Status Report Iceland

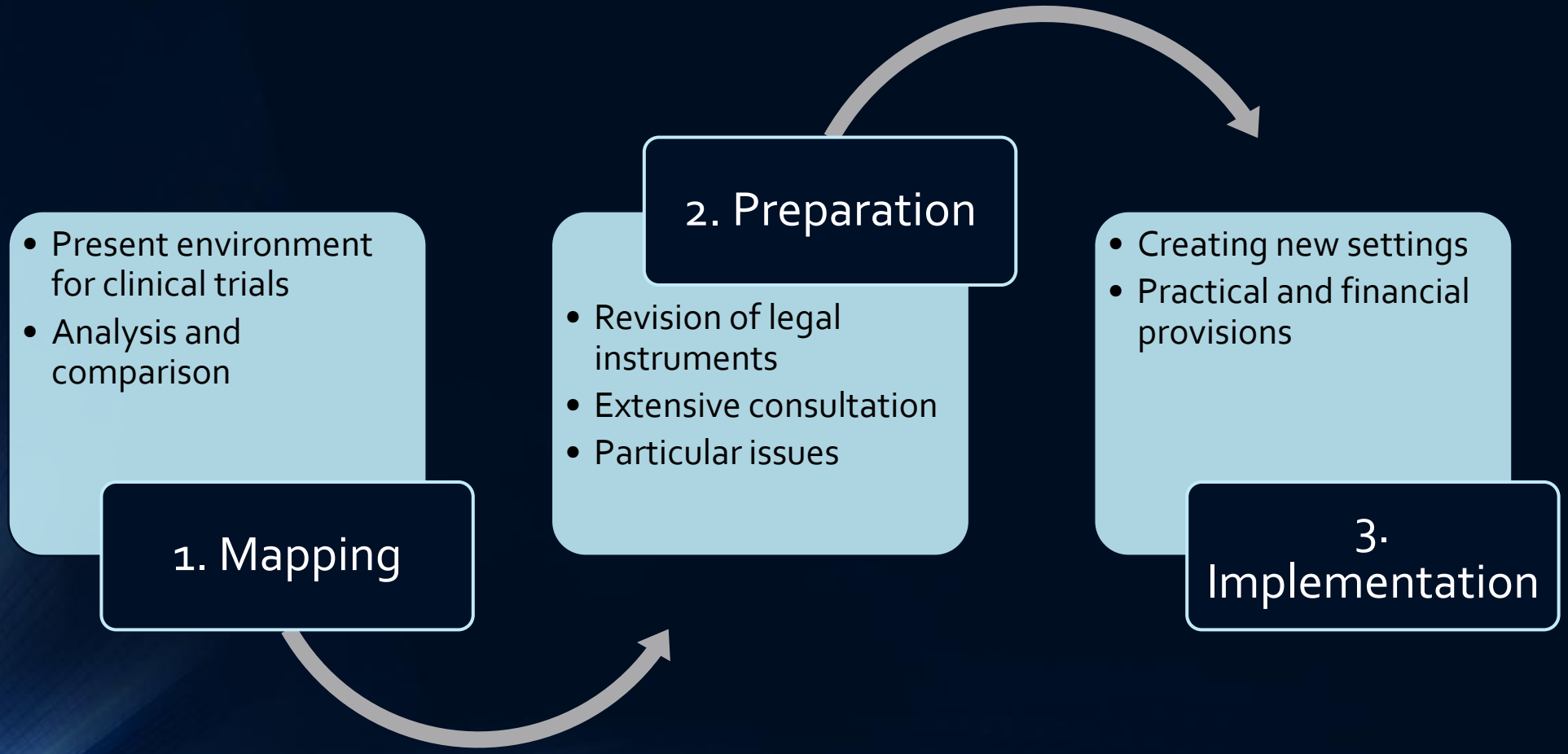
EIRÍKUR BALDURSSON
NATIONAL BIOETHICS COMMITTEE, ICELAND

The Project: Implementing Reg no 536/2014

- Mapping: External expert hired to lay the groundwork (10/2016)
- Preparation: Extensive consultation, preparation for amendment of legal provisions, taking note of particular issues (autumn 2017)
- Implementation: New/changed setting for assessment (part 1 and 2) and introduction of practical arrangements (early 2018)

- Assessment in 3-5 years

EU Regulation 536/2014 in Iceland



Step 1 Mapping:
Present legal environment for clinical trials

- Icelandic legislation on drugs and attached regulations including the clinical pharmaceutical trials regulation which implements the present EU directive
- Law on scientific research within the health sector (44/2014)
- Data protection and the handling of sensitive personal information (77/2000) and 8 attached regulations and the pending new EU regulation
- Biobanks and corresponding collections of health data (110/2000 and as amended)
- Collections of medical records kept by the Surgeon General
- Medical records at hospitals, provisions on stem cell research, etc.

Step 1 Mapping:
Analysis and comparison

- Legal obligations with a view to the EEA-Agreement
- What are the major differences between our present environment and the new EU Regulation on clinical trials and on protection of personal integrity
- What can be maintained in the present legal provisions
- What has to be changed
- Few clinical trials
- Limited manpower
- It is absolutely vital to be able to participate in this work

Step 2: Preparation

- The present regulatory framework for clinical trials will be changed towards a more firm and binding obligations
- The entry into force of the new Regulation on personal integrity and data protection
- There is also a need for amending the law on scientific research within the health sector (44/2014) for other reasons
- There is a need for streamlining the division of labour between the NBC, IMA and DPI
- All this needs extensive consultation and collaboration between the authorities, scientific and medical community and industry

Step 2: Preparation - cont

- Particular situation must be taken into account:
  - The pool of scientific manpower is limited
  - Independence of NBC´s members
  - The size of society and industry
  - Personal integrity
  - Defining research sites in order to avoid compromising the integrity of Committee members
  - Procedures for ensuring adequate competence of the NBC, with a view to protocols with differences in the study populations (children, pregnant women, etc)

Step 2: Preparation - cont

- Research without a financially strong sponsor:
  - Academic research
  - Studies with research training of students
- Streamlining collaboration between NBC, DPI and IMA
- Interface towards the EU-portal and committees

- Necessitates Nordic and international collaboration

Step 3: Implementation

- Creating new settings: Proposals for amending legal instruments will be presented to the Parliament towards the end of the year (exp)
- Practical solutions for the committee work and collaboration within the country will be introduced early 2018
- Preliminary proposals for financial provisions need to be presented before the summer
- Assessment in 3-5 years time