



SA10 - It's easy peasy submitting data to the NMPA, really?

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- The materials provided in this presentation or any comments or information provided by presenter(s) are for scientific knowledge exchange purpose ONLY.

Agenda

- China Filing evolution and preparation
- China Filing Translation
- Early planning and smooth delivery
- eSub for the Future in China
- Key Takeaways

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China Filing evolution and preparation

Old China (e)Sub Requirement

- Rawdata Spec **×**
- No Translation Requirement -
- Rawdata SAS xpt's **×**
- No Translation Requirement -
- Analysis data Spec **×**
- No Translation Requirement -
- Analysis data SAS xpt's **×**
- No Translation Requirement -
- SAS programs **×**
- (occasionally requested by CDE reviewers)
- No Translation Requirement -

New guidance, Effective 1-Oct,2020

- ✓ eSub annotated CRF
- Translate all except for Var name
- ✓ SDTM Define
- Translate all except for Var name
- ✓ SDTM SAS xpt's
- Translate Var & dataset label & MedDRA + WHODrug/GNE coding
- ✓ SDTM Reviewers Guide pdf (SDRG)
- Translate all except for Var name
- ✓ ADaM Define
- Translate all except for Var name
- ✓ ADaM SAS xpt's
- Translate Var & dataset label & MedDRA + WHODrug/Legacy GNE or Roche coding List
- ✓ SAS programs
- No explicit requirement for translating SAS or R programming comments
- ✓ ADaM Reviewers Guide pdf (ADRG)
- Translate all except for Var name

Global & Local Teams Support

Model I

Global study **without**
any **Chinese pts**



Model II

Global study **with**
Chinese pts enrolled



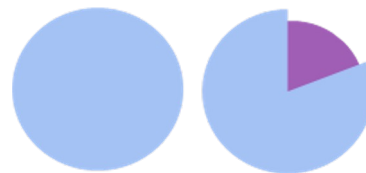
Model III

Global study **with**
China enrollment
extension



Model IV

China standalone study
(**Purely Chinese pts** or
majority Chinese pts)



— Global Population
— China Population

SDTM



ADaM



Subpop SDTM



Subpop ADaM



Translation



Responsibility

— Global Team
— China Team
— Global/China Team



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China Filing Translation: CDISC studies

Roche

Pre-Requisite

9-10 weeks prior to NMPA filing date



Allow sufficient time for translation

Pre-translation

Global eSub package available.
(Model I, II, III)

Model III Sub-pop packages & model IV

Chinese Blank CRF

On-translation

Translate SDTM Spec

Translate ADaM Spec

Translate Annotation

Parallel work

Translated Spec Review

Create bookmark

Manually check aCRF pages

Reviewer's Guide Translation (cSDRG/ADRG)

