

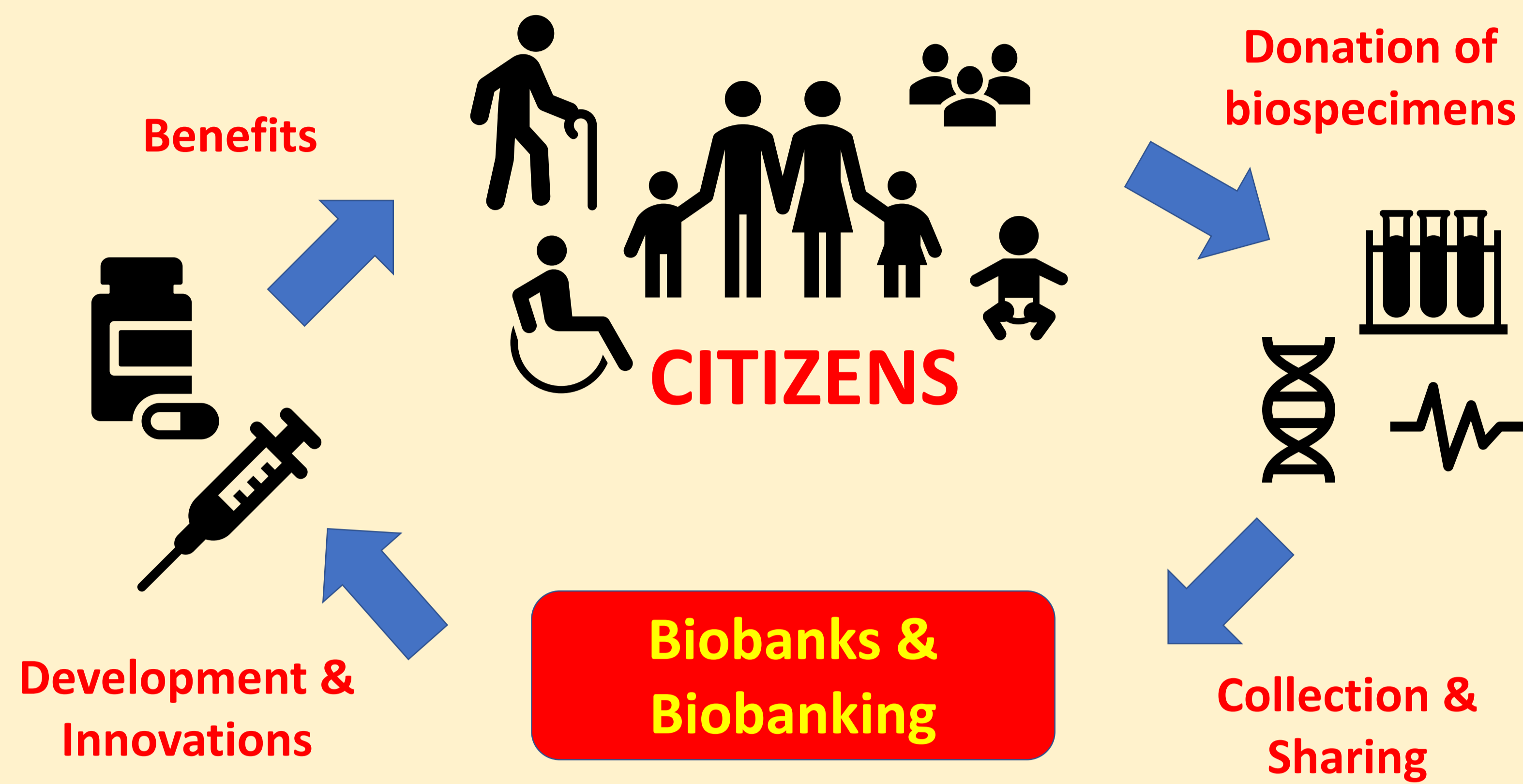
# CIBER: Japanese activity for biobanking sustaining reproducibility

Hiroki Nakae<sup>1</sup>, Junko Ikeda<sup>1</sup>, Koh Furuta<sup>2</sup>

1. Japan Multiplex bio-Analysis Consortium, Tokyo, Japan.
2. Kanagawa Cancer Center Hospital, Yokohama, Japan.

## CIBER's BASIC PRINCIPLES

CIBER has been established to support the social infrastructure (biobanks & biobanking) for the **citizens**.



