Date	Agenda Items	Notes	Action Items
2017-04-05	ISTEST: ☐ CDISC-2826 ☐ CDISC-2615 - Need modeling discussion MICROORG: ☑ CDISC-2870	WIKI Page for: Anti-Drug-Antibodies Modeling Examples	☑ Jordan to follow up with Bess again regarding CDISC-2791
2017-04-12	ISTEST: ☑ CDISC-2826 ☐ CDISC-2615 - Need modeling discussion MBTEST: ☐ CDISC-2875	WIKI Page for: Anti-Drug-Antibodies Modeling Examples	☑ Jordan to follow up with Bess again regarding CDISC-2791 ☑ Jordan to invite SEND requester for CDISC-2615 to virology team to brief the team on the background of the request.
2017-04-26	☑ **CDISC-2615 - Need modeling discussion** ☐ Discuss name change for the Virology team MBTEST: ☑ CDISC-2875	WIKI Page for: Anti-Drug-Antibodies Modeling Examples PPT: 2016-08-26_Novo Nordisk proposal for modelling of ADA_Thomas Gade Bjerregard.pptx 2017-04-26: 1. When you administer a drug in a subject, the drug may stimulate the production of anti-drug antibodies (ADA). It is important to know the presence/absence of the ADA as well as its quantification in titer. If the ISTEST is a generic value: ISTEST = Detection of Anti-drug Antibody, how do you represent the name of the drug to which the ADA is reacting to? Or should the drug name be pre-coordinated into the TEST? 2. A subject produces a certain self-antigen (e.g. glucagon), when you administer an analogue drug (e.g. Glucagon Analogue) that is structurally similar to this self-produced antigen, the ADA evoked by the analogue drug will cross-react to the self-antigen in the subject. There are cases where the ADA may cross-react to multiple self-antigens, it is important to know what the self-antigens are, so it looks like there needs to be a variable or place to represent the specificity of the endogenous antigen the ADA is reacting to. The IS domain currently has no standard variables to represent this type of INFO. AZ, BMS, Merck, and Covance comments: for representing ADAs, these companies have pre-coordinated the name of the drug into the TEST, such as "anti-AZ007 antibody". The AZ007 part will change from a company compound number, to the generic name then to the trade name, so there are at least 3 variations for a single drug. Results would be presence/absence of the ADA and also the titer.	☑ Jordan Li to bring the modeling to MRC for discussion: what fields can we use to house the information requested now in the SCAT variable? The SCAT variable was chosen as the best fit, however a qualifier NSV is needed to better describe the generic value in the TEST-CD variable, otherwise, pre-coorrdinated TEST values would have to be created (which is already done by AZ, Covance, BMS and Merck), but this is not a good approach. ☑ MRC discussion date set on June 2.
2017-05-03	☑ Discuss name change for the Microbiology team ☑ MSTEST-CD: CDISC-2791 (FDA comments) ☐ ISTEST-CD: CDISC-2615 - Waiting on MRC modeling discussion	Additional notes for CDISC-2791: for the IC50 and EC50 terms, they are not in LOINC so there is no concern over LONIC mapping, interchangbility and compatibility.	
2017-05-10	☑ MSTEST-CD: CDISC-2791 (continue to discuss the definitions of the terms; team agreed to add terms. ☐ ISTEST-CD: CDISC-2615 - Waiting on cross-team modeling discussion		

2017-05-17	☑ SDTM IG3.3: Need recommendation from the microbiology Team. Example 1, rows 3 and 6, should these TESTs even be here? Show Erin and Diane's emails. ☑ MBTEST-CD: CDISC-2943 ☑ Changes to Existing for C128982 ☐ ISTEST-CD: CDISC-2615 -Waiting on cross-team modeling discussion	Immunogenicity Specimen Assessments (IS) **SDS-1028** - "Positive" and "Negative" used in 2 different ways in IS domain **IN PROGRESS** 2017-05-17: IGDNA is intergenic DNA, this is the none-coding region of the DNA, and is not unique to Hep C. This should be represented by the MB domain. Suggested MBTESTCD = IGDNA; MBTEST should be Intergentic DNA, and use the organism identifier variable to represent the virus (in this case, HEP C). Microbiology team recommendation is to remove rows 3 and 6 from example 1, and remodel this concept in MB.	
2017-05-24:	☑ MBTEST-CD: CDISC-2943 ☑ MICROORG: CDISC-2957 ☐ ISTEST-CD: CDISC-2615 -Waiting on cross-team modeling discussion ☐		☐ Jordan to talk to Erin about the Terminology Rule document for Microbiology.

Working Documents

File	Modified
2016-08-26_Novo Nordisk proposal for modelling of ADA_Thomas Gade Bjerregard.pptx	Apr 20, 2017 by Jordan Li

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