

Standard Operating Procedure

FROM - Support to Phase I Unit

Identification No. : GEN05

Version: 2

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1. ABBREVIATIONS

ASST-PG23:	Azienda Socio-Sanitaria Territoriale - Papa Giovanni XXIII
CRA:	Clinical Research Associate (Monitor)
CRO:	Clinical Research Organization
DM:	Data Manager
FROM:	Fondazione per la Ricerca Ospedale Di Bergamo
GCP:	Good Clinical Practice
PM:	Project Manager
QAM:	Quality Assurance Manager
SOP:	Standard Operating Procedure

2. SCOPE

This Standard Operating Procedure (SOP) describes FROM roles dedicated to the clinical Phase I Unit located at the Azienda Socio-Sanitaria Territoriale - Papa Giovanni XXIII, Bergamo (ASST-PG23).

3. FIELD OF APPLICATION

This SOP applies to FROM personnel, permanent and consultants, having an active role in the Phase I Unit and cooperating with ASST-PG23 resources involved in Phase I clinical trials .

The roles offered by FROM are:

- Medical Director
- Quality Assurance Manager
- Auditor
- Project Manager
- Data Manager
- Biostatistician
- Clinical Research Associate

4. RESPONSIBILITIES

The responsibilities are not listed in this paragraph because detailed in the paragraph 5 – Procedure.

5. PROCEDURE

The responsibilities of the FROM Data Managers and Project Managers *involved in the management of Phase I trials* are those described in the SOP **FROM – Organizzazione e Responsabilità (GEN02/2)** for the Phase II-IV trials. Therefore they are not described in this SOP.

The responsibilities of other roles requested by the Determina n.809/201 (e.g. Investigator, Research Nurses etc.) are described in the document *Regole di Unita' (attachment 1 of "Linea guida per la comunicazione di informazioni relative alla pianificazione e conduzione di uno studio clinico di fase I")*.

5.1 Medical Director

A Medical Director is requested in an organization performing Phase I trials according to the current Italian regulation (i.e. Determina n.809/2015). The Medical Director has to fulfil the requirements of the abovementioned law in terms of qualification and experience.

The Medical Director is a physician with a strong experience in the medical area and specifically in the clinical trial methodology. He/she is responsible for:

- Ensuring with the collaboration of the Quality Assurance Manager (QAM) and the Project Manager (PM) *specifically dedicated to the Phase I Unit set-up*, to verify the compliance with the requirements of the Determina n.809/2015 of those clinical units willing to perform Phase I clinical trials (according to the *Linea guida per il percorso di adeguamento di una Unità Operativa alla Determina n.809/2015 per la conduzione di studi clinici di Fase I*)
- verifying through the responsible personnel (e.g. Director of UOC in ASST-PG23) the adequacy (i.e. quality and quantity) of the resources to be allocated to Phase I trials
- evaluating clinical trials proposed by the ASST-PG23 Investigators to FROM for a collaboration
- supervising clinical trials performed by the Phase I Units
- ensuring that an emergency plan is written for any IMP used in a Phase I trial according with the *Linea guida per la comunicazione di informazioni relative alla pianificazione e conduzione di uno studio clinico di fase I*
- ensuring the notification of critical GCP and/or protocol deviations or the loss of minimum requirements previously self-certified for the Phase I Unit to AIFA, including laboratories according to the SOP **Management of GCP and trial protocol deviations and notification to AIFA of critical deviations occurred during Phase I trials (CLI012/1)**.

5.2 Quality Assurance Manager (QAM)

The QAM appointed for a Phase I Unit should prove her/his education, qualification and training according to the Decree dated 15.11.2011 (Minimum requirements of a CRO) as requested by the Determina n.809/2015.

The QAM main tasks are those reported in the SOP **FROM – Organizzazione e Responsabilità (GEN02/2)**.