## REPRODUCIBILITY

ISO standards are the systems to assure that the products and services are produced based on the reproducible data. Newly published ISO 20387 and soon-to-be published TR 22758 will work for the biobanking domains.

ISO 20387:2018




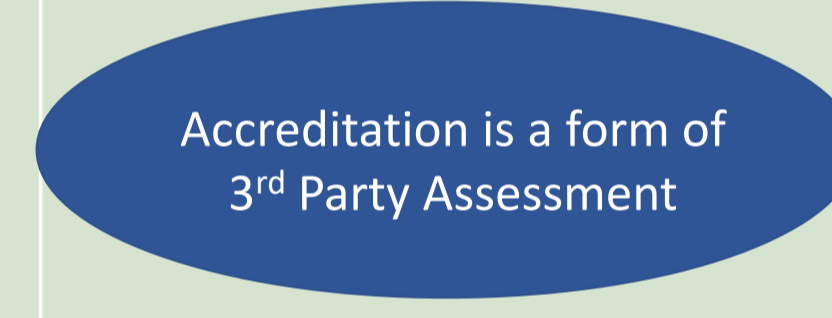
Biotechnology -- Biobanking -- General requirements for biobanking

ISO/AWI TR 22758

Biotechnology -- Biobanking -- Implementation guide for ISO 20387

Toolbox: Conformity Assessment

Slide courtesy of C. Allocca (NIST)

Type	Who performs assessment?	Attestation type?
1 <sup>st</sup> Party: Self-declaration 	Manufacturer or Service Provider (e.g. Biobank)	Self declaration of conformity
2 <sup>nd</sup> Party: Agreement 	Purchaser or client (e.g. Medical researcher)	Contract
3 <sup>rd</sup> Party: Accreditation 	Independent Certification Body, Laboratory, Inspection Body or Accreditation Body	Certificate  

**Neutrality Principle:** Content of standard shall not state a preference for a form or one type of assessment over another

## CIBER PROSPECTUS

The direction of the current medical services in the world is towards the precision medicine based on the genomic medicine. One of the infrastructures of this environment is the storage and/or utilization of bioresources including data. At this point in time, discussions regarding standardization are started in the ISO framework. Some criticized that standardization is negative to progress in technologies. History tells us, however, in some situation standardization may be positive to innovation if direction of standardization is properly placed.

