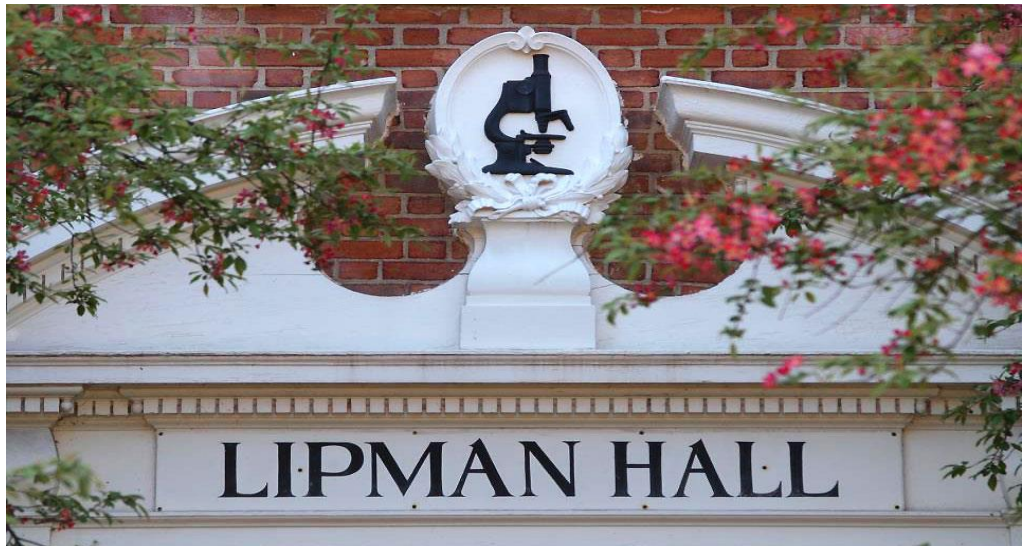
Career journey: Rutgers PhD to Merck MW

Preshita Gadkari, PhD
Senior Medical Writer, Merck
preshita.gadkari@gmail.com

PhD, Microbial Biology (graduation: Jan 2019)



BGB GROUP

The New York Academy of Sciences

gsk Consumer Healthcare

Publication MW
(Feb 2019 to May 2020)

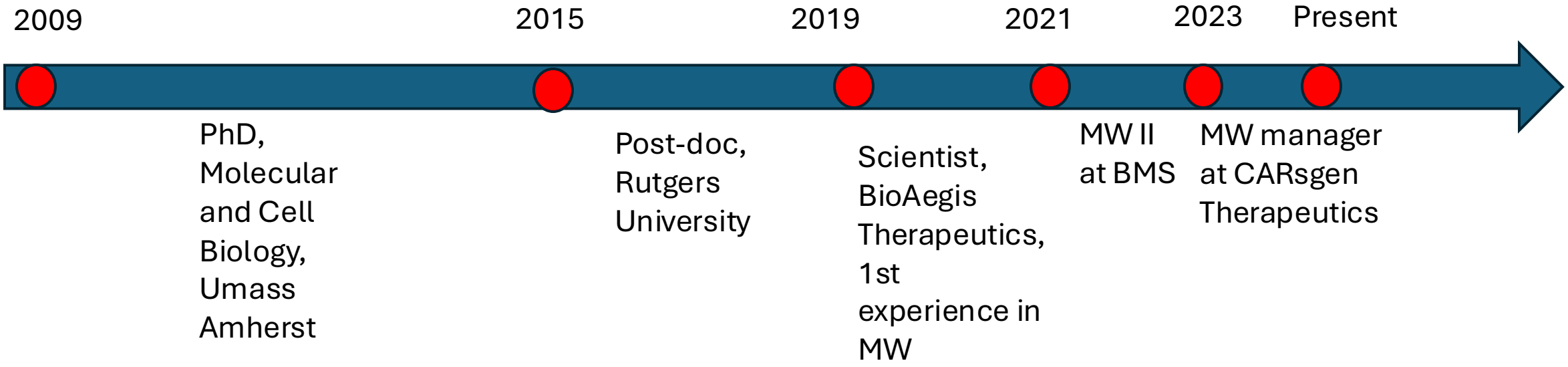
NUCLEUS GLOBAL

Regulatory MW
(May 2020 to present)

