PSQ11417

Introduction of regulatory and health watch in the clinical trials area

Diane Lê (1), Florian Laval (2), Catherine Hamon (1), Adeline Chanat (1)
(1) : Department of clinical trials, Pontchaillou, 2 rue Henri le Guilloux 35000 Rennes, France
(2) : Department of clinical pharmacy, Pontchaillou, 2 rue Henri le Guilloux 35000 Rennes, France

What was done ?

BEFORE

No daily following of the news → in case of regulatory update or health alert → no control of the products.

THEN

Creation of a quality procedure, in compliance with Good Clinical Practice (GCP), including health and regulatory watch.

Why was it done ?

Request of sponsoring a study.

Submission of the file to the National Agency for the Safety of Medicines and the Research Direction of the hospital.

Highlight of the issue of health watch and the management of batch withdrawals.

How was it done ?

- Definition and restriction of the products concerned by the regulatory and health watch.
- Daily statement of health updates on the French Agency for the Safety of medicines website.
- Daily statement of regulatory news on the French law website.

Information collected restricted to :

- Product not supplied by sponsors, for the trial if it has its EU marketing authorization (Jardé law)
- Product without its EU authorization, used in case of adverse event, and asked by the sponsor to be provided by the hospital. *Ex : tocilizumab for cytokin release syndrom.*
- Product supplied by the hospital to other centers, as a sponsor.
- Raw material, in case of product manufacturing.

What was achieved ?

Information collected : drug shortages, recalls and breaks.

All of these data are collected, summarized and marked in spreadsheets.

If needed, a solution is found with the study sponsor or the Clinical Research Department (if the hospital is the sponsor).

If needed, a batch withdrawal letter sample has been prepared and is ready to be sent to others hospitals.

What is next ?

Finalize and validate the spreadsheets and the procedure.

Integrate it into current practices in the clinical trials sector.

Work in harmony with the care units, the pharmacy purchasing sector and the Clinical Research Department.

While having in mind Good Clinical Practice, in order to improve quality and safety of care and patients.