In addition, the QAM should:

- verify the compliance with the requirements of the Determina n.809/2015 of those clinical units willing to perform Phase I clinical trials (according to the *“Linea guida per il percorso di adeguamento di una Unità Operativa alla Determina n.809/2015 per la conduzione di studi clinici di Fase I”*).
- collaborates with the Medical Director of Phase I Unit for the identification, analysis and notification to AIFA of critical GCP and/or protocol deviations or the loss of minimum requirements previously self-certified for the Phase I Unit to AIFA, including laboratories according to the SOP **Management of GCP and trial protocol deviations and notification to AIFA of critical deviations occurred during Phase I trials (CLI012)**.
- collaborate with the Quality Managers of the ASST-PG23 Laboratory(ies) and the Biobank in relation to the correct management of biological samples from clinical trials to ensure that issues related to the clinical biological samples (i.e. with impact on the safety and rights of clinical trial subjects) are taken into due account.
- Collaborates with the appointed auditor in the performance of the annual audits according to the Determina n.809/2015 (i.e. at least one system audit and one trial-specific audit) and in following up any detected non-compliance.

5.3 Auditor

An Auditor involved in Phase I trials should prove her/his education, qualification and training according to the Decree dated 15.11.2011 (Minimum requirements of a CRO) as requested by the Determina n.809/2015. According to the Determina at least one “system audit” and one “trial-specific audit” have to be performed annually within a Phase I Unit. Therefore, an independent auditor (consultant) has been appointed to perform auditing activities.

The Auditor is mainly responsible for:

- preparing and conducting an audit;
- preparing the audit report and the audit certificates.

5.4 Project Manager (PM)

The PM is involved in the Phase I trials according to the responsibilities described in the SOP **FROM – Organizzazione e Responsabilità (GEN02/02)** as regard the clinical trial management.

However a dedicated PM, skilled and experience in the field, is also deeply involved in supporting the ASST-PG23 clinical units willing to perform Phase I clinical trials. In this respect he/she has the following main responsibilities:

- Provide suggestions and support to a clinical unit for the development of the documents requested by the *Linea guida per il percorso di adeguamento di una Unità Operativa alla Determina n.809/2015 per la conduzione di studi clinici di Fase I*
- verify, in collaboration with the QAM, the compliance of a clinical unit with the requirements of the Determina n.809/2015
- track the information regarding to the ASST-PG23 clinical units affiliated to the Phase I Unit (i.e. requirements of Determina n.809/2015 already met) and those units still under evaluation for the admission to the Phase 1 Unit (i.e. requirements of Determina n.809/2015 not confirmed yet).
- track the information of all the Phase I trials carried out at ASST-PG23.

5.5 Data Manager

The main tasks of the Data Manager are those reported in the SOP **FROM – Organizzazione e Responsabilità (GEN02/2)**.

5.6 Biostatistician

The Biostatistician should prove her/his education, qualification and training according to the Decree dated 15.11.2011 (Minimum requirements of a CRO) as requested by the Determina n.809/2015.

The main tasks of the Biostatistician are those reported in the SOP **FROM – Organizzazione e Responsabilità (GEN02/2)**.

5.7 Clinical Research Associate (CRA)

The CRA should prove her/his education, qualification and training according to the Decree dated 15.11.2011 (Minimum requirements of a CRO) as requested by the Determina n.809/2015.

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This activity is delegated by FROM to external consultants. The agreement with a CRA to be involved in a specific trial should be executed after the QAM has verified the compliance with the abovementioned Decree.

The main tasks of the CRA are reported in the SOP **FROM – Organizzazione e Responsabilità (GEN02/2)**.

6. REFERENCES

- Ministero della Salute: D.M. 15/07/97 Recepimento delle linee guida dell'Unione Europea di Buona Pratica Clinica per l'esecuzione delle sperimentazioni cliniche dei medicinali.
- Guideline for good clinical practice E6(R2) (CPMP/ICH/135/95).
- Decree dated 15.11. 2011 Definition of the minimum requirements which CRO shall satisfy in order to work within clinical trials with medicinal product.
- Determina n.809/2015 dated June 19th, 2015 inerente i requisiti necessari per le strutture sanitarie che eseguono sperimentazioni di fase I di cui all'art.1 del decreto del Presidente della Repubblica 21 settembre 2001, n.439 e di cui all'art.31, comma 3 del decreto legislativo 6 novembre 2007, n.200.

7. TEMPLATES

None

8. VERSION HISTORY

Version	Date	Reason for revision
1	30 Sept 2016	Starting document.
2	15.12.2019	<ul style="list-style-type: none"> • Transposition of FROM organizational changes as per organization chart. • Removal of the Medical Pharmacologist since this role belongs to the ASST-PG23 and not to FROM.