MERCK

Career Timeline - **Abla Tannous, PhD**

Medical Writing Manager, CARsgen Therapeutics
ablatannous@gmail.com



Aamani Rupakula Boyanapalli, PhD – Bio/Career

aamanirups@gmail.com
Lead Writer Astellas Gene Therapy

Post-Doc, Dept of Microbiology
SEBS, Lipman Hall
2015-2017

RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

Scientist,
R&D, Oral Care
2017-2019

Colgate
CONSUMER CARE

R&D: *Antimicrobial testing, method development (in vitro, in vivo, clinical studies)*

Writing: *study protocols, reports*

Senior Scientist,
R&D Microbiology
2019-2021 April

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES
MEDICAL DEVICES

Scientific Writer
Nonclinical Pharmacology
Scientific Writing Team,
2021 April- 2024 July

REGENERON
SCIENCE TO MEDICINE
BIOTECH/PHARMA

Lead Nonclinical Writer
Integrative Biology, AGT,
2024 August – Current

astellas
GENE THERAPIES
BIOTECH/PHARMA

ÉCOLE POLYTECHNIQUE FÉDÉRALE DE LAUSANNE

PhD *(Microbiology, Anaerobes, OMICS, Protein Biochemistry)*
2011-2015

VIT
Vellore Institute of Technology
(Deemed to be University under section 3 of UGC Act, 1956)

