



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

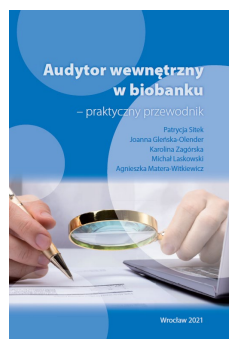
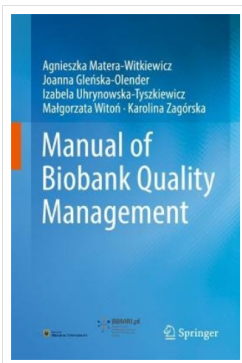
Bücher eBooks Hörbücher Zeitschriften / Datenbanken B2B-Services Medshop

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 Pawlikowski, Dominik Strapagiel (Autoren)

Buch | Hardcover

X, 142 Seiten
2022 | 1st ed. 2022
Springer International Publishing (Verlag)
978-3-031-12558-4 (ISBN)



Internal Auditor in Biobank-a practical guide

Trainings
Workshops
(QSPB
implemtnation)

Audit
Programme
in PBN



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



Table of contents:

DICTIONARY	
1. MANAGEMENT OF BIOBANKS	18
1.1. ORGANIZATIONAL STRUCTURE	18
1.2. BIOBANK'S MISSION AND SCOPE OF ACTIVITY	19
1.3. BIOBANK'S OBJECTIVES AND THEIR MONITORING	19
1.4. COMMUNICATION.....	20
2. QUALITY MANAGEMENT	22
2.1. GENERAL REQUIREMENTS	22
2.2. QUALITY POLICY	22
2.3. SETTING OBJECTIVES.....	23
2.4. RISK AND OPPORTUNITY MANAGEMENT	23
3. DOCUMENTATION AND RECORDS	27
3.1. GENERAL REQUIREMENTS	27
3.2. IMPLEMENTING DOCUMENTATION.....	33
3.3. STORAGE OF QMS DOCUMENTATION.....	36
3.4. VERIFICATION OF DOCUMENTATION.....	37
4. HUMAN RESOURCES MANAGEMENT	39
4.1. HUMAN RESOURCES MANAGEMENT POLICY.....	39
4.2. BIOBANK EMPLOYEE IDENTIFICATION.....	40
4.3. ADMISSION OF AN EMPLOYEE TO THE BIOBANK.....	40
4.4. RESPONSIBILITY AND PERMISSIONS OF KEY PERSONNEL.....	42
4.5. BIOBANK PERSONNEL TRAINING (IMPROVEMENT TRAINING).....	42
4.6. VERIFICATION OF BIOBANK EMPLOYEES' KNOWLEDGE	43
4.7. TRAINING DOCUMENTATION	44
4.8. TERMINATION OF EMPLOYMENT.....	45
5. ETHICAL AND LEGAL ASPECTS	46
5.1. COMPLIANCE WITH ETHICAL AND LEGAL REQUIREMENTS	46
5.2. ETHICAL ADVICE AND APPROVAL	47
5.3. IMPARTIALITY.....	48
5.4. CONFIDENTIALITY AND PRIVACY	51
5.5. RESPECT FOR AUTONOMY.....	53
5.6. SHARING MATERIAL AND DATA.....	57
