

EUROPE BIOBANK WEEK

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VIENNA - AUSTRIA

Koh Furuta: "Status quo and the future; Biobankings in Japan"



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Biobanking in the spotlight – International standards and future perspectives

Status quo and the future; Biobanking in Japan

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Outline of biobanks in Japan

Human:

Biobanks in Japan
are mostly small and diversified
based on individual research activities in the
academic sector.

Human: Three major biobanks

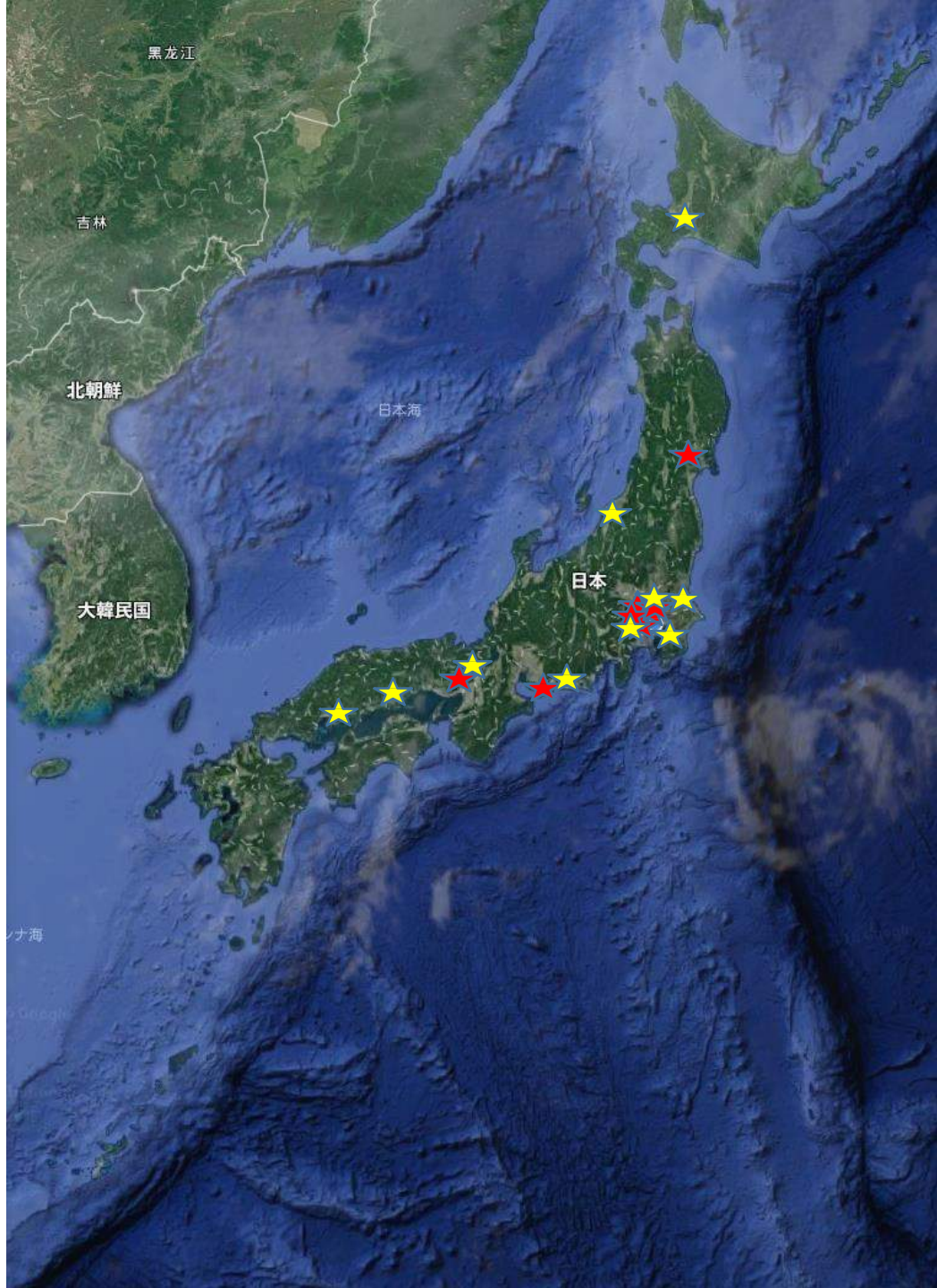
- ◆ Tohoku Medical Megabank Project
- ◆ Biobank Japan
- ◆ National Center Biobank Network:
 - NCC: National Cancer Center
 - NCGM: National Center for Global Health and Medicine
 - NCVC: National Cerebral and Cardiovascular Center
 - NCCHD: National Center for Child Health and Development
 - NCNP: National Center of Neurology and Psychiatry
 - NCGC: National Center for Geriatrics and Gerontology

