



QENDRA SPITALORE UNIVERSITARE  
"NËNË TEREZA"



# ALBANIAN NETWORK FOR CLINICAL PEDIATRIC TRIALS

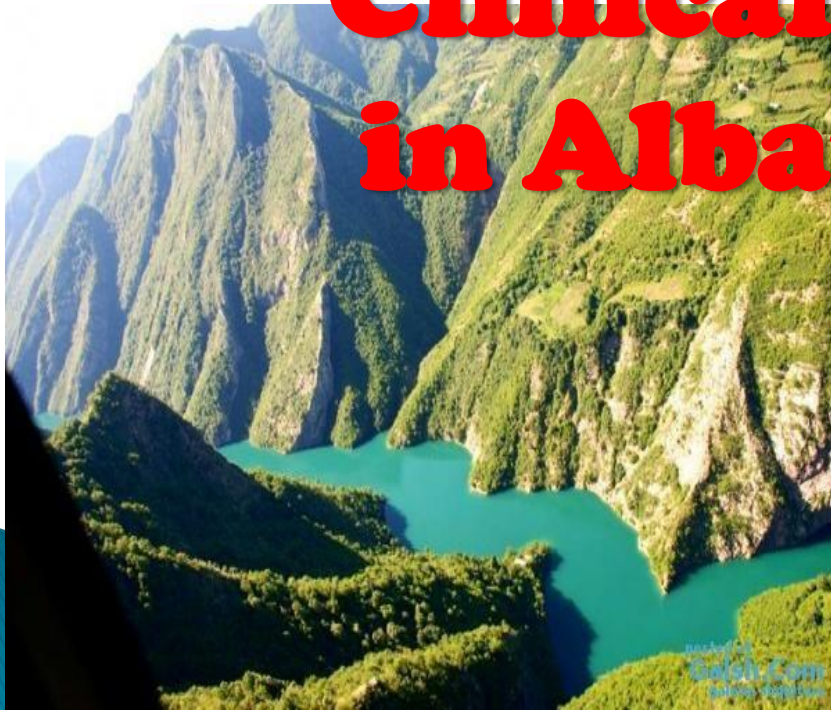
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European Network of Excellence for Paediatric Clinical Research



# **Pediatric Clinical Research in Albania**





# Pediatric C R in Albania

- Some historical data
- The Changes in the recent years
- Actual difficulties in pediatric CT
- Some different facilities
- Our challenges for the future



Population : 3 ml

Pediatric age : 1 ml

Inf. Mortality - 8 ‰

No birth- 36 000/yr

Survival - 75 yrs

GDP (health) - 3 %

GDP (science) - 0.6%

# Pediatric CR in Albania

- ▶ We have not long experience regarding the pediatric CT.
- ▶ On the contrary, we can define our experience like a new mentality, of the last 10 years .
- ▶ This because of different difficulties of a small country in long transition, toward a regime very different from the former
- ▶ Meanwhile, the community of pediatricians is very committed and determined to have her place in the European space.



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## FLETORJA ZYRTARE E REPUBLIKËS SË SHQIPËRISË

Botim i Qendrës së Botimeve Zyrtare

Viti:

Numbri:

### The Albanian Clinical Trial Regulation (2011):



first step in fostering clinical research and innovation



To provide an overview of the Clinical Trial Regulation  
in Albania

# Content . . .

- ▶ Law on Medicines and Pharmaceuticals Service;
- ▶ New National Committee of Medical Ethics;
- ▶ Law on Mental Health;
- ▶ Law on the Transplants of Tissues, Cells and Organs;
- ▶ Law on Reproductive Health;
- ▶ Law on Medical Devices.



# Albanian legislation on medicines and pharmaceutical service (law nr 215 - 2014)

- Medicines at experimental phase;
- Clinical trials;
- Good clinical practice;;
- Protocols;
- Committee of Medical Ethics

Article 22 -  
clinical trail

Article 23-  
human rights

Article 24 - CT  
in children



# Clinical trials . . . 2014

- ✓ Use of medicines on humans for the discovery or verification of clinical, pharmacological and other various pharmacodynamical effects;
- ✓ Study of any adverse effects of medicines;
- ✓ Study on the absorption, metabolism and elimination of medicines, aiming at their safety and efficacy;
- ✓ CT should take place at health care institutions (inpatient services), fulfilling predetermined criteria.





# Human rights

- The interest of the person submitted to clinical trials prevails on any interest of the science or the society.
- Special provisions on the protection of the rights of persons submitted to clinical trials:
  - ✓ children
  - ✓ adults
  - ✓ disabled persons



**Law No.10 454, date 21.7.2011**

## **Law on Mental Health**



- Scientific and medical research involving persons having mental disorders;
- Informed consent;
- Such research does not apply to persons under involuntary treatment for any mental health disorders, or persons that don't have the power to exercise the legal rights and obligations.



**Law No.10 454, - 21.7.2011**

# **Transplants of Tissues, Cells and Organs**

- The transplant of brain and gonads is forbidden;
- The genetic manipulation of embryos, including such actions for any purpose of transplants, is forbidden.





