Available Online through   *Review Article*
www.ijptonline.com

AWARENESS OF CLINICAL DATA MANAGEMENT IN PHARMACEUTICAL STUDENTS WHEN INDIA IS SET TO BECOME HUB FOR CLINICAL DATA MANAGEMENT; CLINICAL RESEARCH

Mohammad Gayoor Khan*, Umama Yezdani, Siddhant Prasad Thapa,
[Hari Baskar] [1], [Madhivanan E] [1]
Department of Pharmacy, Truba Institute of Pharmacy, Bhopal - 462038, India.
Department of Pharmacy Practice, MRM college of Pharmacy, Hyderabad -500059, India.
Department of Pharmacy, KMIPS, Rourkela, Odisha - 769015, India.
[Department of Pharmacy Practice, KMCH college of Pharmacy, Coimbatore - 641048, India.][1]
Email: rk981487@gmail.com

Abstract

According to a new era of clinical research in India the fundamental and it' methodology is quite difficult to understand due to unawareness in education system like institute, hospital, research organizations, forums, etc. Where Clinical data management is referred to critical process of clinical research which leads scientific data and high-quality standard from clinical trials. It ensures that the integration & collection or data availability within time and economically cheaper or cost-effective. According to NIH(National Institute of health) clinical data management support with respect to management, analysis of studies for clinical research.[1] The current scenario of CDM in India is different here lots of organization day to day working for standard and better management they offered guarantee compliance of clinical data management process and all regulatory requirements such as technical support, data collection, cleaning, data management software, database system management etc.[2]

The market has grown at almost 37% percent in the past two years and is pegged to grow even more by 2016, To evaluate the adaptation of the pharmacy students with respect to the contemporary situation, a survey based on a set of questionnaires was designed and conducted in different pharmacy colleges of Bhopal. Awareness is very essential among Indian students to adapt to the CDM hub for clinical research.

Key Words: Clinical research, hub, software management, clinical trials.

Introduction

Clinical data management is a major part of clinical research which is useful for management purpose, audit, record; software management as a tool, useful to making an SOP, CRF or it is well recognized an emerging technique for pharmaceutical, health and research organization. In India, the clinical data management scenario is quite different as compared to the gulf, United Nations, etc. For clinical trials, it plays a major role whereas, India has a global market share around 45% in clinical research; CDM for clinical trials. More than 14000 hospitals, 720 research organization familiar with clinical trials 500,000 doctors making it an ideal country to conduct clinical trials.[3]

Several pharmaceutical and research organization depends upon clinical research; clinical trials and for maintaining their records clinical data management play a very important role. The job opportunity in clinical data management is also incredible or increasing day to day especially in South India Part higher opportunity as compared to other parts of India because the majority of big MNCs, research organization, Pharmaceuticals in South India mostly but clinical research with respect to CDM are useful globally and recognized as well.

Objective

The main motto of this study was to assess the Indian student's awareness on clinical data management. It was a prospective study conducted in various pharmacy colleges of Bhopal. Because Bhopal is one of the emerging educational hub of Central India and it's having more than 32 pharmacy colleges.

Materials and Methods

Few standard questions were designed to evaluate and analyze about awareness of clinical research and clinical data management among pharmacy students. In this study, I designed eight standard questions for analysis purpose among the students and collect the data to evaluate and prepare a statistical analysis. Even I have done this experiment in my past NFPS 2nd international Conference Hyderabad in Youth Debate 18th August 2018. But before going to a final conclusion I involve Bhopal Pharmacy College as well so that I can assess the awareness among pharmacy students.
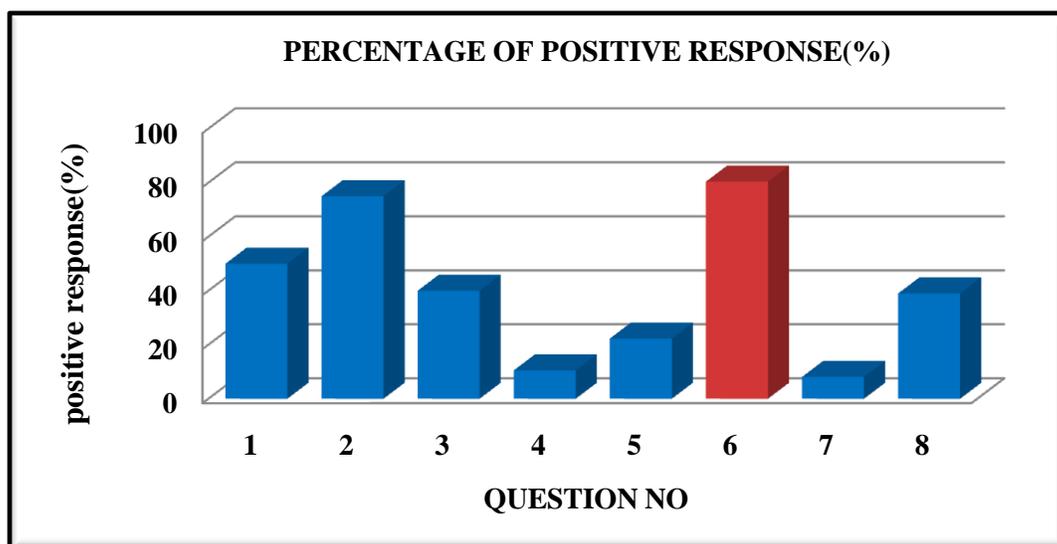
Experimental Method

These following top eight questions were designed to evaluate the awareness about clinical data management among the pharmacy students.