Human: Other biobanks

- ◆ Clinical biobank Study Group:
 - Hokkaido University
 - Chiba University
 - Kyoto University
 - Okayama University
- ◆ Tsukuba University
- ◆ BioResource Center: Tokyo Metropolitan Geriatric Hospital and Institute of Gerontology
- ◆ Brain Bank: Brain Research Institute, Niigata University
- ◆ Rare Disease Bank: NIBIO (National Institute of Biomedical Innovation)
- ◆ Radiation Effects Research Foundation
- ◆ Kanagawa Cancer Center

Human: BRC, Stock

- ◆ Cell Bank : Riken BioResource Center (BRC)
- ◆ CiRA : Center for iPS Cell Research and Application,
Kyoto University



Non-human biobanks (BRCs):

Non-human biobanks (BRCs) :

- ◆ Microbiology : National Institute of Technology and Evaluation (NITE)
- ◆ Agriculture : The National Institute of Agrobiological Sciences (NIAS)

BioResource related to various basic researches:

- ◆ Interuniversity Bio-Backup Project for Basic Biology (IBBP)
Cryopreservation Conference

Funding status

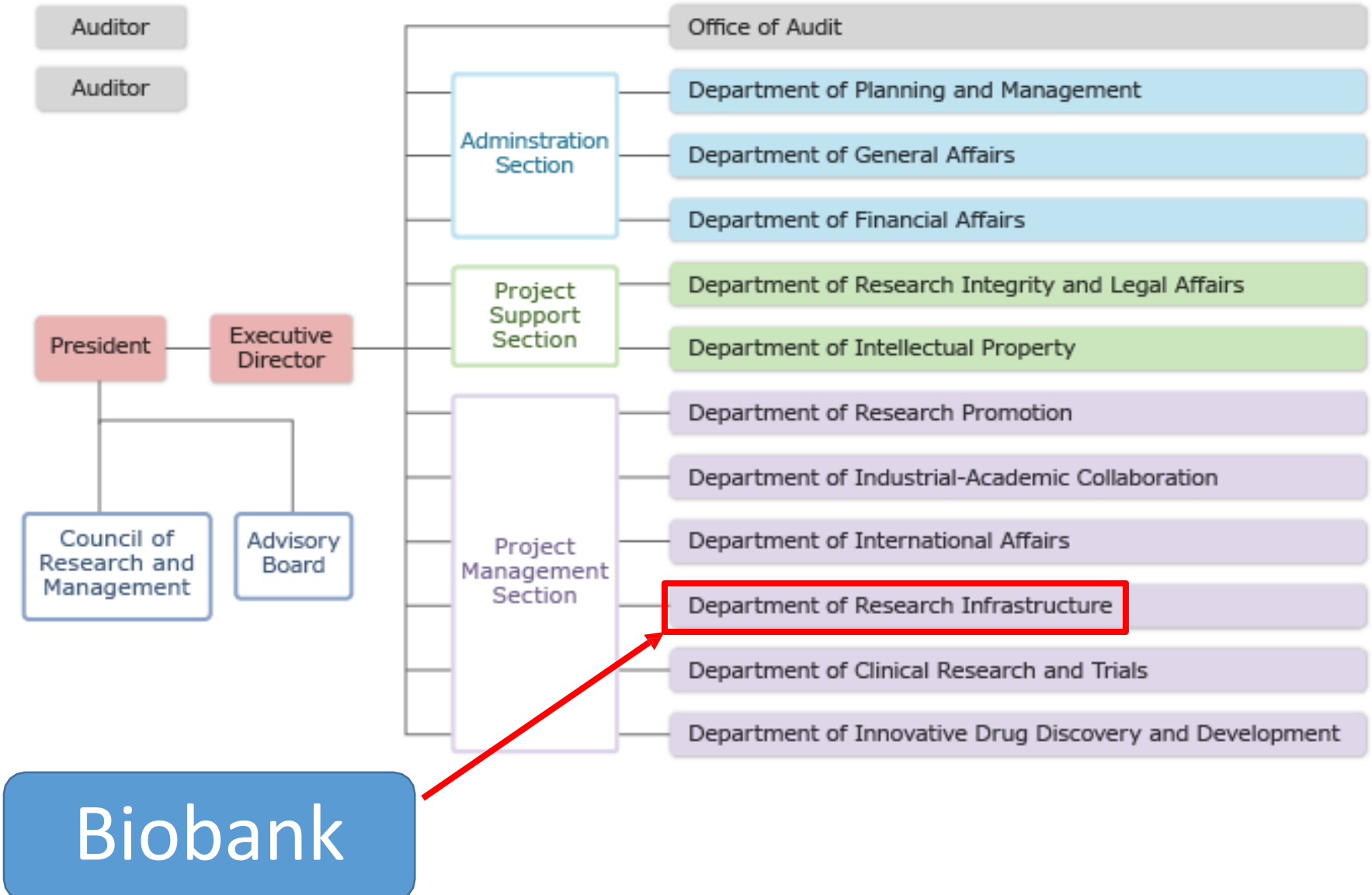
Most of the funding is public, including government sponsored grants of various types.

Public Support:

- ◆ Ministry of Education, Culture, Sports, Science and Technology
- ◆ Ministry of Health, Labour and Welfare
- ◆ Ministry of Economy, Trade and Industry