5.7. PROPRIETARY RIGHTS AND COMMERCIALIZATION.....	59
6. SUPPLIES, MATERIALS MANAGEMENT	61
6.1. MATERIALS RECEIPT RULES.....	61
6.2. RECEPTION, QUALIFICATION AND ACCEPTANCE OF MATERIALS.....	61
6.3. QUALIFICATION OF SUPPLIERS.....	63
6.4. HANDLING OF MATERIALS STORED IN STORAGE SPACE.....	64
6.5. HANDLING OF MATERIALS USED IN DAILY WORK	65
7. EQUIPMENT	67
7.1. ACCEPTANCE OF THE EQUIPMENT.....	68
7.2. RULES FOR SUPERVISION OVER EQUIPMENT	76
7.3. RECORDINGS OF EQUIPMENT OPERATION	78
7.4. WORK WITH EQUIPMENT OUTSIDE THE SUPERVISION	82
7.5. REQUALIFICATION OF CRITICAL EQUIPMENT	83
8. TRACEABILITY	85
8.1. TRACEABILITY SYSTEM	85
8.2. UNIQUE IDENTIFICATION OF BIOLOGICAL MATERIAL.....	87
9. ENVIRONMENTAL AND STAFF HYGIENE	92
9.1. PERSONNEL HYGIENE AND SAFETY	92
9.2. PROCESS ENVIRONMENT	97
9.3. WASTE MANAGEMENT	98
10. BIOBANKING PROCESSES AND QUALITY CONTROL	99
10.1. THE LIFE CYCLE OF BIOLOGICAL MATERIAL AND CRITICAL PROCESSES.....	99
10.2. QUALITY CONTROL	109
11. DEVIATIONS, NONCONFORMING PRODUCT/DATA OR SERVICE	112
11.1. DEVIATIONS/NONCONFORMITIES	112
11.2. CORRECTIVE AND CORRECTION ACTIONS.....	113
11.3. COMPLAINTS.....	113
11.4. NONCONFORMING OUTPUT/SERVICE.....	114
12. AUDITS	117
12.1. INTERNAL AUDIT	117
12.2. AUDITOR'S COMPETENCES AND QUALIFICATIONS	121
13. IMPROVEMENT	123
13.1. TOOLS FOR IMPROVING THE EFFECTIVENESS OF BIOBANK.....	123
13.2. MANAGEMENT REVIEW.....	123
14. BIOBANK COOPERATION IN THE SCIENTIFIC, RESEARCH AND DEVELOPMENT AREA	127
14.1. GENERAL REQUIREMENTS.....	127
14.2. SHARING OF BIOLOGICAL MATERIAL AND DATA FOR RESEARCH	127
14.3. COOPERATION AGREEMENTS.....	127
14.4. COMMUNICATION DURING SCIENTIFIC COOPERATION	128
15. SAFETY & SECURITY	130
15.1. SECURITY PROCEDURES.....	130
15.2. BIOLOGICAL MATERIAL SAFETY.....	130
15.3. INFORMATION SECURITY.....	131
15.4. BASIC METHODS OF SECURING IT INFRASTRUCTURE AND DATA PROCESSING.....	134



