Club Founder
Dr. Mahmoud Bahgat

International
Factories Club
Sharpen your skills

Co-Founder & Host:
Dr. Ahmed Raafat

International Factories Club

REGISTRATION FOR EXPORT (CTD & eCTD)

Online zoom

9 pm EGY-10 pm KSA-11 pm UAE

Dr. Mahmoud El-Aila
Export Sales Manager

SATURDAY 28TH DEC. 2024

Dr. Mahmoud El-Aila

Education:

- **MBA, Eslsca University, 2023.**
- **BSc of Pharmacy, Zagazig University, 2001.**

Experience:

- Export
- Global Regulatory Affairs.

Export Manager:-

- Rameda (2023 – Present).
- LIPTIS (2015 – 2023).
- Al-Andalous (2013- 2015).
- ADWIA (2007- 2013)
- MUP (2003 – 2007)


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Common Technical Document (CTD)

Prepared by:
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Introduction


IMATION
DLTtape IV

ICH

- Efficacy
- Safety
- Quality

- Common Technical Document - CTD

The CTD is an internationally agreed format for the preparation of applications to be submitted to regulatory authorities in the three ICH regions of Europe, USA and Japan.

To:

Save time

Resources

Facilitate regulatory review

Communication.

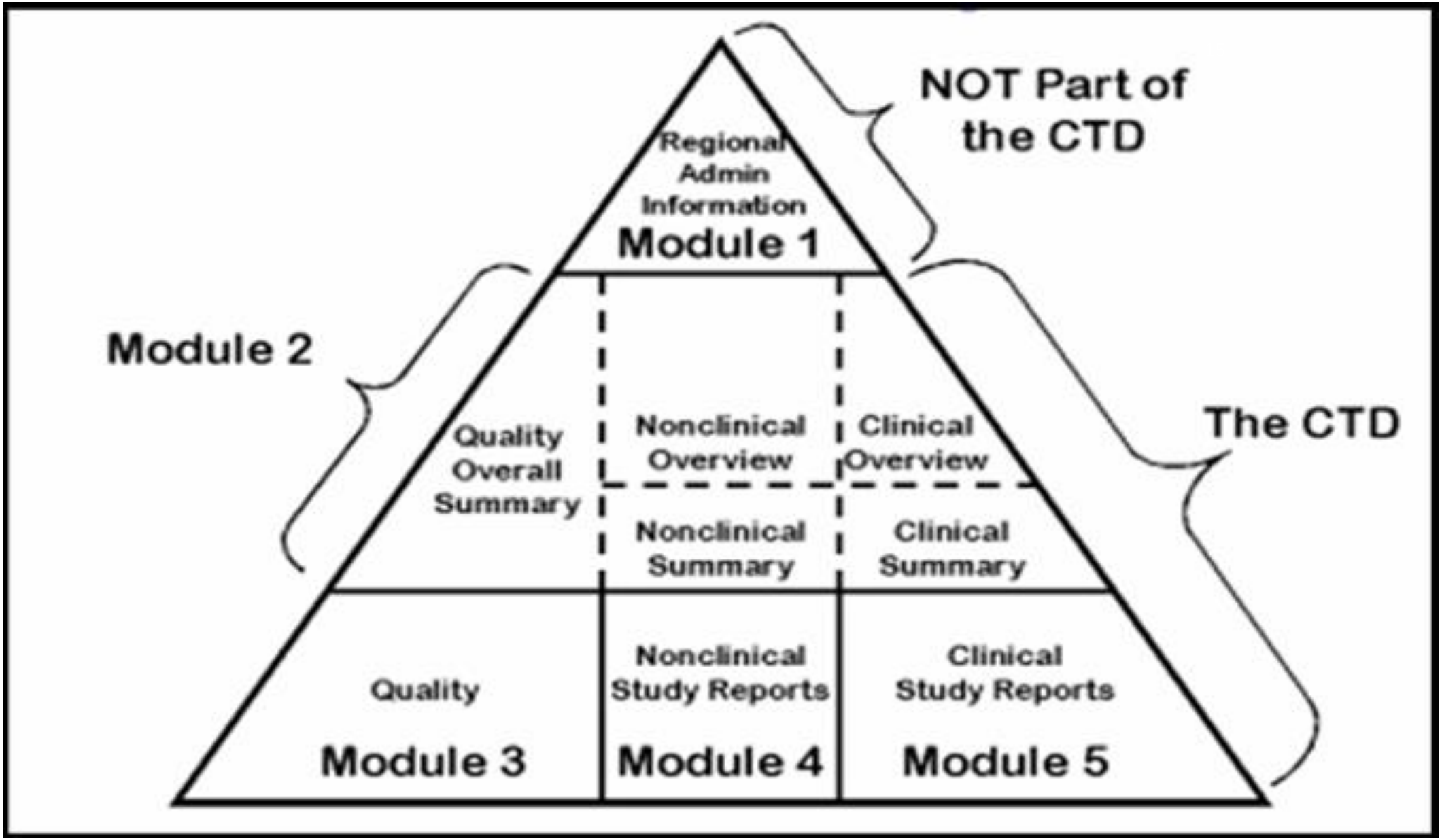
The CTD gives no information about the content of a dossier and does not indicate which studies and data are required for a successful approval.