- ◆ AMED : Japan Agency for Medical Research and Development
 - AMED was established in April 2015.
 - AMED promotes integrated research and development in the field of medicine, from basic research to clinical trials, establishing, maintaining, and providing funding for an environment for integrated R&D through to practical application.
 - AMED consolidates budgets for research expenses, which had previously been allocated from different sources -- the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare, and the Ministry of Economy, Trade and Industry.

AMED : Japan Agency for Medical Research and Development



Sample provision:

Providing samples to outside third parties, especially to industry, had not been active in the past.

Recently however, many funding bodies have encouraged biobanks to provide samples to the outside parties, especially to industry.

Sample Quality:

More than ever the quality of samples but also the quality of management systems came under focus.

Japanese Society of pathology

一般社団法人 日本病理学会
ゲノム研究用病理組織検体取扱い規程

ゲノム研究用病理組織検体取扱い規程 第2版に基づいて

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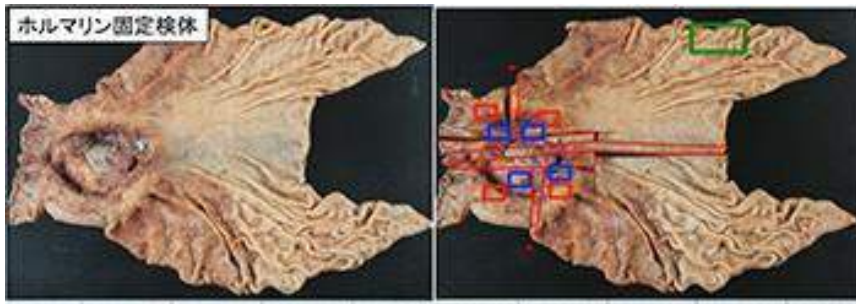
- 第1部 病理検体の適切な採取法
- 第2部 病理検体の適切な保存法
- 第3部 パラフィン埋め込みの注意-留意
- 第4部 検体の凍結保存法

