Comments on the WMA Declaration on Health Databanks and Biobanks

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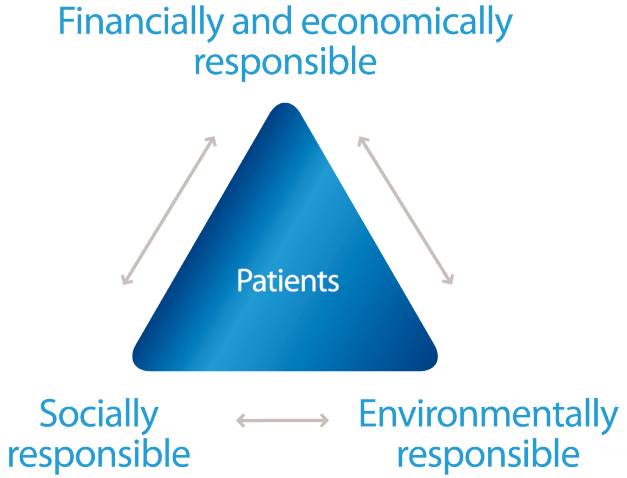
About Novo Nordisk

- Global healthcare company
- Headquartered in Denmark
- 90 years innovation and leadership in diabetes care
- Leading positions in haemophilia, growth hormone and hormone replacement
- 39,000 staff in 75 countries
- Products used in >180 countries
- Bioethics central to the *Novo Nordisk Way*
- Uses human biosamples and data daily in our R&D

changing the future of diabetes

changing possibilities in haemophilia



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The positives

- Creates a bioethics framework that can act as the foundation for internationally harmonised policies and legislation relating to biobanks and databanks
- Recognises that biobanks and databanks are distinct from regular clinical research
- Addresses that the Declaration of Helsinki alone does not cover all the issues
- Can address the impact of local, varying, inconsistent and often incompatible policies and legislation that exists from country-to-country

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The positives

- Could afford citizens across the world a consistent level of protection and opportunity to participate in, and benefit from, research using donated biosamples and/or health data
- Could facilitate research collaboration beyond national borders – larger more powerful studies, better uses of resources, broader applicability of research findings, …
- Recognises the validity of "broad consent"
- The document provides flexibility and scope of interpretation

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Some negatives

- The document lacks specificity and is too open to interpretation
  - Potential to diverge policy and legislation rather than converge and harmonise
  - Definitions required
  - Accompanying commentary or interpretation guide required

- May over limit research whilst aiming to address "*major risk scenarios*" of "*commercial, administrative or political use…*"

- The scope of applicability is not clear
  - What types of biobanks and databanks are in scope?
  - Secondary uses of primary health data and biosamples?
  - Databanks and biobanks primarily created for research?
  - Only databanks and biobanks where the data/biosamples are identifiable?

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Some negatives

- Anonymous – non-identifiable – pseudo-anonymous - identifiable – linked-anonymous – de-identified – identified
  - Which are covered?
  - How defined?

- Consent – specific – broad – conditional broad – blanket – open
  - Information is the key and autonomy should allow donors to agree to whatever they wish
  - Information + opt out maybe as valid
  - Where concerns about provision of adequate information, can be counterbalanced by the need for ethics review of the intended uses

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Some negatives

- Emphasis on the need for consent and autonomy overbalanced in comparison with other bioethics principles of beneficence and justice

- The narrow waiver of consent provision could close the door on beneficial research using legacy healthcare data and biosample collections
  - Retrospective consent can be impracticable, unwarranted, unnecessarily distressing, not affordable……
  - Routine "*front-door consent*" - neither warranted nor affordable and provides a false promise scenario
  - Prevention of research will necessitate accumulating equivalent data / biosamples prospectively *with* consent, which may take many years if even possible, delaying or preventing benefit

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Some negatives

- A balance between consent and donor protection by ethics review/approval can be better achieved
  - Declaration of Helsinki, para 32 – "… *situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.*"

- Maintenance of this position is strongly recommended

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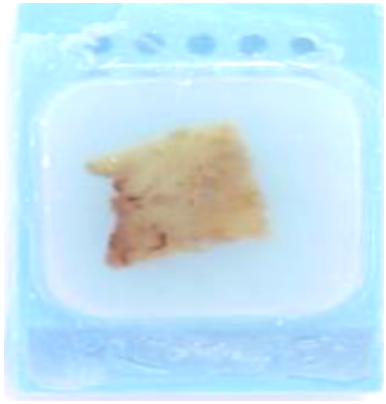
Biosamples are data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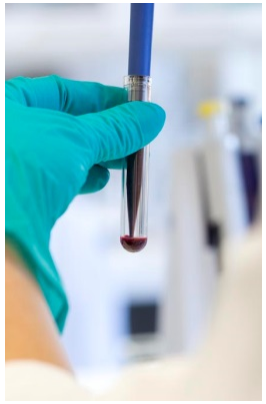
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- In governance terms, management of samples should be similar to management of sensitive personal (health) data.
- Biobanking is a form of Data Processing.
- Biobanks are Databanks.

Concluding remarks

- Potential impact
- With regard to research for the benefit of the public
  - Beneficence
  - Non-maleficence
  - Justice
  - Autonomy
- Clarity, proportionality, practicality and affordability

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ISBER: Goals of the Society

- Disseminate information on **repository management** issues
- **Educate and share** information and tools within the society and with stakeholders
- Act as the voice for repositories to **influence regulations and policy**
- Develop **best practice guidelines**
- Provide **centralized information** about existing repositories
- Bring members together to work on **emerging issues**

ISBER: The International Voice for Repositories on Science Policy Issues

Through its ISBER Science Policy Committee,ISBER serves as the international voice for repositories on science policy issues by:

- Communicating with and soliciting input from ISBER members on emerging science policy issues that may affect the biorepository community
- Providing input on numerous national and international policy documents
- Submitted comments on WMA Draft Declaration on Ethical Considerations Regarding Health Databases and Biobanks
- See: http://c.ymcdn.com/sites/www.isber.org/resource/resmgr/documents/2015.06.11_ISBER_Comments-WM.pdf