

PHUSE EU Connect 2020

Virtual Conference

9th – 13th November 2020

NMPA Submission (Data submission in China)



Presented by

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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of PHUSE.*



Agenda

1. From SDA to NMPA
2. Data Submissions in China
3. Consultation Meetings
4. China Specific Documents
5. Guidelines and Deliverables
6. Expectations for the Future

From SDA to NMPA

SDA -> **SFDA** -> **CFDA** -> **CNDA** -> **NMPA**



1998 – 2003

**State
Drug
Administration**

2003 – 2013

**State
Food and
Drug
Administration**

2013 – 2018.03

**China
Food and
Drug
Administration**

2018.03 – 2018.09

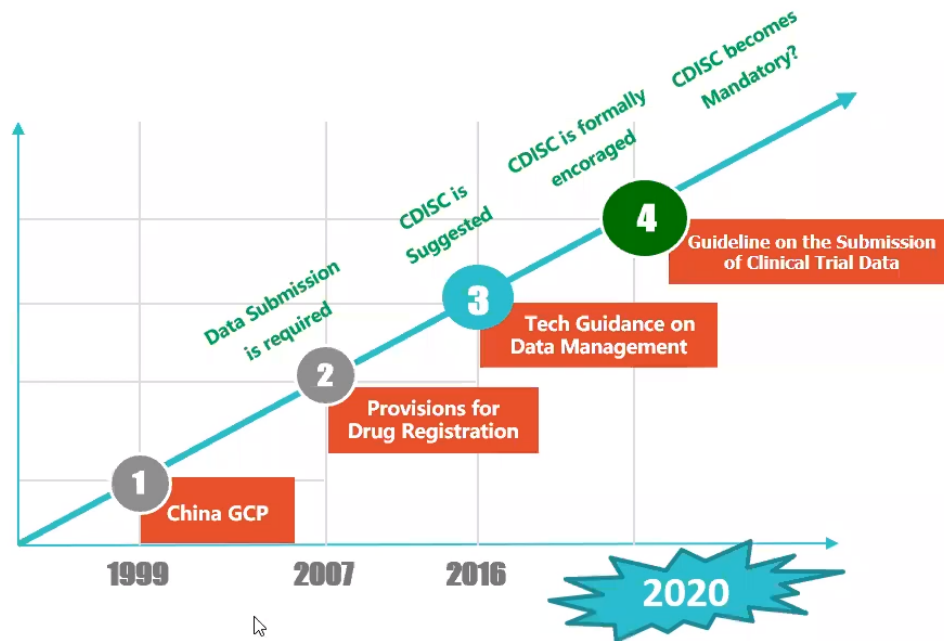
**China
National
Drug
Administration**

2018.09 – Present

**National
Medicinal
Products
Administration**

Data Submissions in China

Data Submission in China

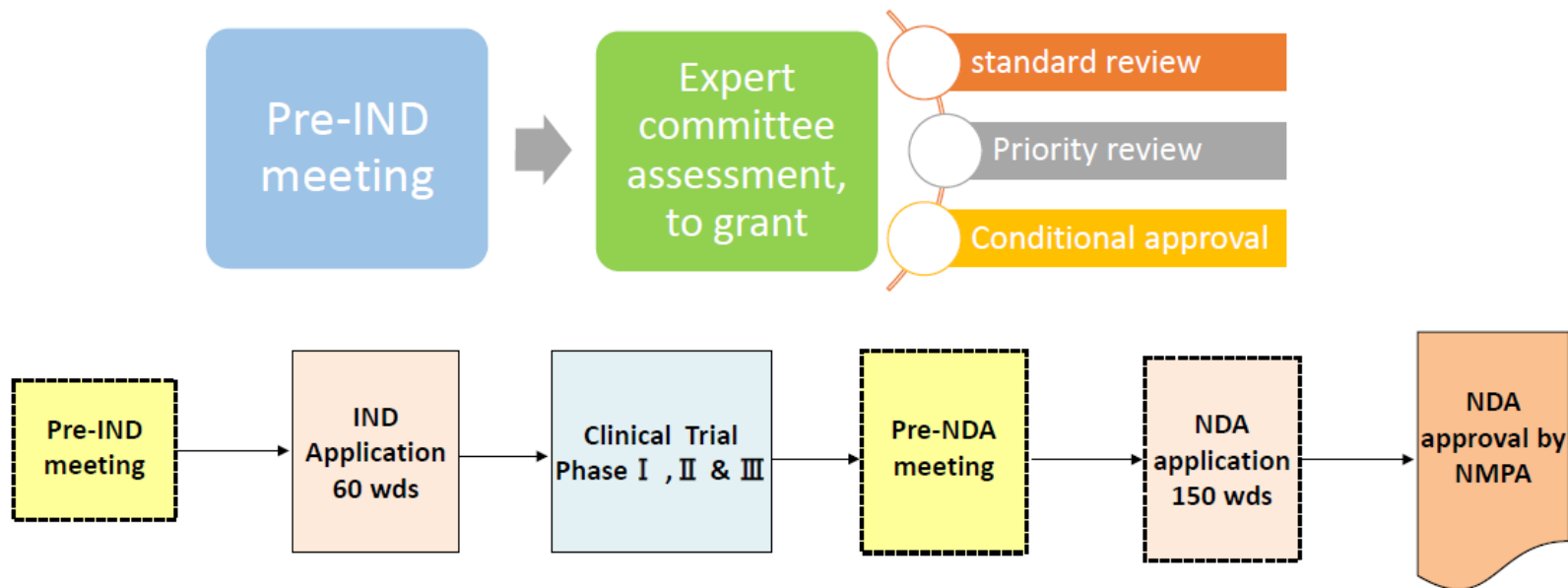


Source:
https://data42.cn/c3c/webinar/20200527/C3C_NMPA.mp4



Consultation Meetings

Pre-IND/NDA consultation meeting



Formal Consultation Meetings



Type I

1. A meeting that is necessary for solving a critical issue in clinical trials of an innovative drug or to address an important safety issue

Type II

1. Meeting at critical development stages Pre-Phase I, End of Phase II, Pre-Phase III and Pre-NDA
2. Risk Evaluation and Management Meeting pre-NDA approval

Type III

1. Any meeting other than Type I or Type II of new drug, and critical issues in the development of improved new drugs and generic drugs

Source: <https://www.pharmasug.org/proceedings/2019/SS/PharmaSUG-2019-SS-014.pdf>

China Specific Documents



Note: It should be written in Chinese.

Report contents:

- Participating entities/departments and their responsibilities
- Data management milestones
- CRF and database design
- Data validation and cleaning
- Medical coding
- External data management
- Quality evaluation of data management
- Data transfer at key milestones
- Version change record for key documents

... and appendices

**China
Specific
Document –
Data
Management
Report**

Source: Appendix Guidelines for the Planning and Reporting of
Data Management and Statistical Analysis of Drug Clinical Trials



Note: It should be written in Chinese.

**China
Specific
Document –
Foreign
language
database**

- Dataset label
- Variable label
- Adverse events terms
- Generic name of concomitant medications
- Medical history
- Names of the clinical endpoints in normalized datasets
- CRFs
- aCRFs
- Data definition files
- Data reviewer's guides

Chinese translations in database should be consistent with all other documents in submission package