Masters *Microbiology*
2010

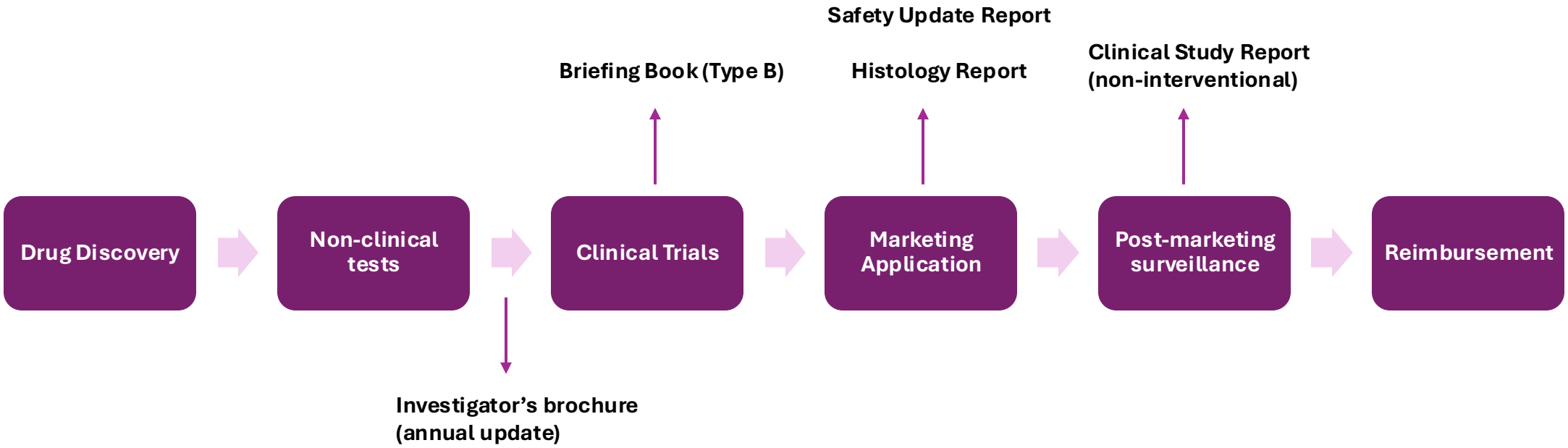
Botswana

CAMBRIDGE
International Examinations
Excellence in education
Cambrige
O Level

Maryam Alapa, PhD

Regulatory Medical Writing Scientist, J&J

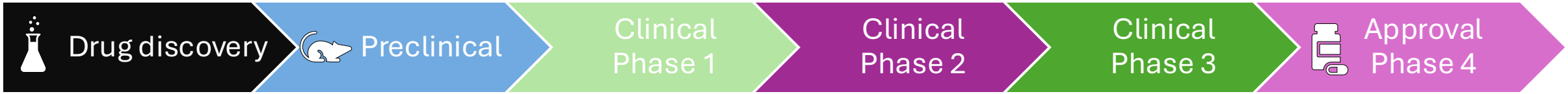
MAlapa@ITS.JNJ.com



<u>Addendum/Erratum</u>

Clinical Study Report
Investigator's Brochure
