TEDDY Working Group:
"SOPs for the conduct of paediatric CTs"

Members: M. Felisi (CVBF, facilitator), F. Martinon Torres, C. Serén Trasorras (SERGAS), C. Manfredi, S. Pulici, K. Musaraj, B. Tempesta (CVBF), F. Bartoloni (FGB), A. Nardone (PENTA)

Why an Working Group?

DEFINITIONS according ICH GCP E6 (R2)

***5.1. Quality assurance and quality control* (5.1.1.)**

The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with *written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).*

TEDDY Self assessment - EnprEMA

Criterion 4.1 → *Adherence to GCP*

TEDDY has set up a ***'trial management infrastructure'*** including SOPs in order to deal with the complexity of multinational and multi-centre clinical trials.

Criterion 4.4 → *Availability SOP*

SOPs are available for clinical trials activities as requested by ICH GCP guidelines and shared among partners by request.

A list of SOPs to be implemented in a clinical trial is available at the TEDDY website

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

compliance with the protocol, GCP, and the applicable regulatory requirement.

A list of SOPs to be implemented in a clinical trial is reported below.

Teddy Network is available to share its own SOPs with all partners and put at disposal its expertise to create ad hoc SOP for paediatric clinical trials. All Teddy SOPs are drafted taking into account the specific paediatric context.

- + WRITING
- + REGULATORY AND ETHICS
- + STUDY MANAGEMENT
- + MONITORING
- + ADVERSE EVENTS MANAGEMENT
- + DRUG MANAGEMENT
- + QUALITY ASSURANCE

www.teddyoung.org

USEFUL LINKS

National Regulatory Authorities in Europe

Paediatric medicines development and evaluation

Networking

RECENT POSTS

› TEDDY Network will participate in the ENCePP plenary meeting that will be held on November 21st, 2017 at EMA in London

› The new EMA action plan to

WRITING

Trial protocol and amendments

The purpose of this SOP is to describe the procedures for drafting, approval, distribution and storage of the study protocol and the related amendments.

IB and IMPD preparation

This SOP describes the purposes, contents, creation and maintenance of the Investigator's Brochure (IB) and Investigational Medicinal Product Dossier (IMPD), respectively, for products used in clinical trials.

Final study report

This SOP describes the purposes, contents and preparation of the final clinical study report documenting the results and interpretation of the trial.

