration Labs**
- ***fit-for-purpose*** for each type of biological material / collection
- **scope** of accreditation
- **collection process- in/out of scope**; if yes: requirements for service providers; if no- how to ensure the quality?
- **proficiency testing**: lack of QC for all BM/data?
- **validation/verification** for all methods (even if manufacturer has performed validation)
- **all critical actions must be identified & monitored** for whole biobanking life cycle (!calibrated equipment)
- **critical equipment**-also IT infrastructure!
- **objective evidence for impartiality** – how to do that? (policy, declarations, statements, ELSI procedure..)
- **QC methods** for all processes and material at each critical step
- 4-year contract vs. **prices**

# HOW TO ENSURE QUALITY

