Clinical Research and Data Collection During the Investigation: Influence of a Dedicated Staff

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03946501	COMPLETED	MAY 10, 2019	MAY 10, 2019

STUDY DESCRIPTION

Brief Summary

The aim of the study was to evaluate the interest of the recourse of a staff dedicated as CRA to data collection in clinical research

Condition or Disease: Clinical Research Inclusion

Intervention/treatment: Other: Data collection

Phase: N/A

DETAILED DESCRIPTION

Objectives of clinical studies are notably to evaluate new therapies, to improve diagnostic techniques, to make medico-economic decisions and to enrich scientific knowledge. Clinical studies findings can influence medical practice, or even motivate decisions by public health authorities. The rigor in their behavior is therefore an imperative to respect.
Thus, the quality of the data collected is essential. However, even if the reliability of the clinical data is guaranteed by the monitoring, the completeness of the data remains exceptional.
The increase of data required in clinical studies has led to the emergence of a specialized staff to assist investigators: the clinical research assistants. With dedicated time and specialization in data collection, they facilitate the conduct of clinical studies. However, this data collection aid has not been evaluated.

STUDY DESIGN

Study Type: Observational

Estimated Enrollment : 400 participants

Intervention Model : N/A

Masking: N/A

Primary Purpose: N/A

Official Title: Clinical Research and Data Collection During the Investigation: Influence of a Dedicated Staff

Actual Study Start Date: March 2015

Actual Primary Completion Date: April 2015

Actual Study Completion Date: May 2015

GROUPS AND COHORTS

Groups/Cohorts	Intervention/treatment
: clinical research visit	Other: Data collection

OUTCOME MEASURES

Primary Outcome Measures: 1. Missing data [Time Frame: Day 0]
Data was considered missing because of its absence when finalizing the data

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- clinical research visit performed in Reims university hospital between January 2010 and January 2015

CONTACTS AND LOCATIONS

Contacts

Locations

France	Damien JOLLY	Reims

Sponsors and Collaborators

CHU de Reims

Investigator

MORE INFORMATION

Other Publications	Ghenim S, Féron T, Barbe C, Wolak-Thierry A, Jolly D. [Clinical research and data collection during the investigation: Influence of a dedicated staff]. Therapie. 2018 May - Jun;73(3):267-272. doi: 10.1016/j.therap.2017.10.003. Epub 2017 Nov 11. French.
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ClinicalTrials.gov Identifier :	NCT03946501
Other Study ID Numbers :	2018Ao003
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Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by CHU de Reims:	*clinical research* *missing data clinical research assistant*