MEDICAL
RESEARCH
AGENCY

OUR MISSION

Through research to health



AAA



PL

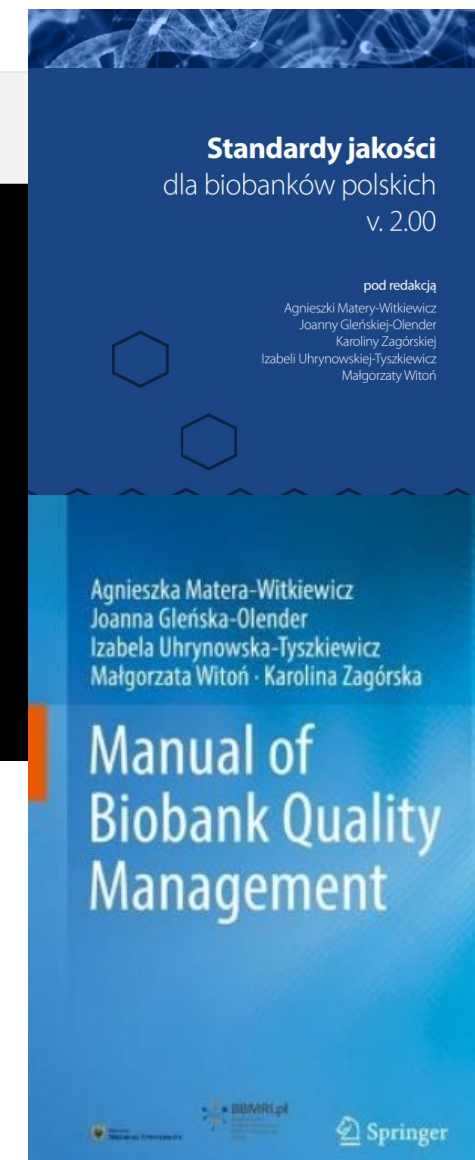


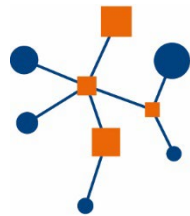
News Calls for proposals Polish Clinical Trials Network Recruitment of external experts About us



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***





BBMRI.pl

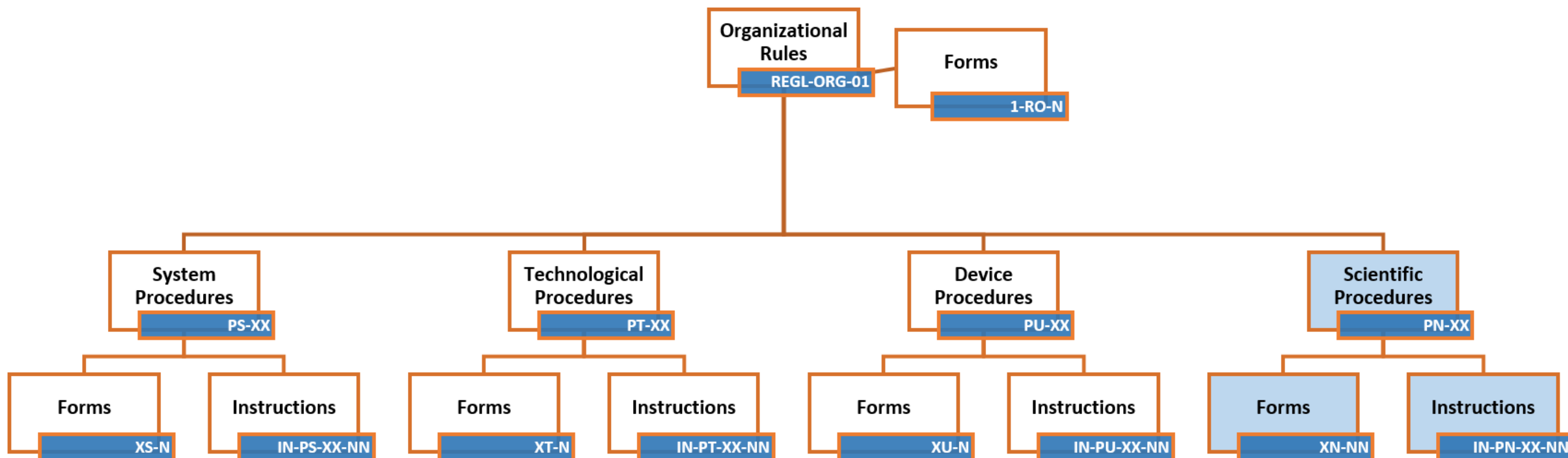
Biobanking and
BioMolecular resources
Research Infrastructure
Poland

**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,

**BI
BANK**

WROCLAW
MEDICAL
UNIVERSITY

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

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2019-04-02

Latest Revision Date: 2019-04-02

Effective Date: 2019-04-02

Expiry Date: 2022-04-01

Page: 1 of 1



...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000

BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.

**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

Agnieszki Matery-Witkiewicz
Joanny Głęskiej-Olender
Karoliny Zagórskiej
Izabeli Uhrynowskiej-Tyszkiewicz
Małgorzaty Witon


**Bioethical
Committee
opinion**

QMS creation

**BBMRI.pl
Q-mark**



[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

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.




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 20387:2018 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.