Clinical Overview

Clinical Trial Phases and Associated Regulatory Documents

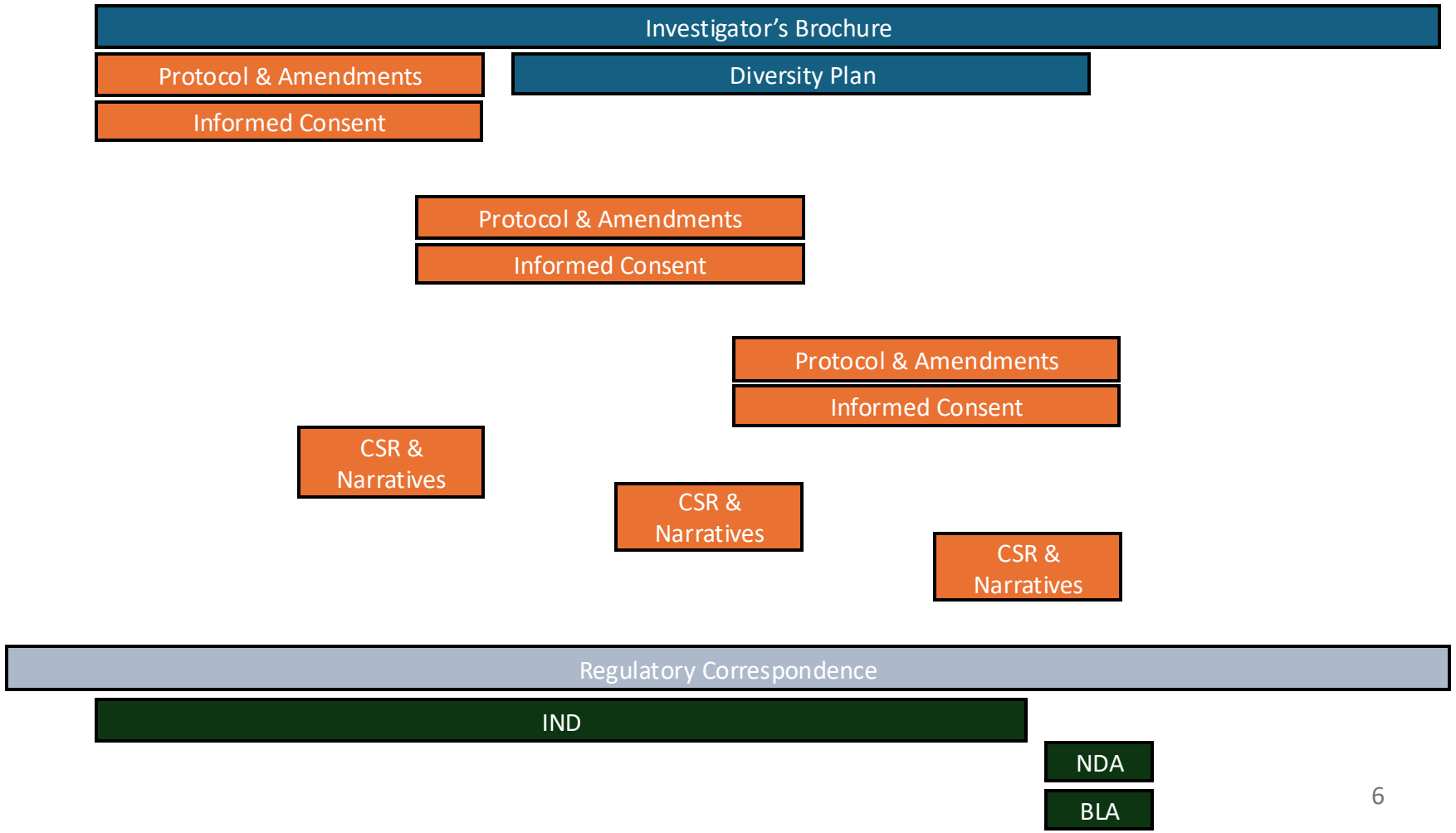


Documents:

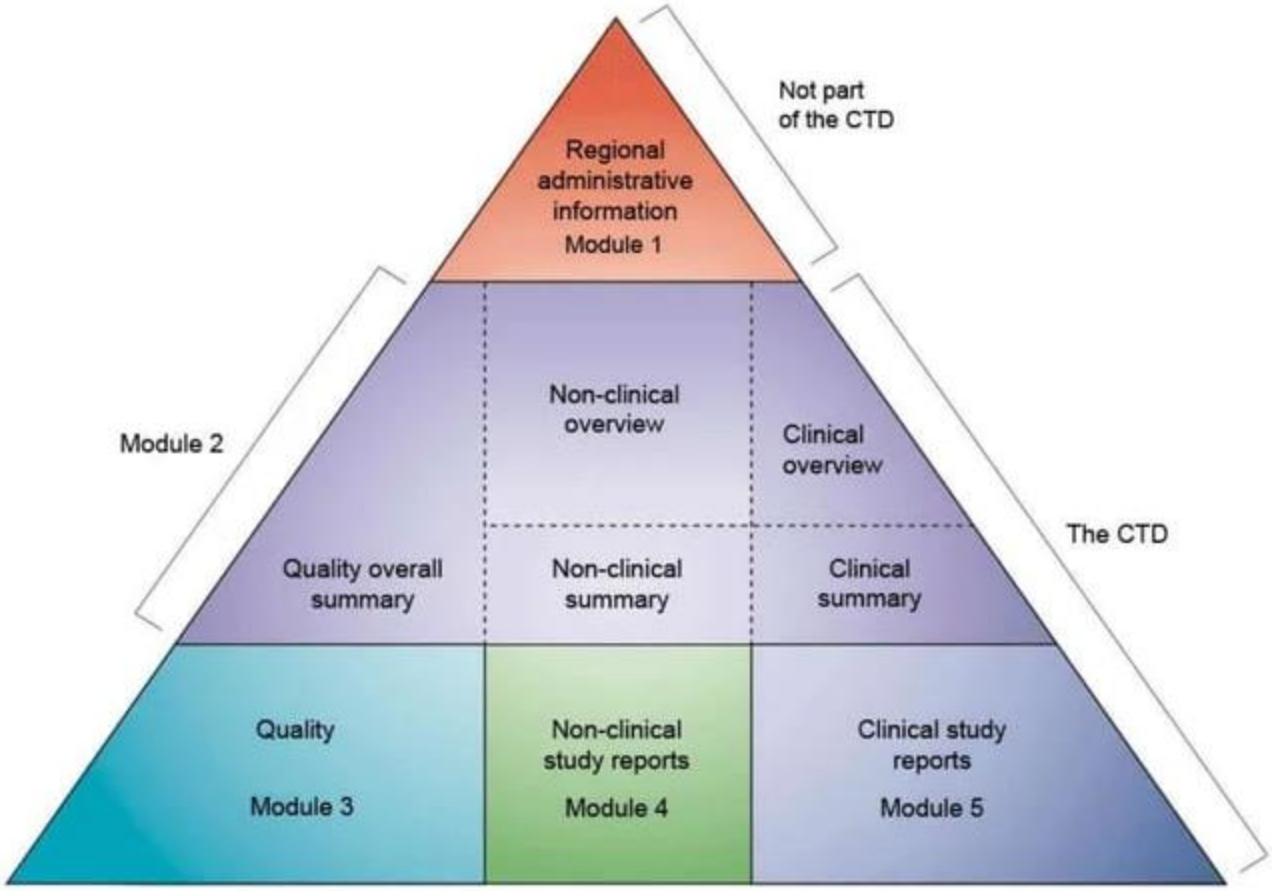
- Investigator's Brochure (IB)
- Diversity Plan
- Protocol and Amendments
- Informed Consent Form (ICF)
- Clinical Study Report (CSR)
- Patient Safety Narratives