病理組織検体のゲノム等オミックス解析は、疾患発生の分子基盤を明らかにし、バイオマーカー開発や創薬標的の同定に結びつきます。

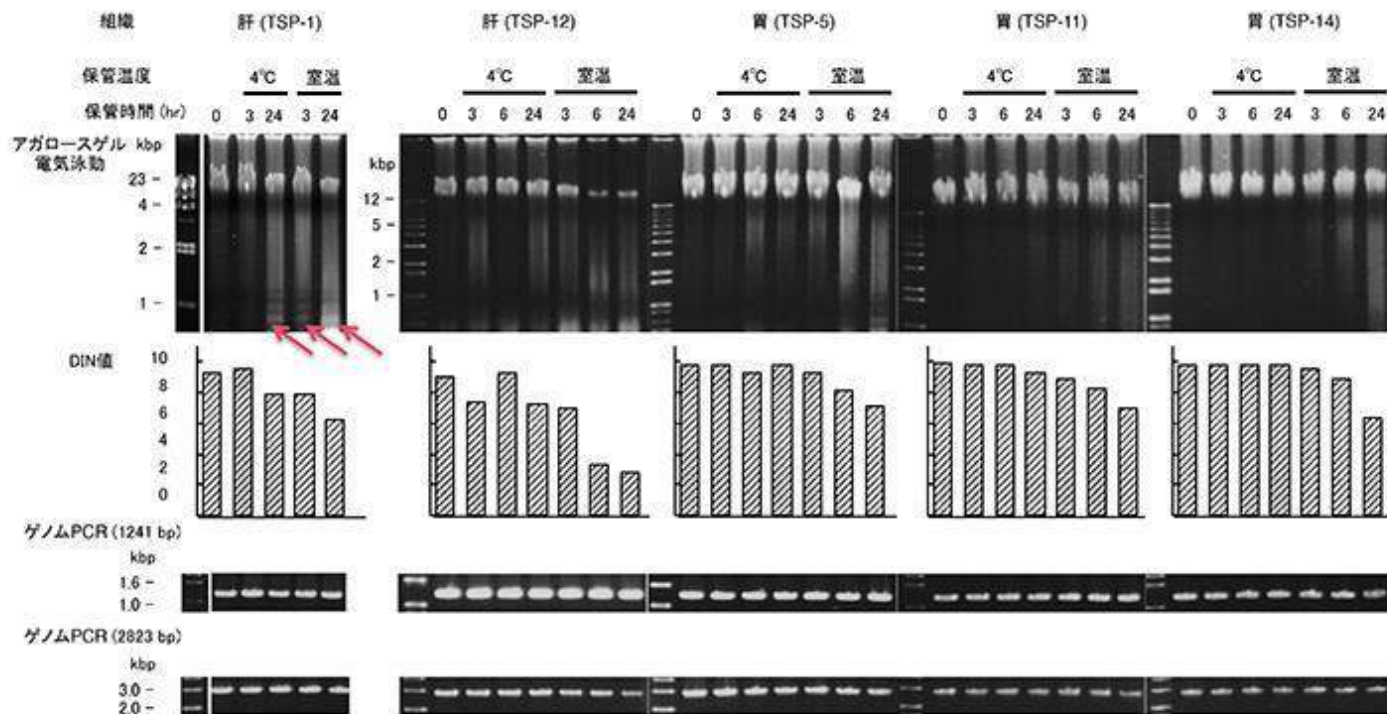
病理組織検体の質は、このようなデータ駆動型研究の成否の鍵を握っています。

質の高い病理組織検体を多くの医学研究者に提供できるよう、一般社団法人日本病理学会は、検体の迅速採取・保存方法を定めた「ゲノム研究用病理組織検体取扱い規程」を定めます。

