

**From GMP to GBP –
Fostering Good Bioethics Practices
Among the European Biotechnology
Industry
Final Conference
“Bioethical Guidelines and Recommendations”**

Anne Dupraz Poiseau, Ph.D.

dupraz@voisinconsulting.com

Voisin Consulting – France Biotech

Clinical Trials Frameworks, Issues and Recommendations

- Harmonised legislative & regulatory frameworks paramount for patient safety, however:
- Divergent national interpretation of IMP
- Different national vigilance requirements
 - Reporting of SUSARs occurring in the targeted country or of all IMP related SUSARs, blinded or unblinded?
- Divergence in national requirements: substantial vs non substantial amendments

Clinical Trials Frameworks, Issues and Recommendations

- Investigator sponsored trial : Cost-effective monitoring strategies adapted to the context of non-commercial research should be evaluated, then implemented; need to strengthen the capacity of public institutions to act as a public sponsor in national and in EU studies
- Role and limits of the Legal representative responsibilities still need to be better defined

Clinical Trials Frameworks, Issues and Recommendations

- Clinical Trial on ATMP
- Recital (16) of ATMP Regulation:
 - *“Directive 2005/28/EC laying down principles and detailed guidelines for GCP as regards IMP for human use should be adapted by laying down rules tailored to fully take into account the specific technical characteristics of advanced therapy medicinal products”.*

Clinical Trials Frameworks, Issues and Recommendations

- New technology related risks often difficult to assess, in particular the long term impact or environmental impact in case of gene therapy products
- Design of the study : difficulties in having double blinded CT : moving toward evaluator blinded CT?
- Non reversible treatment : how to properly define “first-in-man” requirements?
- Efficacy of treatment highly dependent on surgical act: how to obtain adequate control of the practices?

Clinical Trials Frameworks, Issues and Recommendations

- A lot of ATMP are not “ready-to-use products”: require preparation just before use (defreezing of the cells and resuspension) : how to control these manufacturing steps? Should each hospital have a certified GMP/GTP laboratory?
- Specific concerns for autologous cell based products: difficulties in having GMP compliant investigational products in the first in man clinical studies; how to validate first three batches?

Clinical Trials Frameworks, Issues and Recommendations

- Should the biopsy procurement be considered within the CT framework or not? Biovigilance /Pharmacovigilance?
- Importance of traceability: need to properly define responsibilities, patient follow-up after completion of clinical trial for safety & data collection, cross reference to DG Sanco blood / tissue & cells directive (2004/23/EC)
- Ethical issues raised with embryonic stem cell donation?
- Ethical issues raised with pediatric ATMP

Clinical Trials Frameworks, Issues and Recommendations

- Recommendation:
- All stakeholders involved in such research should be properly trained : Investigators, Regulators, Ethic Committees and Sponsors

• Thank you!