CAT Stakeholders Workshop

Focus group: Incentives for Academia, hospitals and charities

Optimising resources

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Agenda

-Optimising resources: is it possible to have one set of data for different procedures?

-Can criteria for assessment of data follow the same rationale during the entire product development?

Optimising resources

-<u>Several type of Meetings and Dossiers</u>:

-Briefing meeting (ITF)

-Classification

-Scientific Advice or Protocol Assistance (OD)

-Orphan Drug dossier

-Pediatric Investigation Plan (PDCO)

Optimising resources

-For each type :

-A specific form

Harmonization → should be possible

Specific information → needed

-Dossier

Common part → possible (POC; NC)

Specific part → needed

-Possibility to update the document when already submitted for a Briefing Meeting

Optimising resources

-Clinical Trial Authorization (CTA)

-National

-Begining of harmonization: VHP

-Doesn't work for GMO products → Gene therapy

Cell therapy →

CTA	PIP	MA
National evaluation	Centralised PDCO (EMA)	CAT/ CHMP (EMA)

-Proposition: A common procedure for CTA (*a major point for O.D.*):

One common evaluation → including GMO

One Submission →

One Authorization →

Optimising resources

-Clinical Trial Authorization

The File: The IMPD European legislation

Clinical trials Directive 2001/20/CE	Detailed guidances Vol 10 Eudralex
	CTA for competent Authority -Oct .2005 : *CT1* (detailed) -30 March 2010: O.J.E.U.
	-Quality: EMA Guideline CHMP/QWP/185401/2004 -Non clinical : CTD Module 4 Eudralex Vol 2B -Clinical : previous CT CTD Module 5 (Eud Vol 2B)
GMP Annex 13 (3/02/2010) GCP 2005; specific to Ad Th (2009)	IMP

Not designed for biotech products and for ATMP

Need to have this information in one regulatory data base

Optimising resources

THE IMPD FOR EX VIVO GTMP

Common Technical Document

2.1.S Drug substance
2.1.S.1 General information
2.1.S.2 Manufacture
2.1.S.4 Controls
2.1.S.7 Stability

2.1.P Drug product (Medicinal Product)
2.1.P.1 Composition
2.1.P.2 Pharmaceutical Development
2.1.P.3 Manufacture
2.1.P.5 Controls
2.1.P.8 Stability

2.1.A Appendix
Facilities, equipment

Specificities for ex vivo GTMP

2.1.S Drug substance
2.1.S.2.3 Starting Materials
- viral vector
- patient cells

2.1.S.2.4 Drug substance
(transduced cells)