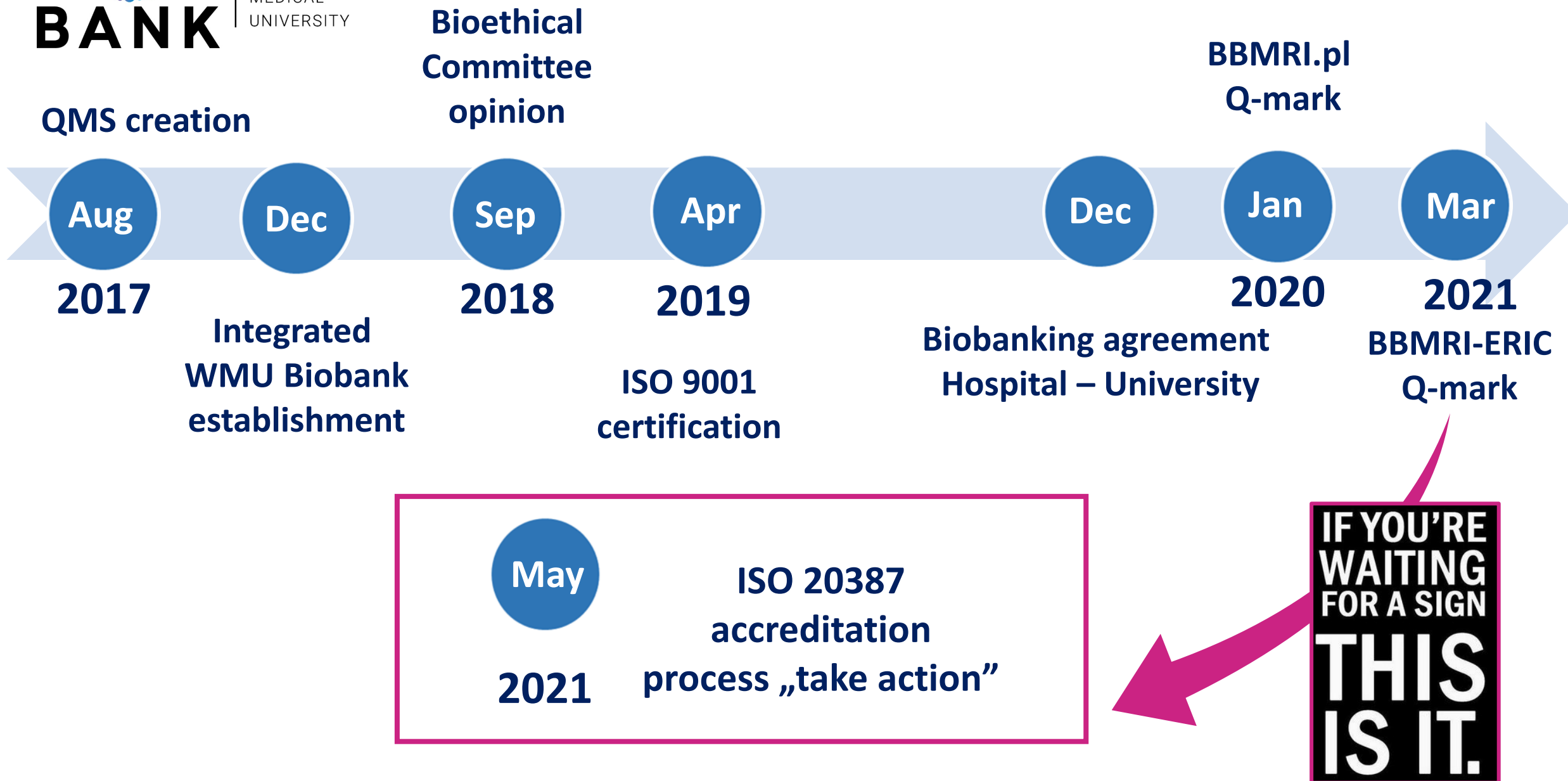
WMU Biobank was created to ensure the enhancement of biological material availability not only for internal cooperation but also for external partners, where the highest quality standards will be accomplished.

