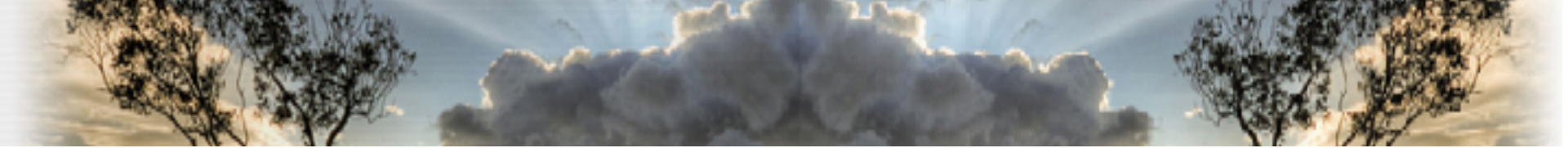

EBF

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EBF GCP Implementation FotP Feedback

Tom Verhaeghe, on behalf of the EBF

Introduction

- There are implementation challenges for a lab given that in GCP the BA lab is not specifically mentioned
- FotP prompted by a discussion within the GCP team to evaluate the current status of the GCP implementation in the EBF
- FotP aimed to evaluate the regulatory framework and requirements of the regulators in terms of GCP at the lab.

Survey Question

1. My organisation is
a. CRO
b. Pharma
2. In our lab we analyse samples from
a. Both GLP and GCP studies
b. Only GCP studies
c. Only GLP studies -
3. My laboratory is based in:
a. UK
b. Other

Outcomes

Question 1:

- 21 CRO
- 18 Pharma

Question 2:

- Both GLP and GCP Studies - 31
- Only GCP – 5
- Only GLP – 3

Question 3:

- UK - 8
- Other– 28

Survey Question

4. Are your laboratory being inspected by the regulatory authorities for GCP compliance?
a. No
b. Yes. (if yes, please specify by which HA)
5. If yes in question 4, is your laboratory being inspected:
a. As part of an inspection program. If so, which is the inspection frequency, every X year
b. As part of regulatory submission. If so, which type of trials are inspected?
c. Other, please specify.

Outcomes

Question 4:

- No - 21
- Yes - 15

(7 MHRA, 4 EMA, 6 FDA, 1 AIFA, 1 SwissMedic, 1 AGES, 1 Dutch agency, 1 Spain agency)

Question 5:

- As a part of inspection program – 11, (X=1-2-3) by MHRA, Spain Agency, AIFA, Dutch Agency, AGES
- As a part of regulatory submission – 4, BE studies by EMA, FDA and SwissMedic

Survey Question

6. Do your internal QA perform audit on your inhouse GCP analysis?
a. Yes, for every trial
b. Please indicate which type of trials that are audited!
c. Process based inspection
d. No
7. If yes in question 6 , what standards do your QA use during inspection on your inhouse GCP analysis:
a. GCP
b. GCP and GLP
c. Other, please specify Xx

Outcomes

Question 6:

- *Yes, for every trial - 21*
- Yes, for particular trials - 4 (BE and upon request)
- Process Based – 18
- No – 0

Question 7:

- GCP – 7
- *GCP and GLP - 28*
- Other - 4 GcLP

Survey Question

8. For which of the following GCP processes do you currently have procedures?
a. a. Training
b. b.Subject confidentiality protection
c. Blinded/Un-blinded sample analysis
d. Handling of unexpected results
e. Obtaining information about patient's consent status
f. Other. Please state which

Outcomes

Question 8:

- Training- 35
- Confidentiality -35
- Blinded/unblinded sample analysis -35
- Handling unexpected results -35
- Obtaining patient ICF status -32
- Other – 5 (Equipment validation, clinical QMS aspects, contracts, samples receipt)

Survey Question

9. Which are your two most important strategic GCP aspects for an EBF GCP team to focus on in their initial work? (highlight only 2)
a. GCP training needs
b. Subject confidentiality protection
c. Blinded/Un-blinded sample analysis
d. Handling of unexpected results
e. Obtaining information about patient's consent status
f. Communication with other members of clinical trial team
g. Other. Please state which

Outcomes

Question 9:

- GCP Training- 7
- Confidentiality -5
- Blinded/unblinded sample analysis -10
- Handling unexpected results -14
- Obtaining patient ICF status -15
- Communication with other members of clinical trial team - 16
- Other – 2 (GCP quality management and data transfer)

Moving forward with more questions…

- After the initial survey results digestion – additional questions were sent aiming to understand scope/guidelines used for Bioanalytical inspections/reviews conducted outside UK (MHRA)

1. What is the scope of the regular GCP inspections conducted by the authorities at your lab?
2. Are there any specific national guidelines used during the GCP inspections? If yes, could you please specify them.
3. If Not on Q2 - what guidelines are used during these inspections?
4. Are there any statements issued (i.e. certificates) by the authorities?

…and answers

1. What is the scope of the regular GCP inspections conducted by the authorities at your lab?
2. Are there any specific national guidelines used during the GCP inspections? If yes, could you please specify them.
3. If Not on Q2 - what guidelines are used during these inspections?
4. Are there any statements issued (i.e. certificates) by the authorities?

Outcomes (AIFA)

Question 1: Accreditation Program

Question 2: D.M. (Italian Ministerial Decree) 19 March 1998 and "Determina" AIFA 2015.

Question 3: NA

Question 4: Statement by AIFA which states that the labs are subscripted to the Private labs which are able to perform analysis in support to the clinical trial including Phase 1 studies.

Outcomes (Dutch agency)

Question 1: General inspections of the lab are performed by the GLP department of the Dutch Healthcare inspectorate. The scope of the GLP audits is general study performance, archiving and QA activities

Question 2: There are no general GCP inspections for the lab.

Question 3: NA

Question 4: The Dutch Healthcare Inspectorate does not issue certificates for GCP compliance inspections. However, for the GLP inspections an Endorsement of Compliance is issued.

Outcomes (AGES)

Question 1: "Side aspect" of GLP inspection

Question 2: No

Question 3: Not specified

Question 4: No

Focus Areas

- Communication with other members of clinical trial team (this topic combine “handling unexpected results”, “obtaining information about patient ICF status”, “Blinded/unblinded sample analysis”)
- Conducting GCP audits of bioanalytical lab - risk based approach on study selection and the scope of audits.
- Understand scope/guidelines used for Bioanalytical inspections/reviews conducted outside UK based on the received feedback (AIFA)

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