REGULATORY AND ETHICS

- Information leaflet, consent and assent forms
- Clinical Trial Application

STUDY MANAGEMENT

- Trial Master File and Investigator Folder
- Contracts and agreements

MONITORING

- Site Initiation Visit
- Monitoring Visit
- Close-Out Visit

ADVERSE EVENTS MANAGEMENT

- SAE Reporting
- SAE Processing
- SAE Archiving
- SAE Reconciliation

DRUG MANAGEMENT

- Set-up of Clinical Trials Supply and Drug Management Activities

QUALITY ASSURANCE

- Preparation, review, approval and distribution of SOPs

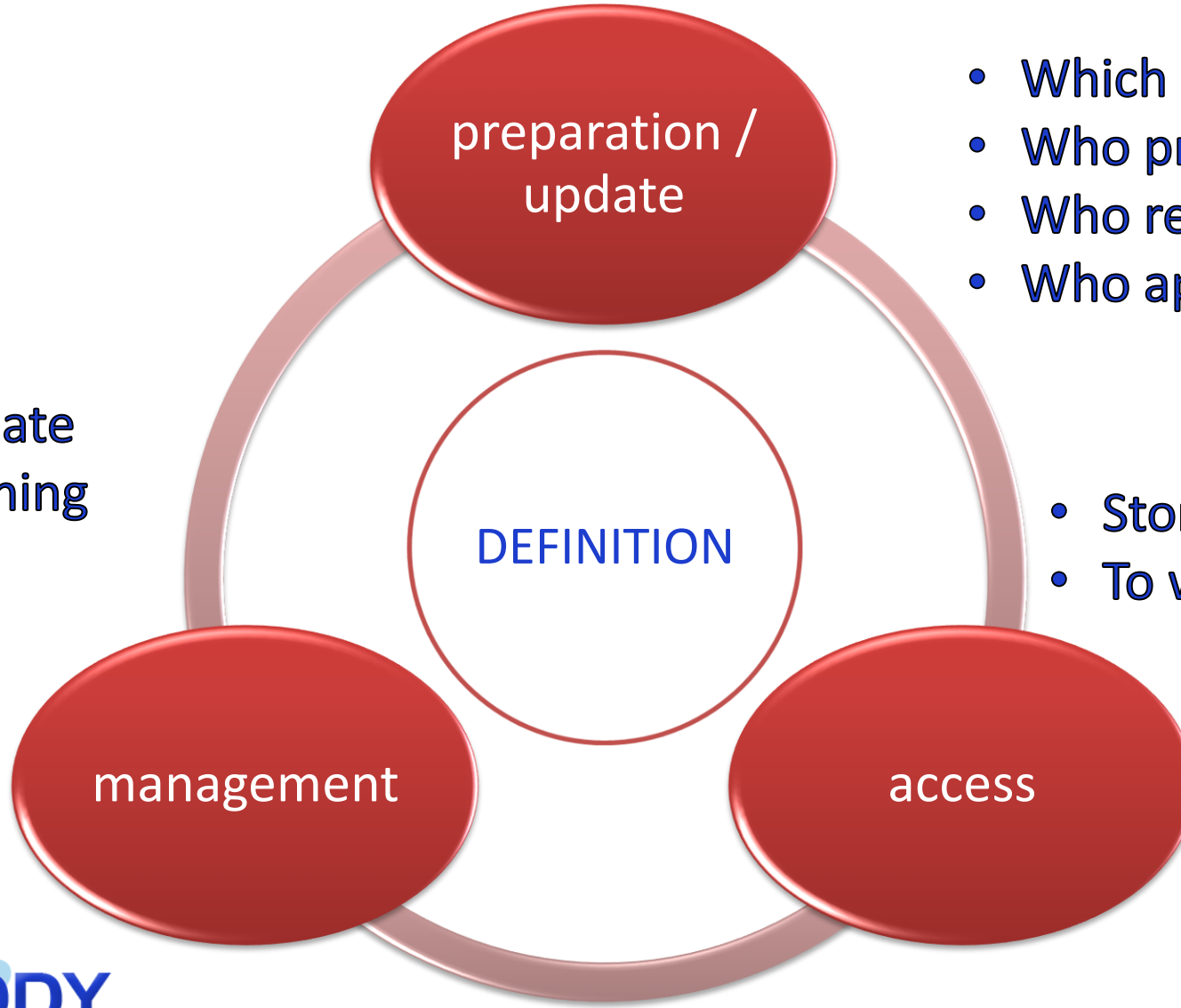
Need for update

The procedures need to be updated to take into account what required by the new regulations, guidelines, directives, etc.

- REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC
- REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).
- Guideline for good clinical practice E6(R2) - 2017 Addendum EMA/CHMP/ICH/135/1995

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

How to move on…



- Which ones
- Who prepares
- Who revises
- Who approves

- Update
- Training

- Stored where
- To whom

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

Plan of action of the WG

1. set of SOPs considered of particular interest for the conduct of paediatric trials

2. process for the production of these SOPs (preparation, revision, approval) and the related timelines

3. the SOP access (where they will be stored and who will have access) and their management

