Biobanking and bioresources
ISO TC 276/WG2

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Quality is a must

Qualité des échantillons un enjeu majeur pour la recherche

Améliorer la qualité et réduire les coûts

Take home message

Improvements also needed for Research

- In a 2009 NIH survey, researchers from 80% of more than 700 responding laboratories said they struggled to obtain standardized specimens for biomarker research.

  Post G.. Bring on the Biomarkers. Nature 469, 156-157, Jan. 2011

- . . . the cumulative (total) prevalence of irreproducible preclinical research exceeds 50%, resulting in approximately US$28,000,000,000 (US $28B)/year spent on preclinical research that is not reproducible - in the United States alone.

  Freedman LP, Cockburn IM, Simcoe TS (2015) PLoS Biol 13(6): e1002165.doi:10.1371/journal.pbio.1002165

⇨ partly caused by pre-analytical errors and quality of samples

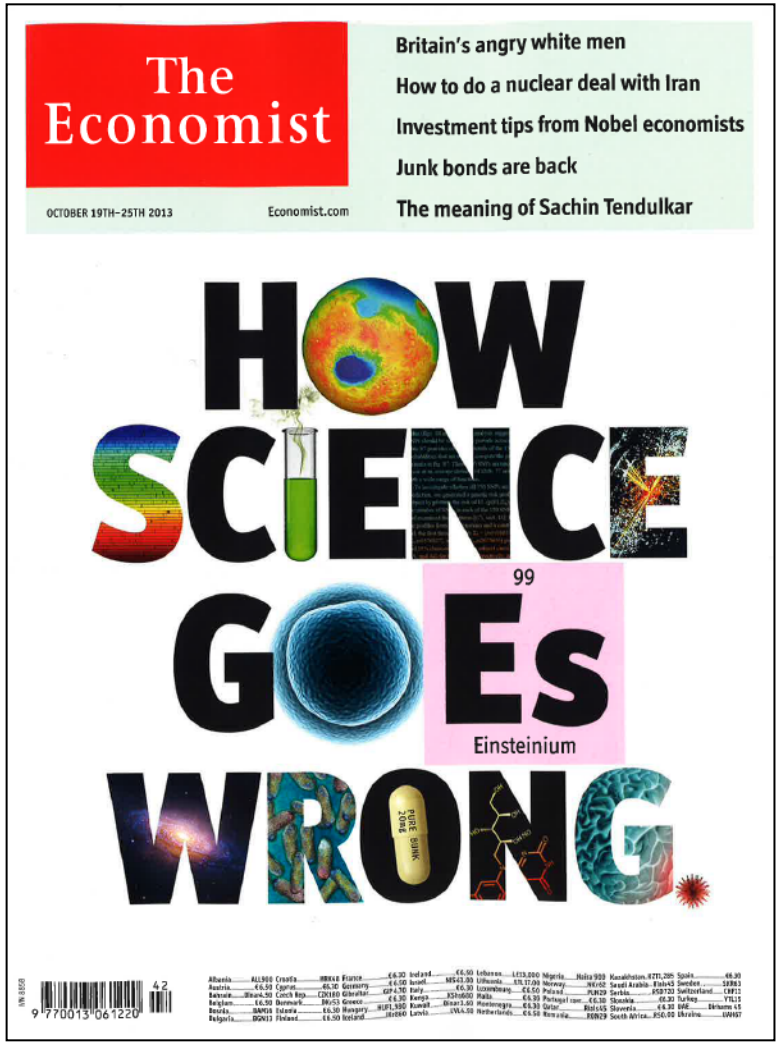
Reproducibility is a complex issue

Quality of samples and solutions is one of the factors

30%

7- 8 B$/year

Lack of Reproducibility of Scientific Studies



Too many of the findings that fill the academic ether are the result of shoddy experiments or poor analysis (see pages 21-24). A rule of thumb among biotechnology venture-capitalists is that half of published research cannot be replicated. Even that may be optimistic. Last year researchers at one biotech firm, Amgen, found they could reproduce just six of 53 "landmark" studies in cancer research. Earlier, a group at Bayer, a drug company, managed to repeat just a quarter of 67 similarly important papers. A leading computer scientist frets that three-quarters of papers in his subfield are bunk. In 2000-10 roughly 80,000 patients took part in clinical trials based on research that was later retracted because of mistakes or improprieties.

Reproducibility in Science Improving the Standard for Basic and Preclinical Research *C.G. Begley, J. P.A. Ioannidis* ***Circ Res****. 2015*

The Increasing Urgency for Standards in Basic Biologic Research *L. P. Freedman and J Inglese,* ***Cancer Res****; 2014*.