Regional requirements may affect the content of the dossier submitted in each region; therefore, the dossier will not necessarily be identical for all regions.

CTD Structure

The Common Technical Document is organized into five modules.

Module 1 – Regional & Administrative
Module 2- All summaries / overviews
Module 3 – Quality
Module 4 – Preclinical
Module 5 - Clinical


NOT Part of the CTD
Regional Admin Information
Module 1
Module 2
Quality Overall Summary
Nonclinical Overview
Clinical Overview
The CTD
Nonclinical Summary
Clinical Summary
Quality
Nonclinical Study Reports
Clinical Study Reports
Module 3
Module 4
Module 5

Contents of Module 1

(m1)

- Administrative, regional or national information is provided in m1

- This module contains the specific Country-requirements for the administrative data (e.g. the application form, legalized docs, the proposed summary of product characteristics, labelling and package leaflet, etc.).

Contents of Module 2

(m2)

m2 Contains:

- Quality Overall Summary (QOS)
- High level summaries for:
  m3, m4 & m5

Contents of Module 3

(m3)

Quality The section of the application covering chemical and pharmaceutical data including data for biological/ biotechnological products).

(S-Part , P-Part)

Non-clinical Study Reports

Module 5:

Regional Specificities

Module 1	Regional Administrative Information (EU, FDA, ……)
Modules 2 & 3	Regional Information (in Sections 2.3.R & 3.2.R)
Modules 4 & 5	No Specific Regional Section
Module 5	Case Report Form (FDA) Tabulated List of Trial Subjects)

Preparing & Organizing
CTD File

- Text and tables should be prepared using margins that allow the document to be printed on A4 paper.

- The left-hand margin should be sufficiently large that information is not obscured through binding.

- Font sizes for text and tables should be of a style and size that are large enough to be easily legible even after photocopying.
- Times New Roman, 12-point font is recommended for narrative text.
- Abbreviations should be defined the first time they are used in each module.

- Pagination and Segregation

- Every document should be prepared in line with Organisation CTD recommendation.