Law No.8876,

## On Reproductive Health

- The use of the human embryos for any other commercial or industrial and experimental purpose is forbidden;
- Sex selection during the use of assisted reproductive technologies is not allowed, except cases of the possible genetically transmitted diseases linked to sex.



# Law No. 89/2014 On Medical Devices



The clinical investigation aims at:

- a) Verifying that in normal conditions of use, the functioning of the devices achieves the effectiveness as developed by the producer;
- b) Identifying any adverse effects of the devices, in normal conditions of their use;
- a) Evaluating whether the devices represent any risks if used not in compliance with their predetermined functions;

**Low 105 - Article 26 - 15. 07 . 2015**

# **National Committee of Medical Ethics Reorganized and restructured**



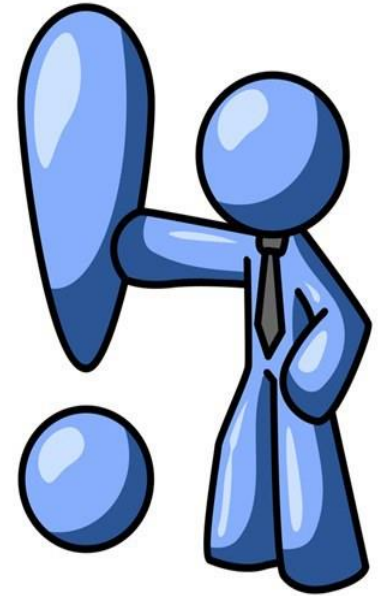
- An independent professional body;
- Guarantees for the protection of the rights of people involved in clinical trials.
- Entitled to propose and take over initiatives and actions on specific issues of medical bioethics.





# Conclusions

- ➡ Some aspects of the clinical research are regulated by the Albanian legislation.
- ➡ At any case, there are clear provisions on the protection of the rights of persons submitted to clinical trials.
- ➡ The existence of a professional independent oversight body guarantees scientific-based and law-abiding procedures.



# Shortcomings to face regarding CT

- ✗ lack of the appropriate and necessary infrastructure
- ✗ The new EC , very well organized and structured (on paper) it is not yet operational. Actually this does not encourage, but blocs the CT
- ✗ Insufficient budget for the researches
- ✗ Big differences regarding health level and of course research 's opportunities between the country's regions.



# Shortcomings to face regarding CT



- ✗ Lack of methodical experience
- ✗ No good cooperation between MOH and MESH, in order to identify the priority needs and health problems , becoming so an disadvantage regarding CT
- ✗ Lack of cooperation between regions and the leading scientific center in Tirana, to identify problematic areas requiring priority scientific insights
- ✗ No good collaboration between APS and MOH
- ✗ Lack of cooperation between sectors of pharmacovigilance ect and researchers





## But . . Some offered Facilities, our good points

- ➡ Human resources regarding CT, are, relatively, on a good level
- ➡ UHC “Mother Theresa” being the unique third center in Albania, centralize and leads all the possibilities and the opportunities regarding CT. This facilitates a lot.
- ➡ UMT and FM , in close collaboration with UHC , actually , are the real leaders regarding the three attributes : clinical, academic and scientific. This is a real benefit for the quality of CT

*I propose, if it is possible, to consider the membership of UMT and FM in the TEDDY network. We must correct their absence*

# Challenges in the future - to improve the role of Albanian universities in the clinical trials

## Lessons from History:

- ☑ At the heart of any university lies a vision to create, advance, disseminate and apply knowledge through education, learning and research to benefit society.
- ☑ Leading research universities play a major role in the intellectual, cultural and economic life
- ☑ in knowledge-based societies, research is increasingly becoming the basic determinant of growth and prosperity.

# Challenge : Evaluating Impact

- ➔ Evaluating and quantifying some aspects of the impact of research is not an easy task
- ➔ Research projects may have a broad range of impacts, and these can be difficult, if not impossible, to predict at the outset.
- ➔ Too narrow a concept of what constitutes 'impact' risks overlooking the unexpected or longer-term outcomes of research.
- ➔ Excellence in research requires considerable and sustained investment





# University Environment and Research

- ➡ It is hard, it is costly, it takes time
- ➡ Universities need to 'skill up' internally
- ➡ universities need a supportive environment that fosters intellectual curiosity and creative thinking.
- ➡ Investment is required on designing and implementing Research Environment changes.



# Research and Fundraising in UMT - a Public University

- ➡ There is also a resistance to fundraising
- ➡ getting started with fundraising is often the hardest job of all; it requires the devotion of considerable time and resources before results are visible.
- ➡ UMT no experience in the area.
- ➡ A minimum period of 2-3 years seems to be required, together with appropriate financial and human support.




# Necessity of PT

- ➔ A better public awareness of the need for research in children would increase the level of parental commitment for the participation of children in trials
- ➔ Media can be an important factor and actor to raise awareness of the benefits of CT
- ➔ We must realize events for more information and awareness of young professionals, but also of health institutions and sectors being involved in PT, because we need the support of all of them



CHALLENGE

  
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