1) What is clinical data management?

2) Why clinical data management are is important?

3) Why you should you be interested in CDM?

4) Which is first big Professional organization for clinical data management?

5) What do you understand CRF (Case Report Form) Design?

6) What are the job profile titles for clinical data management?

7) Informed consent?

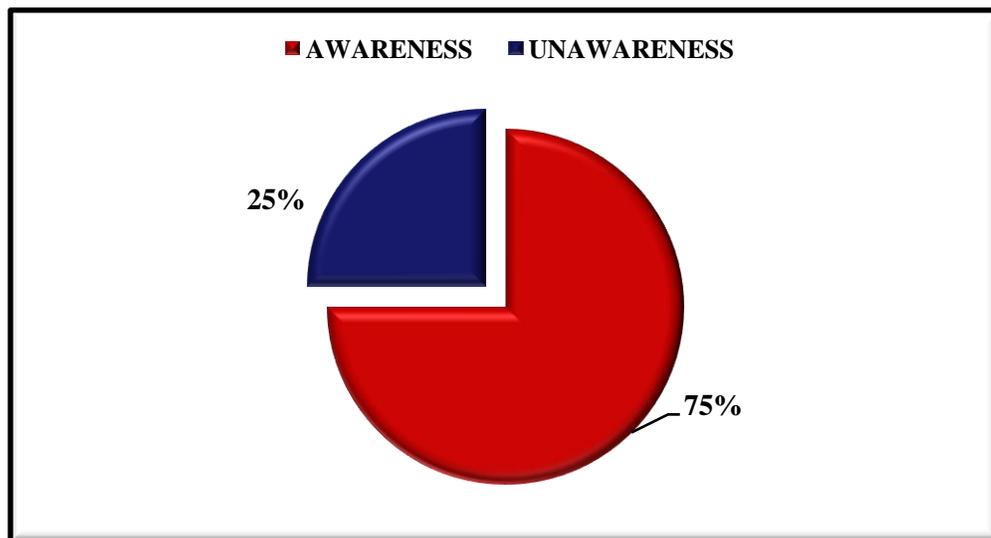8) What protection do you have as a participant in a clinical data management at the time designing SOP'S?

The data was collected and evaluated.

Result

According to collected data the individual question analysis *"Table: 1 individual questions Analysis"* on the basis of evaluation plan was used to prepare an overall study awareness analysis which is shown in *"Pie - Chart: 1.1 among all pharmaceutical students"* of the awareness regarding clinical data management in all pharmacy students.

PERCENTAGE OF POSITIVE RESPONSE(%)

Table: 1 individual questions Analysis.

Pie - Chart: 1.1 among all pharmaceutical students.

The data shown in the pie chart is referred to overall outcome after analysis among all the pharmacy students and data was very disappointing due to unawareness clinical data management; clinical research among the students.

Discussion

The current scenario of clinical data management for clinical research is being a fast growing business as far as the pharmaceutical industry, research organizations, hospitals, medical coding centres, clinical research centres, as concerned, after the outcome result there is a need to educate pharmacy students regarding clinical data management and it's important for future projects and monitoring the clinical research at the next level. There is a lot of scope in clinical data management, clinical research i.e., the various job profiles are there such as clinical research coordinator, clinical research associate, clinical researcher, etc. The clinical market is growing very rapidly which is seen growth in last year's according to CAGR (Compound annual growth rate) hence, the involvement of the Indian government is also essential government have to focus in awareness in among the pharmacy Institutes, research Institutes in India with the help of big organizations, Associations, teachers, etc.

Acknowledgement

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

Reffernces

1. Clinical data management [home page on internet]. 2004-19 [updated 23 may 2019]. Availabe from:

   http://www.wikipedia.org

2. Outsource2india.com [home page on internet]. India: research analysis and articles, inc c 2002-2019 [updated

   2019]. Available from: http://www.Outsource2india.com

3. file:///J:/clinical%20trials/catFull.jsp.htm

Correspondence

*Mr. Mohammad Gayoor khan,

Student in Truba Institute of Pharmacy, Bhopal, Madhya Pradesh - 462038, India.

Email: rk981487@gmail.com