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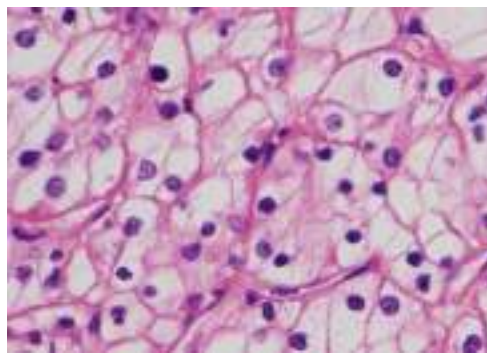
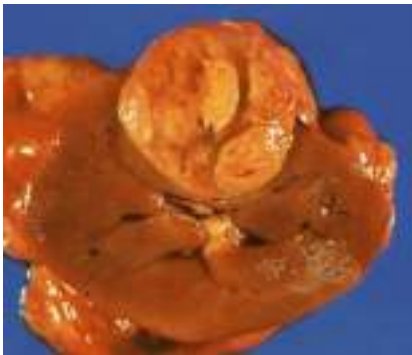
急速凍結までの時間・保管温度のゲノムDNAの品質に対する影響



Biobanking for Data-driven Research of Human Diseases

Yae Kanai, M.D.,Ph.D.

*Department of Pathology, Keio University School of Medicine
Pathology Division and National Cancer Center Biobank,
National Cancer Center Research Institute*



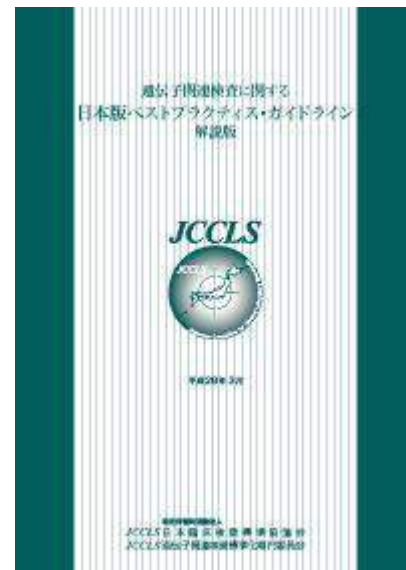
Data-driven type molecular pathological study depends on the quality clinical specimens and detailed and accurate clinicopathological information.

Japanese Society of Laboratory Medicine
Japan Society for Clinical Chemistry

Japanese Committee for Clinical Laboratory Standards

An Approved Guideline for the Quality
Management of Specimens for Molecular Methods

Participation to ISO/TC212



Standardization

Standardization:

ISO15189:

Sixty three clinical laboratories.

10 umbrella organizations of these facilities established biobanks in various contexts.

ISO9001:

Some biobanks or bio-resource facilities.

ISO27001:

Some biobanks or bio-resource facilities

Awareness and need for biobanking standards pushed biobanks and respectively their stakeholders like academia, industry and government into transition to implement applicable standards.

ISO-TC276-WG2 Requirement Matrix

1. Acquisition:
2. Transport:
3. Processing:
4. Testing:
5. Long Term Storage:
6. Sample Recovery:
7. Disposition (including destruction):

- a. The matrix is classified to the detailed points. This could be a merit to the potential users.
- b. The basic concept of this matrix and the attempt in validation of biomarker research seems similar and acceptable.
- c. The end point of this matrix work could be directed to “fit for purpose”.

Summary:

1. AMED ought to be responsible for showing the direction not only for quality management but also for sharing of samples and data.
2. Although providing samples and data to outside third parties, had not been active in the past, recently many funding bodies have encouraged biobanks to provide samples to the outside parties.
3. The quality of samples but also the quality of management systems came under focus.
4. Awareness and need for biobanking standards pushed biobanks and respectively their stakeholders like academia, industry and government into transition to implement applicable standards.
5. We are mostly ready to build up new partnerships in biobanking around the world.