§ Enhance Pediatric Clinical Trials Quality and Availability §

How can **European Regulatory Frameworks** Incorporate **Mental Health Protecting Policies** for Patients to **Mitigate Disparities Between Member States?**

INTRODUCTION

- Paediatric clinical trials are essential due to children's unique physiological and psychological needs when compared to adults.
- SafeCT is an EU-led project uniting 30 countries to jointly improve clinical trial safety.

Key **Challenges:**

- Complexity and high risk and responsibility (Bavdekar, 2013).
- Varying national practices: some states use broad ethical review, others only limited review.
- Lack of adequate focus on psychological burden, risking underprotection of child participants and family.

METHODS

Qualitative research: 2 expert interviews.
Aim: explore mental health policies in EU paediatric trial regulation.
Ethics: informed consent, confidentiality.

RESULTS

Regulations:

- Harmonized via CTR 536/2014, PIPs, ICH guidelines.
- Strong physical safety standards, but psychological protection is lacking **(vulnerable groups).**

Mental health:

- Not formally included.
- Viewed as under-prioritized.
- Only addressed if symptoms appear as adverse events.

Ethics:

- Emphasis on informed consent, physician's role, ethics committees.
- Participation allowed post-adult trials.
- Different level of ethical review per member state creates disparities

Accessibility:

- Low paediatric trial rates (~6%) .
- Physicians key in informing families.
- Registries (CTIS, ClinicalTrials.gov) support transparency.

Finance:

- Industry-funded, Contract Research Organisations manage ~70–80% of costs.
- Insurance, site reimbursement, documentation covered.
- Physician compensation framed as reimbursement, not incentive

CONCLUSIONS

Incorporating mental health, that is currently overlooked in the paediatric clinical trials regulations, would enhance their quality and make it more attractive for public.

RECOMMENDATIONS

SafeCT Collaboration:

- Establish psychological advisory committees to assess the psychological burden of trials.
- Tailor mental health support before, during, and after treatment.
- Enhance cost-efficiency by applying psychological oversight only when necessary, ensuring trial integrity.

Clinician Education:

- Recognize the importance of psychological care, equal to physical safety.
- Encourage transparency about physical and psychological safety with parents.

Public Education:

- Promote public awareness of safety regulations (psychological and physical) through EU-wide efforts.
- Combat the "guinea pig" effect by addressing both mental and physical needs, showing care for the holistic well-being of participants.

Guidelines:

- Incorporate psychological assessments in application guidelines for regulations.
- Provide clearer guidance for assessing "minimal risk" and "minimal burden" of psychological well-being.

Practical Models:

- Use digital platforms (e.g., eSCCIP) for scalable, remote psychosocial support with minimal staff training (Wiener et. al., 2020).
- Adopt a tiered approach to psychosocial care: emotional check-ins for low-risk studies and comprehensive evaluations for high-risk studies.

Affordability:

- Balance trial affordability and market competitiveness with ethical integrity and safety.
- Address potential exploitation in countries with limited ethical review and emphasize comprehensive ethical safeguards.

References

Bavdekar, S. (2013). Paediatric clinical trials. *Perspectives in Clinical Research*, *4*(1), 89. https://doi.org/10.4103/2229-3485.106403

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