"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.

BIOBANK
WROCLAW
MEDICAL
UNIVERSITY

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



Accreditation requirements:

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

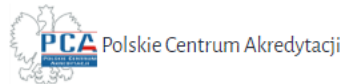
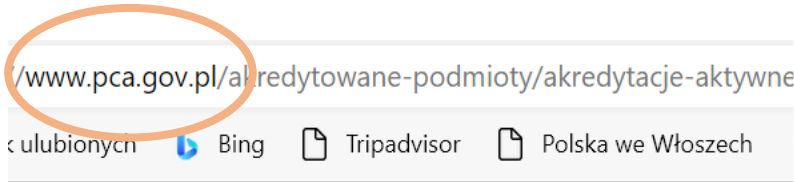
After accreditation:

- ✓ 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



Strona główna | O PCA | AKREDYTACJA | PUBLIKACJE | AKREDYTOWANE

Strona główna | Akredytowane podmioty | Akredytacje aktywne | Biobanki

Akredytacje aktywne

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



BB 001

Biobanki

Dane organizacji:

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

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

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**

May

Nov

Dec

2022

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

Mar

??????



**Processes
improvement**

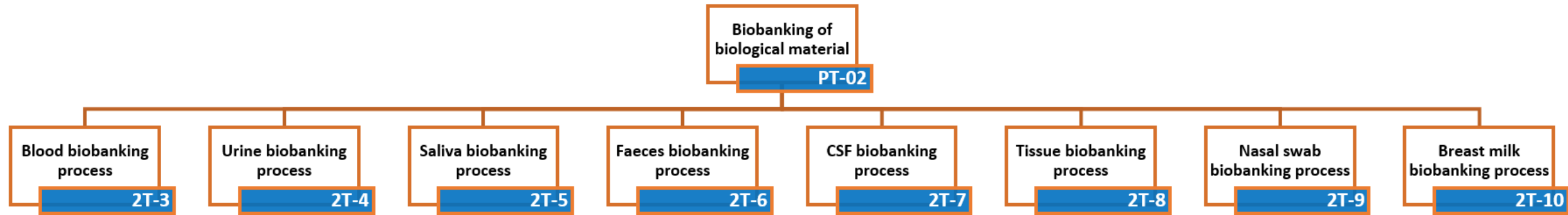
**1st assessment
(remote 4 auditors)**



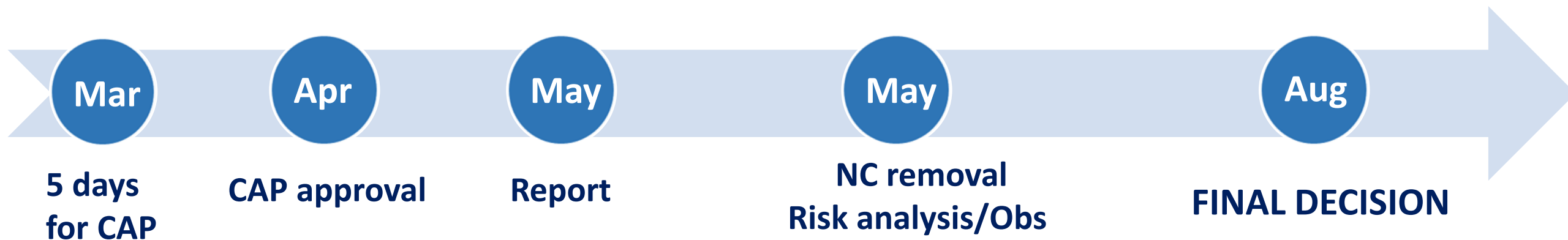
PS-10 Hiring employees and their qualifications		
Copy 1 of 1 ver. 1.08 PS-10	QMS Procedure Hiring employees and their qualifications	Valid from:
Made by	Accepted by	Accepted by

*„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