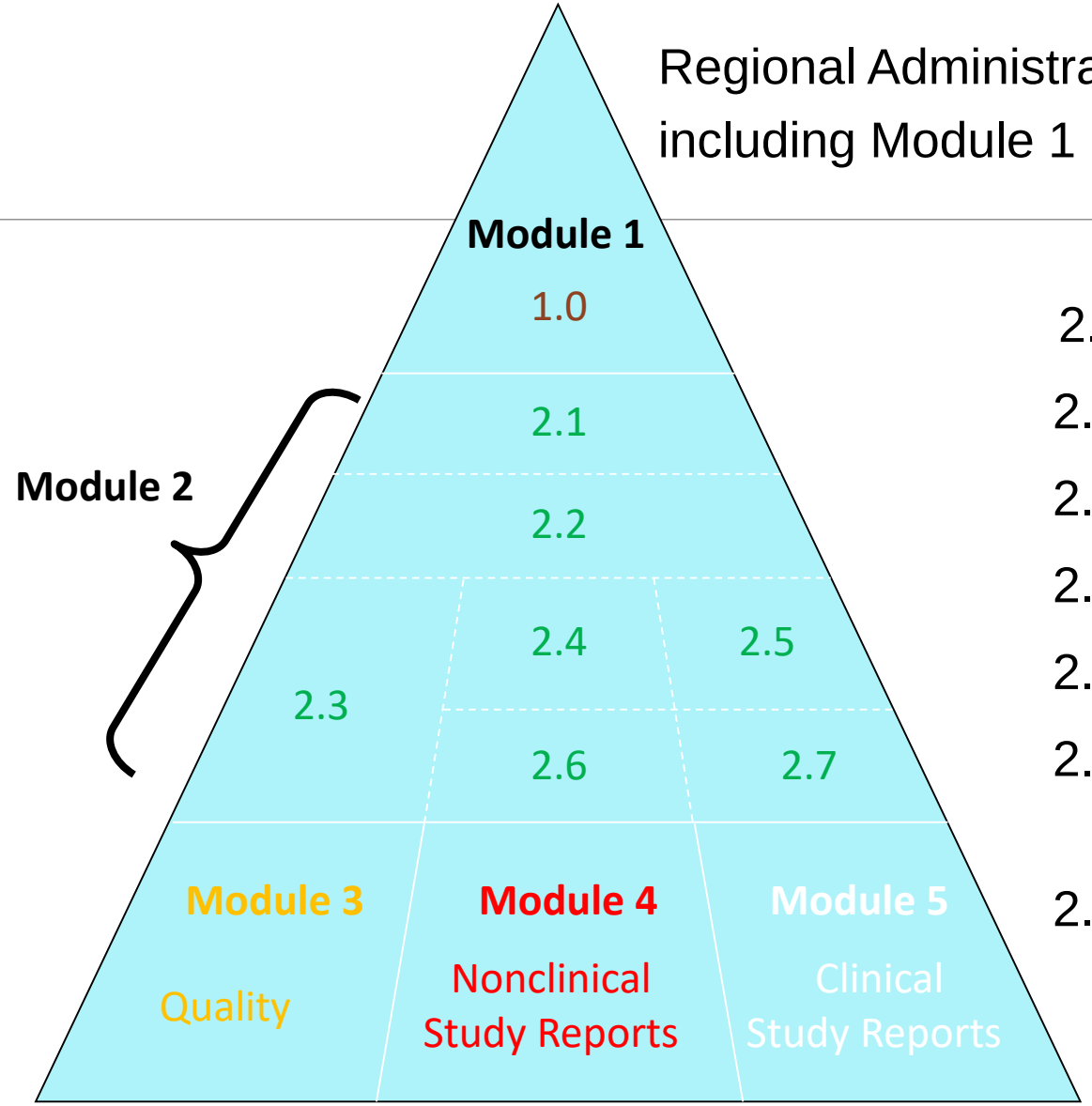
If no information is available or required under a specific heading, that section of the application should be marked **“not applicable”** or **“not relevant”** whilst retaining the section

Title and numbering, and, if necessary, a justification for the absence of a study should be provided in the Quality Overall Summary, the Non-clinical Overview and the Clinical Overview.

Most of the Health Authorities NOT require paper, Some require to submit applications on paper.

Submissions sent electronically are likely to be processed to a quicker timescale than paper submissions.”

CTD Numbering System



Regional Administrative Information1.0

including Module 1 ToC1.1

2.1 ToC of the CTD (m2,3,4,5)

2.2 Introduction

2.3 Quality Overall Summary

2.4 Nonclinical Overview

2.5 Clinical Overview

2.6 Nonclinical Written and Tabulated Summaries

2.7 Clinical Summary

Module 1	Administrative information and product information
1.1	**Comprehensive table of contents for all modules**
1.2	**Cover letter**
1.3	**Comprehensive table of contents for module 1**
1.4	**Quality Information Summary (QIS)**
1.5	**Product Information**
1.5.1	Prescribing information (Summary of product characteristics)
1.5.2	Container labelling
1.5.3	Patient information leaflet (PIL)
1.5.4	Mock-ups and specimens
1.6	**Information about the experts**
1.7	**APIMFs and certificates of suitability to the monographs of the European Pharmacopoeia**
1.8	**Good Manufacturing Practice**
1.9	**Regulatory status within EAC and in countries with SRAs**
1.9.1	List of countries in EAC and countries with SRAs in which a similar application has been submitted
1.9.2	Evaluation reports from EAC NMRAs
1.9.3	Evaluation reports from SRAs
1.9.4	Manufacturing and Marketing Authorization
1.10	**Paediatric development program**
1.11	**Products samples**