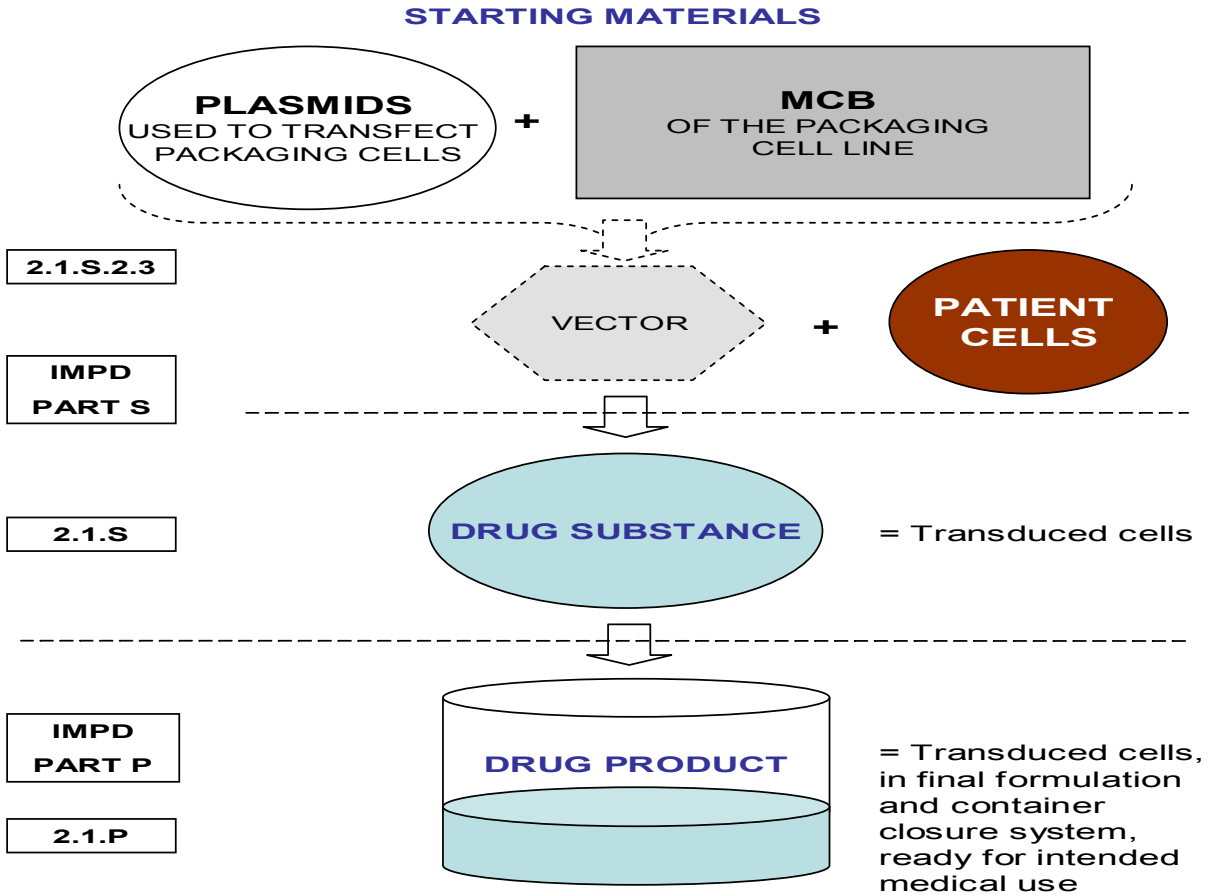
2.1.S.7 Stability

2.1.P Drug Product

Transduced cells in final formulation and container
closure system, ready for intented medical use

Optimising resources

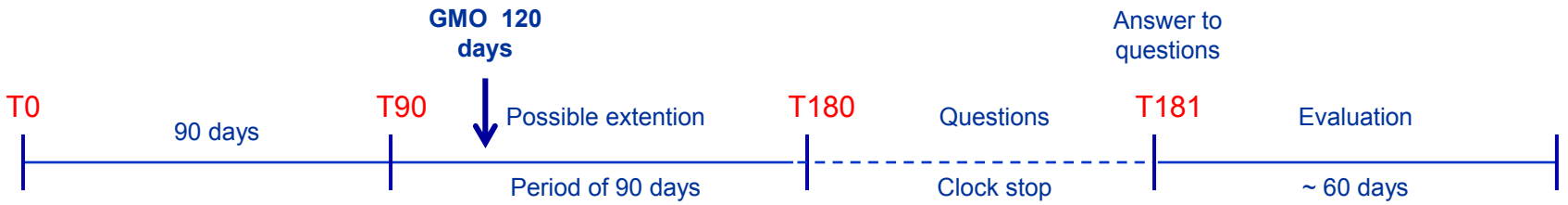
THE IMPD FOR EX VIVO GTMP



Assessment: Common Procedure Criteria

❑ Directive 2001/20/EC: Procedure GT , CT

• Competent National Authorities/Ethical Committee



➢Extended period of 90 days if external consultation needed

-No harmonisation →

Some countries have a fast track system for O.D.
External committee to the C. A.

-No information an common criteria for assessment

-Proposition : creation of a data base to have :
.Information → on national procedures
.Contact points → (Agencies/ GMO committees)
.Common → important criteria

Thank you for your attention

Questions ?

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