Source: Guideline on the Submission of Clinical Trial Data

Note: It should be written in Chinese.



**China
Specific
Document –
Statistical
Analysis
Report**

Report contents:

- Trial Overview
- Statistical Analysis Method
- Results of Statistical Analysis
 - Disposition of Subjects
 - Analysis of Demographic Information and Baseline Characteristics
 - Analysis of Compliance and Concomitant Medication
 - Efficacy Analysis
 - Safety Analysis
 - Statistical Conclusions

... and appendices

Source: Appendix Guidelines for the Planning and Reporting of Data Management and Statistical Analysis of Drug Clinical Trials

A vertical decorative bar on the left side of the slide, featuring a close-up of orange capsules on a blue background.

Guidelines and Deliverables

NMPA Guidelines:

NMPA Guidance for Clinical Trial Datasets and Related Materials in eCTD (draft SEP 2020)

Guideline on the Submission of Clinical Trial Data (final JUL 2020)



国家药品监督管理局
National Medical Products Administration

中国药品监督 中国药闻 中国药监APP 邮箱 政务信息报送

请输入关键字

机构概况 政务公开 药品 医疗器械 化妆品

习近平出席第二届中国国际进口博览会开幕式并发表主旨演讲

习近平倡议共建开放合作、开放创新、开放共享的世界经济 宣布中国采取新举措推动更高水平对外开放 | 演讲全文

中国药械监管政策交流会

中国药械监管政策交流会
Meeting on Drug, WHO Intended for Policy Regulation in China

http://www.nmpa.gov.cn/WS04/CL2056/359716.html

要闻 国务院 | 市场监管总局 药监局

网站使用指南

- 中国药械监管政策交流会在进博会期间举办 (2019-11-06)
- 国家药监局有条件批准轻度至中度阿尔茨海默病药物甘露特钠胶囊上市 (2019-11-02)
- 国家药监局召开党组扩大会议传达学习党的十九届四中全会精神 (2019-11-01)
- 国家药监局召开直属机关工会第一次会员代表大会 (2019-10-31)



Guidelines

- The guidance (NMPA Guideline on the Submission of Clinical Trial Data) was final Jul-2020
- The guidance (Application Requirements for Clinical Trial Dataset and Related Materials in eCTD) is a draft version – it has been out for review
- We do not know when the final version is expected

DRAFT



Deliverables according to guidelines

Collected data:

- **aCRF** in pdf format and in Chinese
- **Tabulation dataset** containing all original data collected from the CRF and external files
 - Dataset labels and variable labels in Chinese
- **Define file** for SDTM in **xml or pdf** format – in Chinese
- **Reviewer's guide** in Chinese

Analysis data:

- **Analysis dataset** for statistical analysis should contain all the variables required for the analysis
 - Dataset labels and variable labels in Chinese
- **Define file** for ADaM in **xml or pdf** format – in Chinese
- **Reviewer's guide** in Chinese
- **Key programming code** (such as the derivative process of analysis database and the generative process of main analysis results). The programming code should be **readable, not contain complex external program calls** and use **text format (.txt files)**.