Module 2	
2.1	OVERALL CTD TABLE OF CONTENTS OF MODULES 2, 3, 4, AND 5
2.2	INTRODUCTION
2.3	QUALITY OVERALL SUMMARY
2.3.S	DRUG SUBSTANCE
2.3.S.1	General Information
2.3.S.2	Manufacture
2.3.S.3	Characterization
2.3.S.4	Control of Drug Substance
2.3.S.5	Reference Standards or Materials
2.3.S.6	Container Closure System
2.3.S.7	Stability
2.3.P	DRUG PRODUCT
2.3.P.1	Description and Composition of the Drug Product
2.3.P.2	Pharmaceutical Development
2.3.P.3	Manufacture
2.3.P.4	Control of Excipients
2.3.P.5	Control of Drug Product
2.3.P.6	Reference Standards or Materials
2.3.P.7	Container Closure System
2.3.P.8	Stability

Module 2 (Cont.)	
2.3.A	APPENDICES
2.3.A.1	Facilities and Equipment
2.3.A.2	Adventitious Agents Safety Evaluation
2.3.A.3	Novel Excipients
2.3.R	REGIONAL INFORMATION
2.4	NONCLINICAL OVERVIEW
2.4.1	Overview of the Nonclinical Testing Strategy
2.4.2	Pharmacology
2.4.3	Pharmacokinetics
2.4.4	Toxicology
2.4.5	Integrated Overview and Conclusions
2.4.6	List of Literature Citations
2.5	CLINICAL OVERVIEW
2.5.1	Product Development Rationale
2.5.2	Overview of Biopharmaceutics
2.5.3	Overview of Clinical Pharmacology
2.5.4	Overview of Efficacy
2.5.5	Overview of Safety
2.5.6	Benefits and Risks Conclusions
2.5.7	References

Module 2 (Cont.)	
2.6	CONTENT OF NONCLINICAL WRITTEN AND TABULATED SUMMARIES
2.6.1	Introduction
2.6.2	Pharmacology Written Summary
2.6.3	Pharmacology Tabulated Summary (Appendix B)
2.6.4	Pharmacokinetics Written Summary
2.6.5	Pharmacokinetics Tabulated Summary (Appendix B)
2.6.6	Toxicology Written Summary
2.6.7	Toxicology Tabulated Summary (Appendix B)
2.7	CLINICAL SUMMARY
2.7.1	Summary of Biopharmaceutics and Associated Analytical Methods
2.7.2	Summary of Clinical Pharmacology Studies
2.7.3	Summary of Clinical Efficacy
2.7.4	Summary of Clinical Safety
2.7.5	References
2.7.6	Synopses of Individual Studies

Module 3	
3.1	MODULE 3 TABLE OF CONTENTS
3.2	BODY OF DATA
3.2.S	DRUG SUBSTANCE
3.2.S.1	General Information
3.2.S.2	Manufacture
3.2.S.3	Characterisation
3.2.S.4	Control of Drug Substance
3.2.S.5	Reference Standards or Materials
3.2.S.6	Container Closure System
3.2.S.7	Stability
3.2.P	DRUG PRODUCT
3.2.P.1	Description and Composition of the Drug Product
3.2.P.2	Pharmaceutical Development
3.2.P.3	Manufacture
3.2.P.4	Control of Excipients
3.2.P.5	Control of Drug Product
3.2.P.6	Reference Standards or Materials
3.2.P.7	Container Closure System
3.2.P.8	Stability

Module 3 (Cont.)	
3.2.A	APPENDICES
3.2.A.1	Facilities and Equipment
3.2.A.2	Adventitious Agents Safety Evaluation
3.2.A.3	Novel Excipients
3.2.R	REGIONAL INFORMATION
3.3	LITERATURE REFERENCES

Module 4	
4.1	MODULE 4 TABLE OF CONTENTS
4.2	STUDY REPORTS
4.2.1	Pharmacology
4.2.2	Pharmacokinetics
4.2.3	Toxicology
4.3	LITERATURE REFERENCES

Module 5	
5.1	MODULE 5 TABLE OF CONTENTS
5.2	TABULAR LISTINGS OF ALL CLINICAL STUDIES
5.3	CLINICAL STUDY REPORTS
5.3.1	Reports of Biopharmaceutic Studies
5.3.2	Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials
5.3.3	Reports of Human Pharmacokinetic (PK) Studies
5.3.4	Reports of Human Pharmacodynamic (PD) Studies
5.3.5	Reports of Efficacy and Safety Studies
5.3.6	Reports of Post-Marketing Experience
5.3.7	Case Report Forms and Individual Patient Listings
5.4	LITERATURE REFERENCES

Benefits of the CTD