Biomedical research: increasing value, reducing waste. *Macleod MR et al.* ***Lancet*** *2014*

Six red flags for suspect work. *Begley CG.* ***Nature****, 2013*

Raise standards for preclinical cancer research. *Begley CG, Ellis LM.* ***Nature*** *2012*.

Believe it or not: how much can we rely on published data on potential drug targets? *F. Prinz et al.* ***Nature Review****, 2011*

Améliorer la qualité et réduire les coûts et garder la confiance du public

Take home message

Une qualité appropriée des ressources biologiques repose sur 3 pillliers

- Contrôle des variables pré-analytiques
- Management qualité
- Contrôle qualité

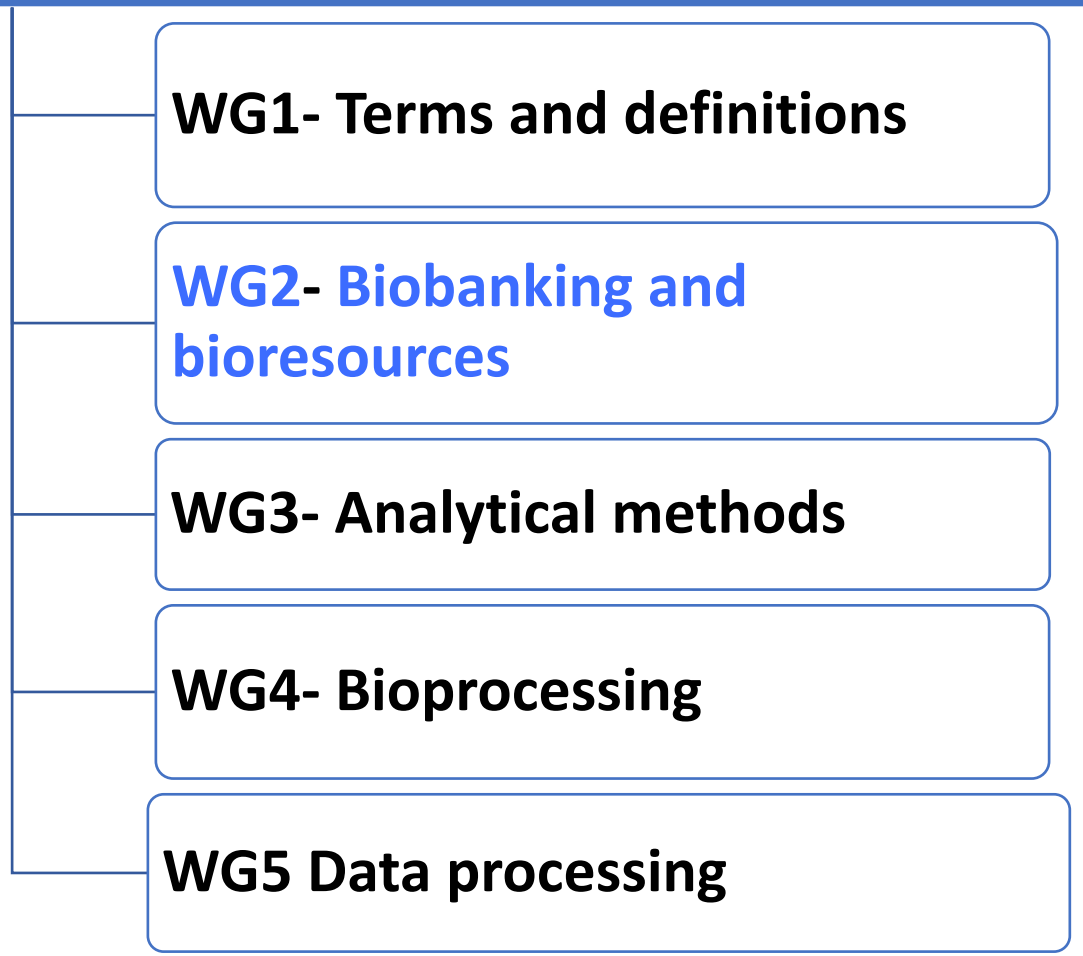
Etat de l’art

- Centaines de SOP
- Plus de 80 guides de bonnes pratiques (OECD, IARC,ISBER…)
- Management qualité: 70 biobanques certifiées en France (NFS 96900): humain, micro & vegetal
- Management qualité: 30 biobanques en Europe (ISO 9001)
- Accreditation of plusieurs biobanques de micro-organismes
- Accreditation de plusieurs biobanques de tissus, ISO 17025 ; ISO 17020, ISO guide 34…
- Accreditation de plusieurs laboratoire d’analyses medicales (ISO 15189)

…La nécessité de définir et **mettre en place** des normes internationales

Several initiatives

ISO/TC 276 *Biotechnology*



80 guides de bonnes pratiques pour les biobanques

Which one is the most appropriate?