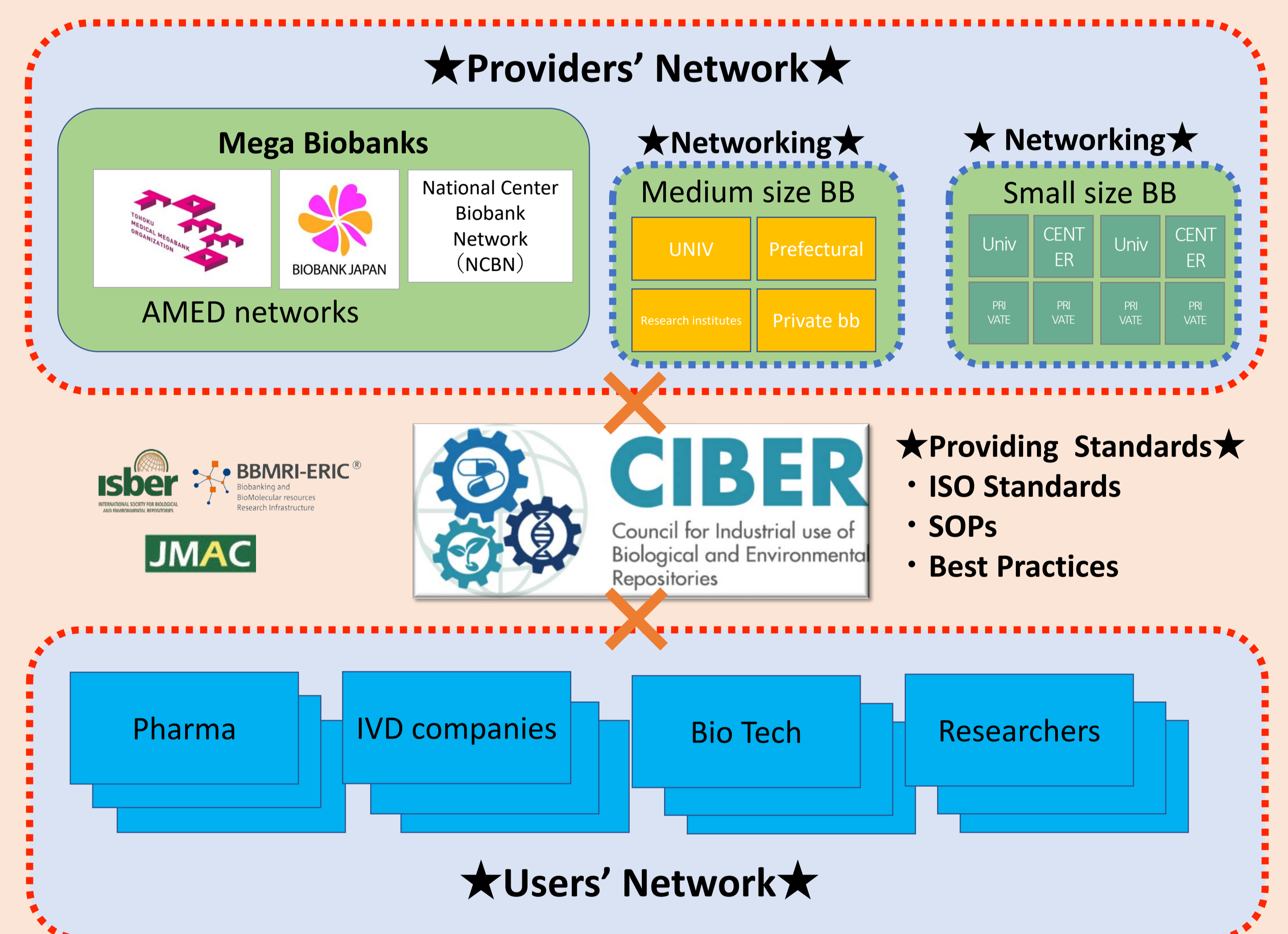
We can say that discussions shall be driven by users of biorepositories, not by providers. History indicates us again that innovations are with users of technologies. Although the precision medicine seems promising, some critics point out that the precision medicine may produce medical divide. One solution to these inputs could be to set up the opened framework of biological and environmental repositories. Considering the roles of biological and environmental repositories, it is urgent for the current generation to prepare and maintain this framework in a sustainable way.

Along with declining birthrate and the following population aging, it is easily assumed that public funds may not afford to provide supports to all the social infrastructures. Under these circumstances, users of biological and environmental repositories as private partners are expected to participate to this framework in a proactive and pre-competitive manner.