Deliverables according to guidelines

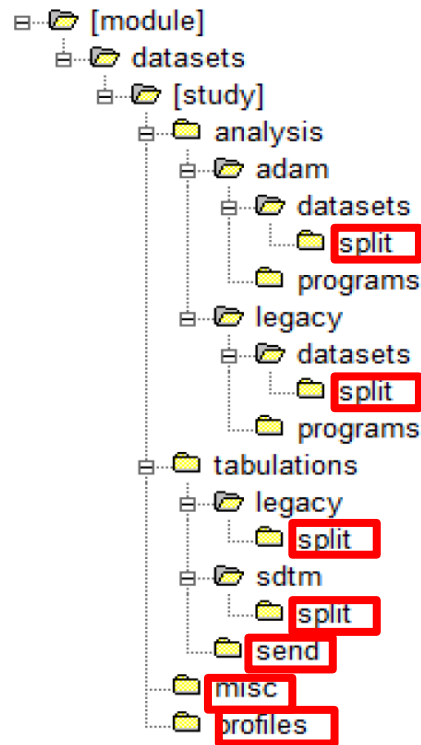
General:

- NMPA has stated that they can accept data **in accordance with the CDISC standards**
- Must be delivered as **SAS XPORT** (version 5 or higher transport format) – xpt format
- If the size of a single dataset is too big, it need to be split, and the splitting must be explained in the Define file and reviewer's guides.

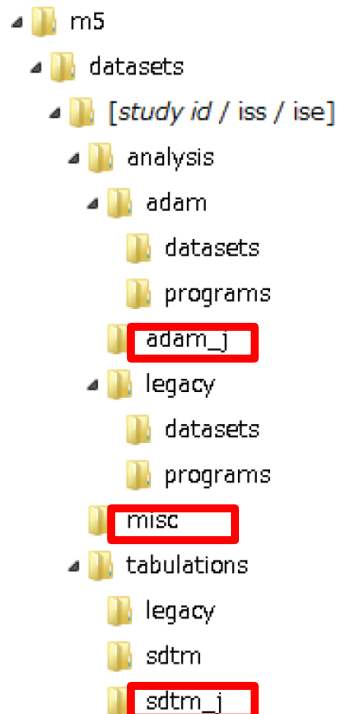
eCTD folder structure

Very much like the FDA structure

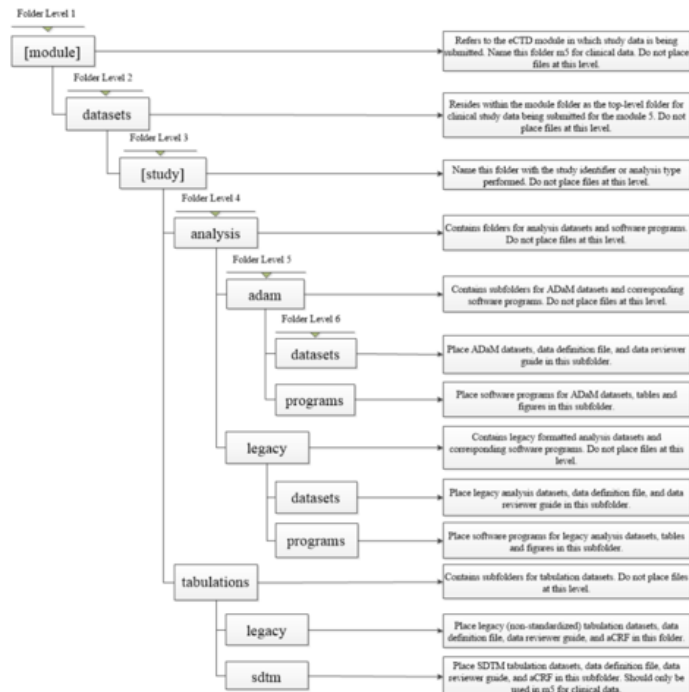
FDA



PMDA



NMPA





Expectations for the Future



Expectations for the future

- **Draft guideline will be finalised**
 - **The version out for review has aligned to the FDA guideline wrt**
 - size of datasets
 - eCTD folder structure naming
- **To provide further guidance to the sponsors NMPA could consider to create**
 - **Data Standards Catalogue**
 - **Technical Conformance Guide**

Thank You for Your Attention!

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