Regulatory Submissions:

- Investigational New Drug (IND) Application
- New Drug Application (NDA)
- Biologics License Application (BLA)



Clinical Technical Document (CTD)



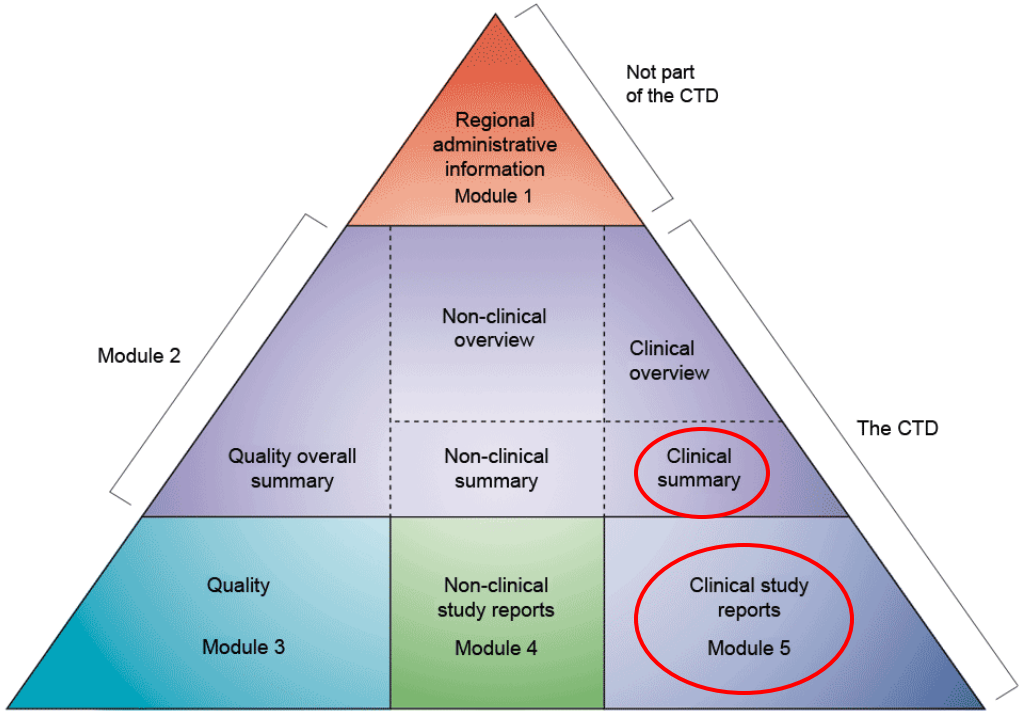
https://www.accessdata.fda.gov/cder/eCTD/backgr/backgr/fd_02_01_0030.htm

Submissions and Marketing Applications

- Worked on submission documents: BLAs (biological licensing applications); Ex:

  - Module 2:
    - Summary of Clinical Safety
    - Summary of Clinical Efficacy

  - Module 5
    - CSR
    - PK/PD reports
    - Population PK report



Other ex. of regulatory documentation types:

- Investigator Brochure:

Comprehensive document summarizing the body of information about an investigational product ("IP" or "study drug") (Pre-clinical, CMC [Chemistry, Manufacturing and Controls], Clinical, Summary of Data Guidance for investigators [including risks])

- Briefing Books:

Prepared ahead of meetings seeking advising from FDA

Meeting Types:

- Type A:

  A Type A meeting is a meeting needed to help an otherwise stalled product development program proceed.