Post-translation

Review and deliver

Convert to XML define

Check all the links

Datasets Translation

Whole package review

Translation tool update

China Vendor

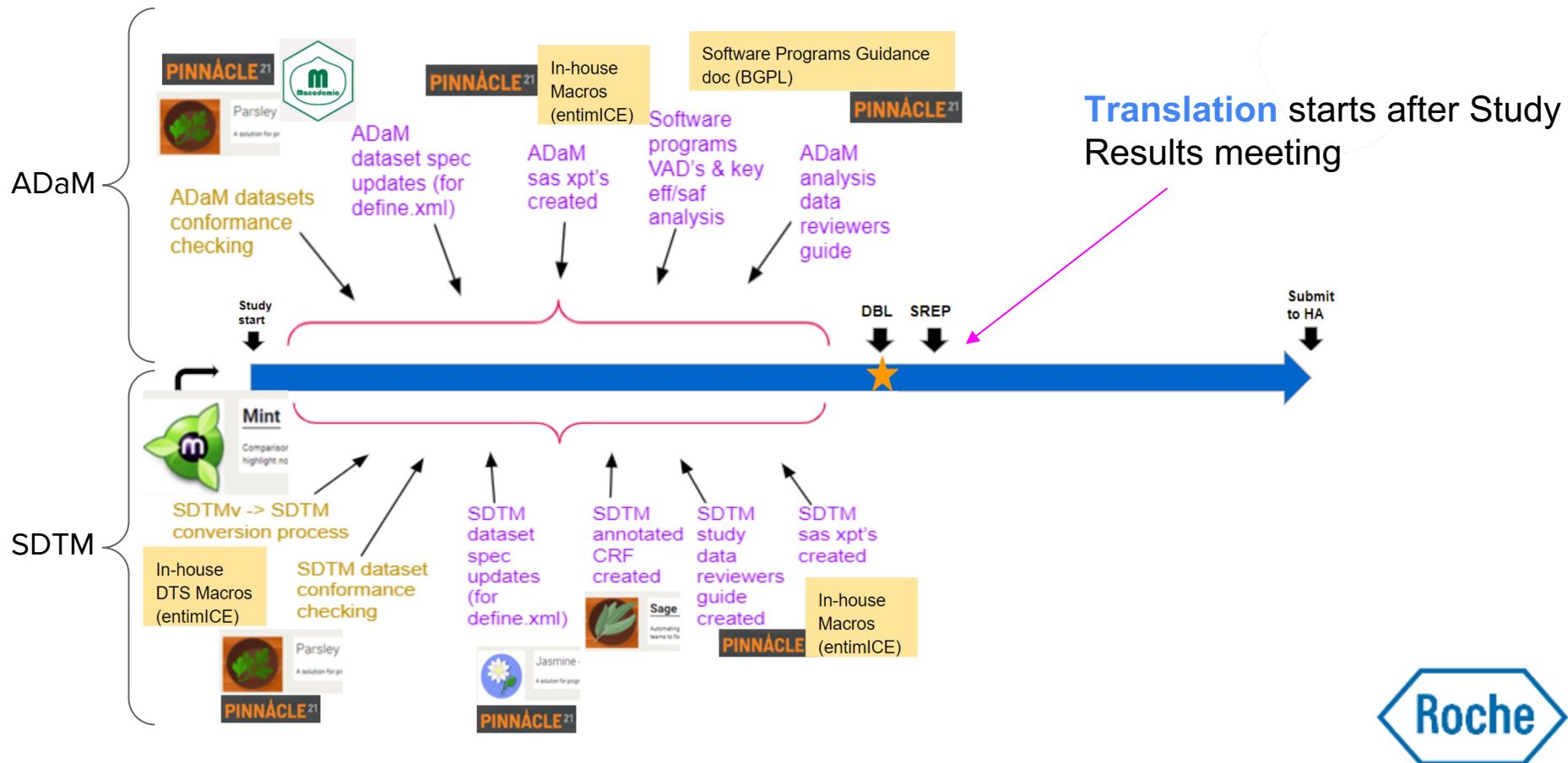
China Study Team

Global Study Team

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Early planning



Smooth delivery

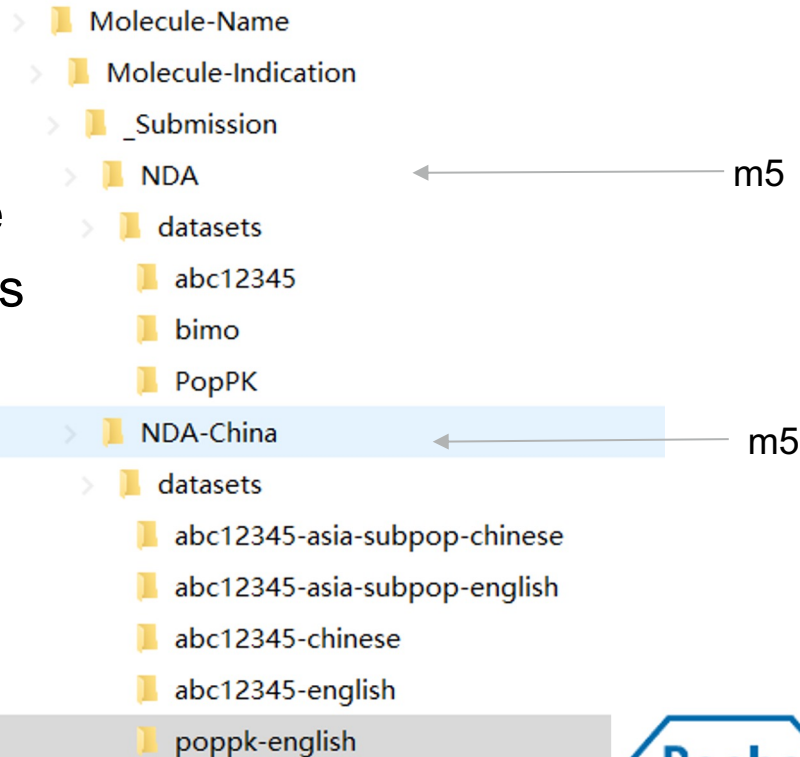
- Internal filing ticket and Data Collection sheet (DCS)
 - Filing scope - studies included, pk, pooling etc
 - Filing components - RG's, aCRF, datasets etc
 - Filing timelines - internal & external



Smooth delivery: closely collaborate with Regulatory

- eCTD submission

- Data scientist prepare data package
- Work with Regulatory to pass checks
- Upload to server in an eCTD folder structure and share the path with Regulatory
- Regulatory package all the things and submit to HA



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eSub for the Future in China

- eCTD: **Currently** different requirements from FDA
 - Only certain file types accepted (pdf, txt, xpt, xml, xsl)
 - No folders for multilingual filings
 - No 'misc' folder allowed
- Max 4GB on data size
- PDF settings differ
- **Future**
 - One size fits all - across all HA's
 - Acceptance of packages produced by different languages (R, python etc)
 - Ongoing work on Chinese metadata and E2E translation engine will accelerate delivery greatly
 - Fine tuning and streamlining of our internal processes and tools

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Key takeaways

- CDISC data standards **mandated** by FDA & PMDA
- Draft guidance from NMPA **follow** CDISC standards but the requirements **continue to evolve**
- 4 different China filing study models with different prep work
- Interactions to **start early** between China and Global teams
- **Closely collaborate** with Regulatory
- eCTD filing requirements **differ** from NMPA to FDA
- **Collaborate** with industry & NMPA on R submissions for future

Given all the activities we've gone through, is it really easy peasy to submit to China NMPA?



What do you think?

THANK YOU

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