WMA Conference
on the Revision of the Declaration of Helsinki
- focused on research in resource-poor settings -
18-19 January 2024
Vatican City

POST-TRIAL ACCESS
AND THE DECLARATION OF HELSINKI
Clinical Researcher's & Patients' View

Prof. Jozef Glasa, MD, PhD[2]

DCP FM & IHCE FNPHS SMU in Bratislava (Slovakia)
EF GCP, EUPATI, CDBIO, PAL, EACPT

1

Conflict of Interest Declaration

Nothing to declare.

N.B.

A strong, long-lasting professional and personal ***interest*** in the topics covered in this presentation.

2

Overview

- definitions
- evolution of DoH language (1964 – 2013)
- scope of the post-trial access
- stakeholders in the post-trial access
- benefits/risks/burdens of a subject's participation in biomedical research/clinical trials
  (in low resource settings)
- benefits/burdens/risks of a physician's/other health professional's participation in biomedical research/clinical trials
  (in low resource settings)
- responsible (bio)medicine
- conclusions

3

Post-trial access, Low-resource settings research
Definitions

- **post-trial access – access to IMP** (*investigational medicinal product*) to the subjects after completion of their participation in a clinical trial (research)
- **post-trial access provision** - two main options:
  - ✓ ***open-label extension trials***: extensions of the original clinical trial, where patients who participated in the trial are given continued access to the IMP under an open-label condition
  - ✓ ***expanded access programs***: separate programs that provide access to the IMP outside of the clinical trial setting, typically to patients who do not meet the inclusion criteria for the trial but have a serious or life-threatening condition for which there is no other satisfactory treatment
- **low-resource settings research:** research conducted in regions, where inadequate healthcare resources exist and the healthcare system does not meet the acceptable global standards

4

Evolution of DoH language (1964 – 2013)

- **2000 (Edinburgh)**
  - **8.** Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized.
  - **30.** At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.
- **2004 (Tokyo)**
  - [2]***Note of clarification on paragraph 30 of the WMA Declaration of Helsinki.***
    The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.
- **2008 (Seoul)**
  - **17.** Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

5

Evolution of DoH language (1964 – 2013)

- **2008 (Seoul)**
  - **17.** Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.
  - **33.** At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.
- **2013 (Fortaleza)**
  - **13.** Groups that are underrepresented in medical research should be provided appropriate access to participation in research.
  - **19.** Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection.
  - **20.** Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.
  - **34.** In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

6

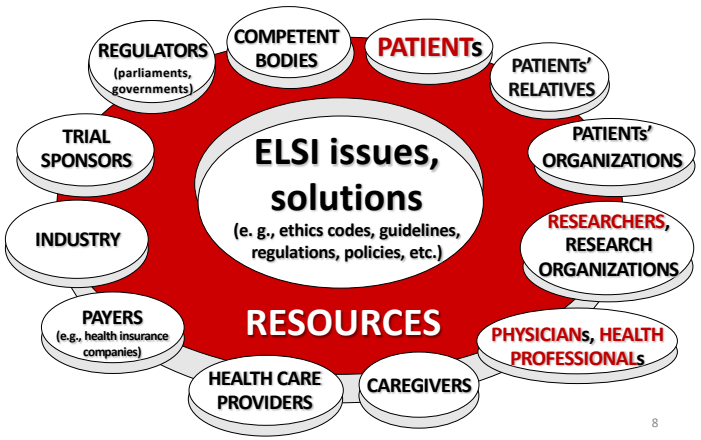
Scope of the post-trial access

- scope of what goes to the trial: **HEALTH TECHNOLOGIES**
  - ► medicaments, medical devices, in vitro diagnostics
  - ► other, e.g., IT, AI applications, telemedicine, digital health, nursing procedures, novel diets, new materials, instruments, appliances, etc.
  - → scope of the post-trial access

7

Stakeholders in the post-trial access

[(unmet) needs, benefits, burdens, risks, harms, damages, competing) interests, conflicts, etc.]



8

Advantages and Disadvantages of Post-Trial Access Solutions

Criterion	Open-label extension trials	Expanded access programs
Definition	An extension of a clinical trial in which all participants receive the investigational medicine product (IMP), usually after the placebo-controlled phase was completed.	A program that provides access to an IMP to patients who do not qualify for a clinical trial or have completed a trial.
Advantages for sponsors	Enables collection of long-term safety and efficacy data, can potentially lead to FDA/EMA approval, helps to retain participants in the study.	Provides an alternative mechanism for patients who do not qualify for a clinical trial, generates real-world safety and efficacy data, and can build goodwill with patient communities.
Advantages for patients	Provides access to an IMP, which may have benefits for their health, and ensures continued monitoring and follow-up.	Provides access to an IMP, which may have benefits for their health, and allows patients to contribute to research efforts.
Disadvantages for sponsors	May be costly and time-consuming to conduct and may not always lead to regulatory approval or iincreased market share.	May be logistically challenging to set up and manage, may not be financially sustainable, and may generate data that is difficult to interpret.
Disadvantages for patients	Patient may be required to continue to comply with the study protocol, which may include frequent visits to the study site/and or regular monitoring, and they may not have access to the IMP after the study ends.	Patients may not qualify for this program, and even if they do, there is no guarantee that the IMP will have benefits for their health.

According to Volkov D. (2023) https://www.linkedin.com/pulse/choosing-right-path-key-considerations-sponsors-access-den-volkov/

9

Responsible (bio) medicine

- **responsibility to**:
  - **patient**, his/her relatives, friends, 'important ones',…
  - **society** (incl. future generations and the 'Mankind')
  - environment (incl. biodiversity,…)
  - own **profession** (professional standards, ethics…)
- **efficacy**, **safety**, **effectiveness,** sustainability, accessibility, affordability, etc.
- 'old' and 'new' **roles** and **goals** in community and society
- **ethical-moral, social values** – protection, development
- **misuse/abuse** – prevention, detection, adequate addressing

10

10

How to become, in a *personal* (and *institutional*) manner, the „Good Samaritans“, bringing and adequate help, treatment, and care to the needy ones in our very complex, dynamically developing (or degenerating (?)) World ?

Giordano, Luca (1632-1705) ***The Good Samaritan***, *1685, Musée des Beaux-Arts, Rouen*

11

11

Conclusions

- in post-trial access solutions, the present scope of health technologies tested should be considered (incl. the applicable results of HTA – Health Technology Assessment)
- in post-trial access solutions, the needs, rights, legitimate interests of all relevant stakeholders should be considered and appropriately balanced
- in addressing post-trial access issues, effective procedures should be put in place to enable adequate dialogue and solutions finding process involving, without unjust discrimination, all the respective stakeholders
- the roles of research ethics committees and of the national competent authorities in dealing with the post-trial access issues should be strengthened and enabled
- the development and implementation of adequate national legislation and guidance on post-trial access should be encouraged, promoted (and required) worldwide, with a special attention to vulnerable and disadvantaged individuals, groups and communities, and to the low resource settings

12

Thank you for your attention!

13