

SHREE NARANJIBHAI LALBHAI PATEL COLLEGE OF PHARMACY, UMRAKH

Webinar Report (Guest Lecture)

Date: Tuesday, 22 June, 2021.

Topic: “Clinical Data Management”.

Resource Person – Mr. Nikunj Patel. Director, Data Management and Bio-statistics

CBCC Global Research, Ahmedabad, Gujarat, India

No. Of Participants: 48

Summary of Session:

IIC and IQAC of Shree Naranjibhai Lalbhai Patel College of Pharmacy, Vidyabharti Trust, UmraKh, organized a guest lecture on - “**Clinical Data Management**”. The event started at 11:00 AM with a welcome speech by Prof. Vipulkumar Gajera, Assistant Professor, SNLPCP, UMRAKH. He welcomed the speaker of the event **Mr. Nikunj Patel**, Director, Data Management and Bio-statistics

CBCC Global Research, Ahmedabad, Gujarat, India and Dr. Dhiren P. Shah – Principal of SNLPCP, Faculties and Participants of the event.

The Honourable Speaker Mr. Nikunj Patel has explained the various Phases of Clinical trial. He explained entire process of clinical trial by very effective diagram. He has also discussed role of CDM in clinical trial process. He has also explained about the major documents required for clinical trial and responsibilities of stake holder. He has described DM life cycle and various CDM acronyms

He has presented everything by good diagrams. At the end of session various queries were put forward by the participants. Mr. Nikunj Patel has answered the questions of participants regarding clinical trial.

To conclude the session, Prof. Vipulkumar Gajera showed his gratitude and appreciation to Mr. Nikunj Patel for his valuable time. SNLPCP is thankful to Mr. Nikunj Patel - Speaker and participants.



**IIIC AND IQAC OF
SHREE NARANJIBHAI LALBHAJI PATEL COLLEGE OF PHARMACY,
(Vidyabharti Trust Institution, Umrahk)
Approved by AICTE, New Delhi and Affiliated to GTU, Ahmedabad.**



**Organizes
Online Webinar on**

CLINICAL DATA MANAGEMENT



Convener

Dr. Dhiren Shah
Principal
SNLPCP, Umrahk

Speaker

MR. NIKUNJ PATEL

**Director, Data Management & Bio-statistics
CBCC Global Research, Ahmedabad, India**

Date and Time

**22 June 2021, Tuesday
11.00 am to 12.00 pm**

Co-ordinator

Prof. Vipulkumar Gajera
Assistant Professor
SNLPCP, Umrahk
Mo.: 99092 40815

Vidyabharti Campus, At & Po Baben, Ta: Bardoli, Di. Surat, Pin: 394601.

CDM in Clinical Trial Process

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    graph TD
      subgraph "Data Management relevant activities"
        DP[Development Plan]
        P[Protocol]
        DMP[Data Management Plan]
        SAP[Statistical Analysis Plan]
        ECRF["(e)Case Report form"]
      end
      HA[HA Approval]
      SS[Site selection]
      IEC[IEC/IRB Approval (Site)]
      TS[Trial Supplies]
      SI[Site Initiation]
      PR[Patient recruitment and follow up monitoring]
      DV[Data verification]
      DCR[Data cleaning / reconciling]
      SDC[Study documentation]
      DL[Database locked]
      SC[Sites closed]
      A[Archive]
      AR[Analysis and Reporting]
      RS[Regulatory submission]

      DP --> HA
      P --> SS
      DMP --> IEC
      SAP --> IEC
      ECRF --> IEC
      HA --> SI
      SS --> SI
      IEC --> SI
      TS --> SI
      SI --> PR
      PR --> DV
      DV --> DCR
      DCR --> DL
      DL --> SDC
      SDC --> SC
      SC --> A
      SC --> AR
      AR --> RS
  
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11:16 AM | qcx-hmph-qzu

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11:16 AM 22-06-2021

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REC Nikunj Patel is presenting

Key Stakeholders: Data Manager to collaborate with X functions for delivering best quality and results

- Project Manager/Lead**
 - Heads the trial/study team
 - Overall accountable for study deliverables to Sponsor/Client
- Field Monitor/Trial Operations**
 - Manages investigator site monitoring
 - Verifies data with source data
- Investigator**
 - Key player in Clinical Research
 - Responsible for trial conduct at a site
- Trial Programmer**
 - Manages programming of data in tables, figures and listings
- Medical Writer**
 - Develops content for Clinical Study Reports
- Specialists**
 - Different specialists within Client reviewing and managing data for specialized fields like Biomarker, Imaging, PK etc.
- Pharmacovigilance**
 - Manages safety reporting
- Trial Statistician**
 - Performs statistical analysis of data

11:50 AM | qcx-hmph-qzu

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REC Nikunj Patel is presenting

EDC: DM Lifecycle

12:04 PM | qcx-hmph-qzu

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