



DEVELOPING SEND FOR CBER

– COLLABORATIVE WORKSTREAM INITIATIVE

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FDA Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.

Collaborating to Achieve Intent

“The Center for Biologics Evaluation and Research (CBER) intends to receive SEND datasets in future submissions.” ¹

Today....

Future....

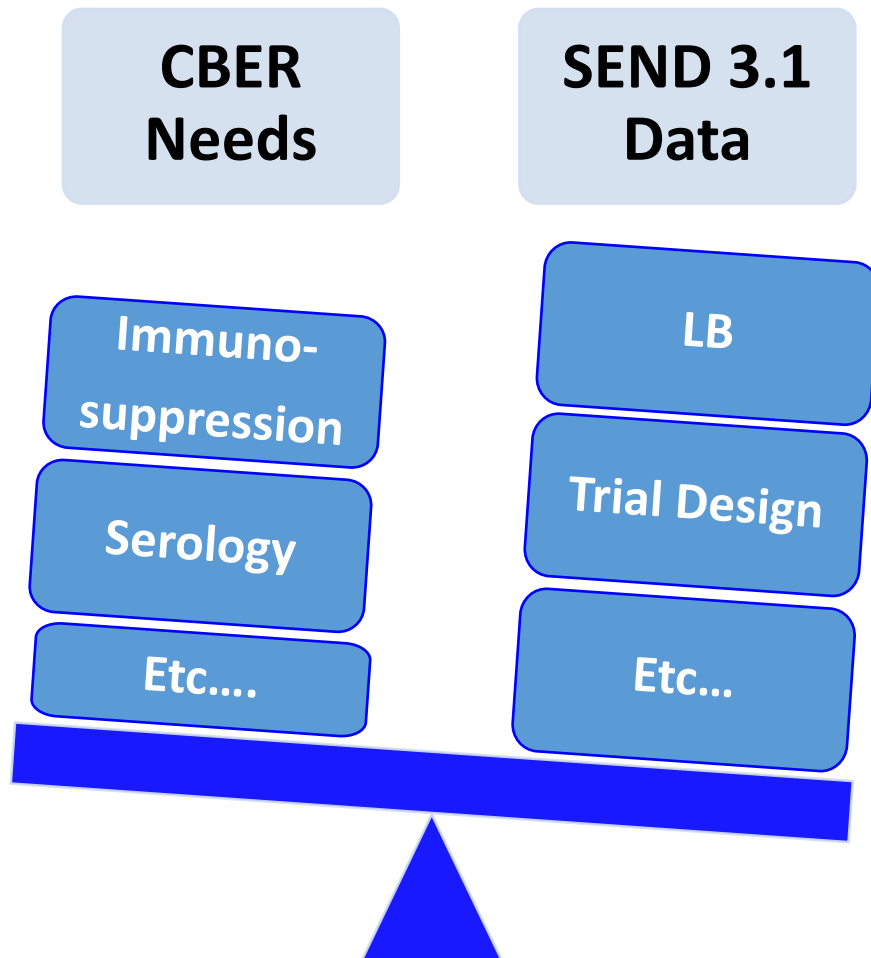
Use	Data Exchange Standard	Supported Implementation Guide Version	FDA Center(s)
Animal study datasets	Standard for Exchange of Nonclinical Data (SEND)		
Animal study datasets	SEND	3.1	CDER, CBER



We are on the way!
Assessing, Analyzing, Recommending, Piloting

¹ Developing SEND for CBER – Collaborative Workstream Initiative

Workstream Mission: Assess & Analyze for CBER



- Is SEND 3.1 sufficient?

➔ Comparing needs to the published and developing Standard Domains

- What knowledge is needed?

➔ Assuring expertise and information sharing

- What are the gaps?

➔ Publishing gap identification & analysis results

- How to mitigate the gaps?

➔ Developing recommendation to CDISC for evolving SEND & support a Pilot for SEND 3.1 submission to CBER

Team Operations & Accomplishments

- Biweekly Workstream Teleconferences
 - Working meetings with Domain reviews, data samples and IG review
 - Open to new participants!
- Published Work Products on CDISC WIKI
 - CBER Study Types and Endpoints by Office Inventory
 - Developing GAP Analysis

PROGRESS: DOMAIN REVIEW AND GAP IDENTIFICATION

BG	CL	IA	PP	TA
BW	VS	OE	SE	TS
MA	EX	AT	CO	REC
MI	IB	AG	DM	SUPP--
TF	DS	EG	TX	POOLDEF
OM	IS	PC	TE	

DONE!

TO DO...

Preparing for Future Implementation Tools & Training



- Provide Training for Reviewers
 - CDISC study data standards
 - Analysis tools including JMP, JMP Clinical, MAED, Jreview
- Explore tool for visualizing SEND data
- Provide consultation service to CBER reviewers on reviewing SEND data

Preparing for Future Implementation Submission Standards



- Conduct Fit-for-Use Pilot by the end of 2019
- Follow the procedure to add SEND to FDA Data Standards Catalog via Federal Register Notice (FRN) when time is ready
- Standards will be required in 24 months after FRN publishes

Conclusion

- Achieve a robust assessment of SENDIG 3.1 for implementation use on CBER submissions
- Additional activities for CDISC workstreams will be defined
- Continue maintain a close relationship with CDISC SEND team
- Fit for Use Pilot will be on the way
- Additional participation is welcome

For Your Reference

- FDA Data Standards Catalog
<https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>
- FDA Data Standards Program Action Plan
<https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM608348.pdf>
- Confirmed Data Endpoints for Exchange (CoDEx) for SENDIG v3.1
<https://wiki.cdisc.org/display/SENDCODEX/CoDEx+for+SENDIG+Compiled>
- Nonclinical Fit for Use Workstream
<https://wiki.cdisc.org/pages/viewpage.action?spaceKey=SEND&title=Nonclinical+Fit+for+Use+Workstream>

Any Questions ?



THANK YOU!

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And at anytime, you can send questions to CBER:

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