80 raisons

un échec annoncé

85% Overlap of the requirements
of 8 international guidelines
items

A set of ISO standards was drafted and is submitted to national mirror committee.

First Draft was discussed in Japan Oct 2015,

second draft in Washington, May 2016

METHODOLOGIE
NORME BIOBANKING

Guidelines:

- OECD
- ISBER
- NCI
- Biobank Quality Standard (UK)
- NF S96-900
- MMI (Ireland)
- Brazilian Standard
- Tissue/cells regulation

ISO Standards:

- ISO 15189
- ISO 17025
- ISO Guide 34
- ISO 17020
- ISO 27799
- ISO 13485

CHAMP D'APPLICATION
SCOPE

The ISO/TC 276/WG2 will elaborate a package of International Standards in the Biobanking field including human, animal, plant and microorganism resources for Research & Development, but excluding clinical diagnosis and therapeutics.

WHAT ARE THE REQUIREMENTS FOR A BIOBANK TO ASSURE AN APPROPRIATE QUALITY OF SAMPLES AND DATA ?

- Introduction
- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 General requirements
- 4.1 General
- 4.2 Impartiality
- 4.3 Confidentiality
- 5 Structural requirements
- 6 Resource requirements
- 6.1 General
- 6.2 Personnel
- 6.2.1 General
- 6.2.2 Personnel competence and competence assessment
- 6.2.3 Personnel training
- 6.3 Infrastructure
- 6.4 Environmental conditions
- 6.5 Control of externally provided processes, products and services
- 6.5.1 General
- 6.5.2 Type and extent of control
- 6.6 Equipment
- 6.7 Principles of access for Provision of Biological Resources
- 7 Process requirements
- 7.1 General
- 7.2 Biological material collection
- 7.2.1 Collection information
- 7.2.2 Pre-analytical steps
- 7.2.3 Collection procedure
- 7.3 Transport
- 7.3.1 Transport from and to the biobank (shipment)
- 7.3.2 Transport within the biobank
- 7.4 Reception and distribution of biological resources
- 7.4 Reception and distribution of biological resources
- 7.4.1 Reception of biological resources (accession/logging procedure)
- 7.4.2 Distribution of biological resources
- 7.5 Traceability of biological resources
- 7.6 Preservation and storage of biological material
- 7.7 Quality control of biological material and data
- 7.7.1 General
- 7.7.2 Process-related quality control
- 7.7.3 Data specific quality control
- 7.8 Validation and verification of methods
- 7.8.1 General
- 7.8.2 Validation
- 7.8.3 Verification
- 7.9 Information and data management
- 7.10 Nonconforming outputs
- 7.10.1 General
- 7.10.2 Control of nonconforming output
- 7.11 Complaints
- 8 Management requirements
- 8.1 Options
- 8.1.1 General
- 8.1.2 Option A
- 8.1.3 Option B
- 8.2 Management system documentation (Option A)
- 8.3 Control of management system documents (Option A)
- 8.4 Control of records (Option A)
- 8.5 Actions to address risks and opportunities (Option A)
- 8.6 Improvement (Option A)
- 8.7 Corrective action (Option A)
- 8.8 Internal audits (Option A)
- 8.9 Management reviews (Option A)
- Annex A (normative) Documentation requirements
- Annex B (informative) Implementation guidance for Annex A

3 pilliers

- Compétence du personnel
- Validation de méthode
- Contrôle qualité

- Management qualité

ISO/AWI 20387 :
General requirements for biobanking (V. 19)
Requis généraux pour le biobanking

- Plus de 12 réunions face à face
- 5 enquêtes pour le recueil de commentaires
- Plus de 1100 commentaires reçus et traités
- Interaction avec ISO TC 212

- Enquête publique : recueil de commentaires pour une discussion à Rome, nov 2017.

- Guide d'implémentation de la norme pour le biobanking ISO 20387
  - Rédaction en cours (7 chapitres sur 8)

Débats, rumeurs et défis

- Aucune norme ISO n’est obligatoire
- Elle ne sera pas transcrite en norme française : ISO 9001, NFS 96 900, ISO 20 387, ISO 17 020, ISO 15 189, ou aucune norme

- Le Comité international n’a pas défini les indicateurs pour les audits, ni leur seuil.

- La démarche pas à pas est favorisé dans tous les pays

- Nécessité de trouver les moyens financiers nécessaires à son déploiement