- Type B:

  Pre-IND meeting, end phase meetings, pre-NDA/BLA application meetings

- Type C

  Any meeting other than Type A and Type B

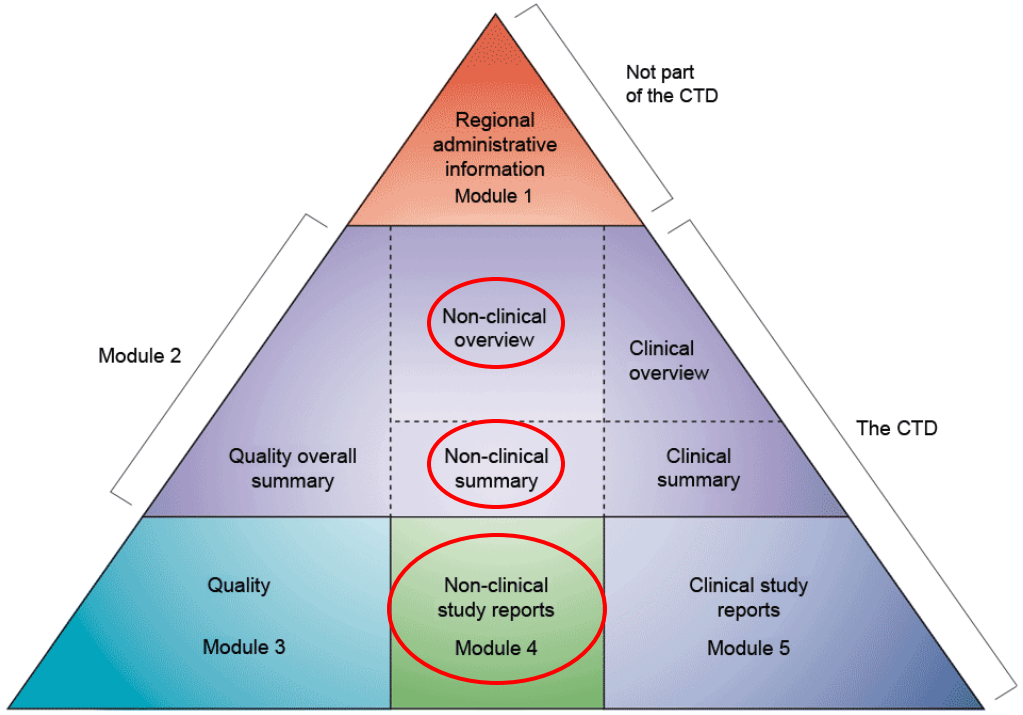
Material needed:

- Meeting request
- Meeting Package (Briefing Book)

Aamani

IND/CTA Submissions

- Worked on submission documents:
  - **Module 2:**
    - Non-Clinical Overview
    - Non-Clinical Summaries
      - 2.6.2 Pharmacology written summary
      - 2.6.2 Pharmacology tabulated summary
      - 2.6.4 Pharmakokinetics written summary
      - 2.6.5 Pharmakokinetics tabulated summary
      - 2.6.6 Toxicology written summary
      - 2.6.7 Toxicology tabulated summary
  - **Module 4**
    - Nonclinical study reports
      - In vitro report
      - In vivo Efficacy report (Mice, NHP, Dogs)
      - SPR/Binding kinetics determination report
      - Toxicology reports
      - Bioanalytical reports
      - PK/PD reports



Experienced in working with programs in:

- **Therapeutic Focus Areas:**
  - Immunology and Inflammation
  - Cardiovascular, general medicine
  - Obesity and Metabolism
  - CNS & Neuromuscular
  - Ophthalmology

Modalities:

Monoclonal antibodies
Bispecific antibodies
siRNA
combination therapies
AAV Gene therapy

Other ex. of regulatory documentation types:

- Investigator Brochure:
  - Pre-clinical sections
- Annual/periodic updates of Investigator Brochure
- DSUR: Development safety update reports (annual)
- FDA Pre-IND and interaction Briefing Books
- FDA Written responses/Requests for Information (RFIs)