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

SOPs of interest

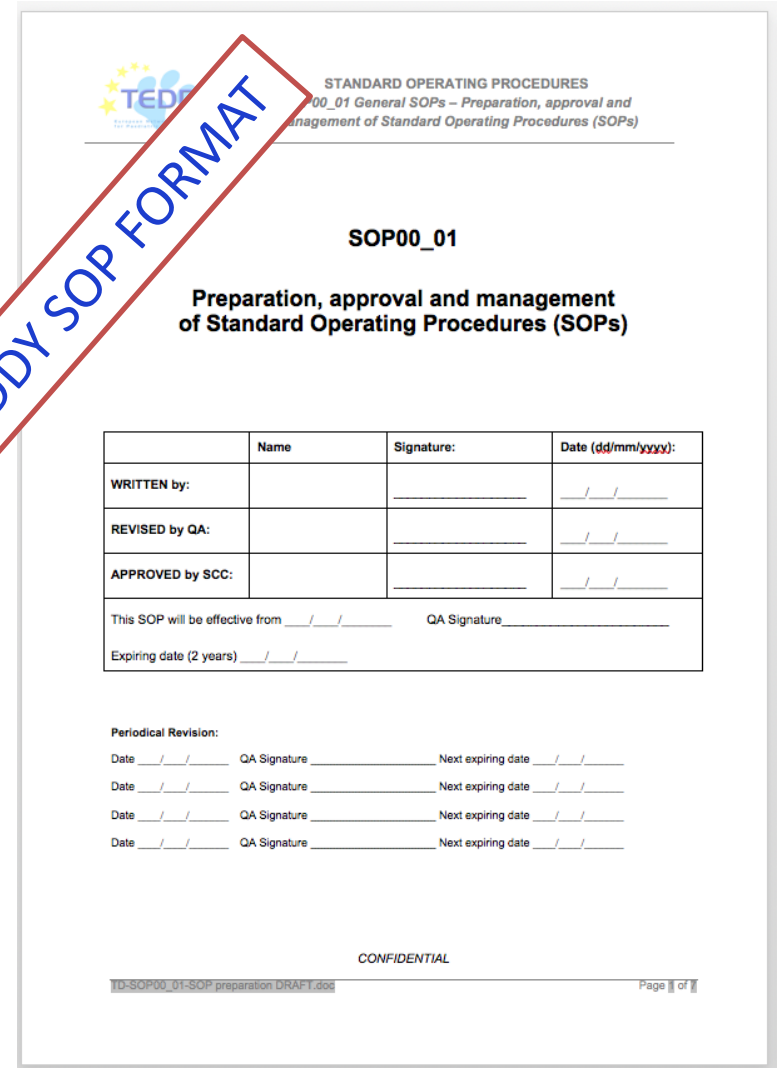
TEDDY TRIALS

- starting from a list of 30 SOPs available
- asking for level of interest:
  - Low (L)
  - Medium (M)
  - High (H)
- Selection of SOP to be prepared/updated first

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

SOPs production

- Definition of the Writing Group
  - Drafting/updating the SOPs
- Revision from Quality Assurance
- Approval by the TEDDY Scientific Coordinating Committee (TBD)



TEDDY SOP FORMAT

STANDARD OPERATING PROCEDURES
00_01 General SOPs – Preparation, approval and
nagement of Standard Operating Procedures (SOPs)

SOP00_01

Preparation, approval and management of Standard Operating Procedures (SOPs)

	Name	Signature:	Date (dd/mm/yyyy):
WRITTEN by:		_____	___/___/_____
REVISED by QA:		_____	___/___/_____
APPROVED by SCC:		_____	___/___/_____

This SOP will be effective from ___/___/_____ QA Signature_____

Expiring date (2 years) ___/___/_____

Periodical Revision:

Date ___/___/_____ QA Signature _____ Next expiring date ___/___/_____

Date ___/___/_____ QA Signature _____ Next expiring date ___/___/_____

Date ___/___/_____ QA Signature _____ Next expiring date ___/___/_____

Date ___/___/_____ QA Signature _____ Next expiring date ___/___/_____

CONFIDENTIAL

TD-SOP00_01-SOP preparation DRAFT.doc Page 1 of 7

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

SOP Format

1. SCOPE AND APPLICATION FIELD

2. DEFINITIONS/ABBREVIATIONS

3. REFERENCES

4. RESPONSIBILITIES

5. PROCEDURE

- 5.1 SOP code and revision number
- 5.2 Cover
- 5.3 Editing
- 5.4 Approval
- 5.5 SOP validity
- 5.6 Distribution
- 5.7 Training

6. DOCUMENTS ARCHIVING

7. HISTORY OF DOCUMENT

8. APPENDIXES

SOP Access

www.teddynetwork.net

with limited access to TEDDY Partners

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

Next STEPS

- **Working/Writing Group set-up**: invitation to other TEDDY partners *(February 2018)*
- **Selection of SOPs to be updated/prepared:** identification of level of interest for each-one *(March 2018)*
- **Drafting and distribution:** preparation, revision, approval and upload on TEDDY website *(March 2018 – December 2018)*

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research