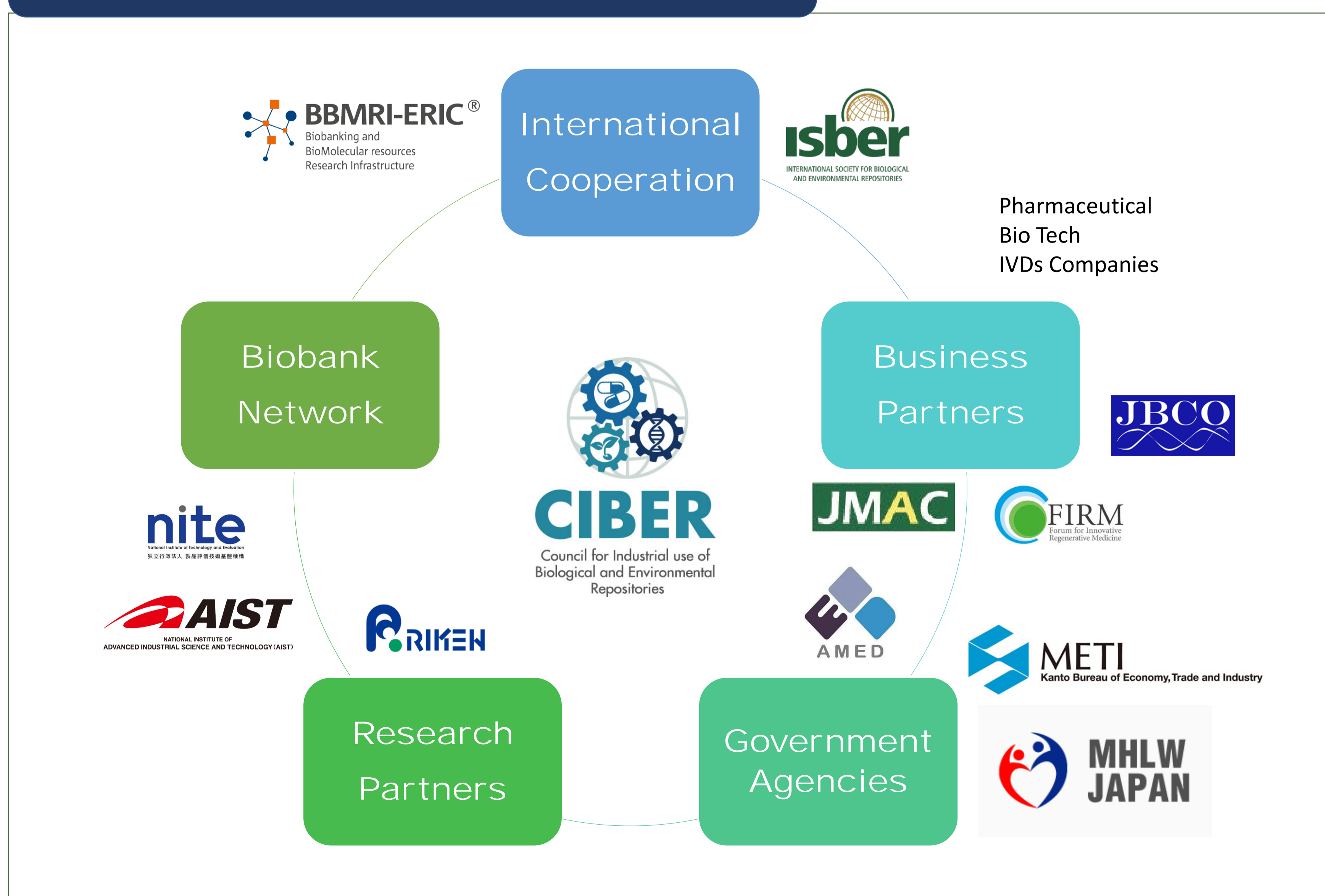
We, mainly users of biological and environmental repositories, decided to network horizontally and further set up a corporation of "Council for Industrial use of Biological and Environmental Repositories (CIBER)" to commit to support a part of roles of medical infrastructure under international standards. Goal of a corporation of "Council for Industrial use of Biological and Environmental Repositories (CIBER)" is to support the social infrastructure without medical divide not only to ourselves but also to our next generations.

2018, January 22  
Founders

## CIBER'S MISSION: CREATING INFRASTRUCTURE



## CIBER NETWORKS



## CONCLUSIONS

The non-profit organization, CIBER, based in Tokyo Japan focuses on:

- to introduce the standardization systems to guarantee the reproducible results for biobank stakeholders & patients.
- to facilitate setting up business models to meet the needs of biobank users/customers.
- to facilitate applying internationally common platforms, standardized methods, and best practices.
- to facilitate setting up conformity assessment eco system including self-assessment, contract, and/or certification/ accreditation.
- to facilitate innovations in the biotechnology field.