Paper SA03

Data Standards Used for Electronic Submission of Real-World Evidence in New Drug Application (NDA)

Nicole Thorne & Kathy Wu,
Janssen Pharmaceutical Group of Companies of Johnson & Johnson,
Springhouse, PA & Raritan, NJ,
Ramesh Sundaram, GCE, Bowmanville, ON

ABSTRACT

The current standard of care therapy for the disease under study, is shown to have a low response for subjects with the specific tumor biomarker alterations we are targeting. Using a real world matched clinical and genomic dataset of patients with the disease, we explored the predictive value of this specific tumor biomarker alteration to the current standard of care therapy. At the pre-NDA meeting results of these real-world analyses were presented and decided to be submitted as a white paper, to be included in the submission. At the same meeting, the Federal Drug Administration (FDA) requested that the data to support this analysis be included in CDISC format. This paper covers our experience in submitting the Real-World Evidence (RWE) data in CDISC format, including the ADaM structure we used, other factors impacting our decisions, and our experience with a FDA technical walkthrough.

INTRODUCTION

In the submission of a novel therapy designated for a breakthrough submission using phase 2 one arm study we explored we learned that the standard of care therapy for the disease under study is shown to have a low response for subjects with the specific tumor biomarker alterations we are targeting with our therapy. Therefore, using real world matched clinical and genomic data of patients with the same disease under study and genomic markers we explored the predictive value of this specific tumor biomarker alteration to current standard of care therapy. Once this analysis plan was finalized, the relevant data located and licensed from multiple vendors targeting genomic centers, and preliminary data analyzed we shared the topline results with the FDA at a pre-NDA discussion.

REQUEST FROM FDA FOR DATA IN CDISC STRUCTURE

Once these exciting results from one RWE vendor were shared with the FDA they immediately followed up with a request for the data to be submitted in CDISC format to accompany the white paper planned to be included in the submission and requested that we explore and analyze multiple data sources. This started a series of challenges as the current format of the data was not in CDISC format and preliminary programming did not follow submission ready format. Immediate efforts were put in place to create analysis datasets in submission compliant ADaM format and to map the source data to SDTM all in a compressed timeframe for a Break Through Designation (BTD) submission. In parallel, analysis plans and explorations into new data sources and contracts were put in place.

SOLUTIONS EXPLORED

Since time was of the essence, we explored the two data flows below to get to CDISC formatted data ready for submission. Before getting into lessons learned and roadblocks, we can look at each pre-requisite.

Understanding RWE source data, data limitations, data availability

Data Transfer Agreements (DTA) between vendors and JnJ is the initial document to shine a light on what we will receive from the vendors. They simply list out files we would receive, variables in files, and expected values of the variables.

Based on what we expect in data and some testing of that data, statisticians work with clinical/informational teams to develop analysis plans. Once completed, statisticians and programmers work out Data Presentation Specifications (DPS) for specifics of the analyses;

Understanding the scope of analyses

Upon receipt of RWE data, programming checks critical variables needed in planned analyses and provide vendors with “data_gap” “data_issue” reports. Often, we find incomplete dates, missing key variables, and derivations with no traceability. Some gaps vendors can explore and eventually provide additional info, some remain missing or blank. Most times, after multiple back and forth conferences with vendors to request key variables, we are told there is no way query since data were collected years back.

While data cleaning remains a significant effort for RWE sources, we decide scope of analysis to be performed using existing nonperfect data with algorithms to work around any gaps. i.e. in the database, there are records indicating ‘Not applicable’ or missing line value to a treatment and their dates don’t correlate to dates of other lines of therapies. It was a struggle to determine these as not receiving IO treatment because there was no information available on what line of therapy these treatments occurred. Yet after long discussions, the team decided to include these subjects who received immunotherapy but no line under “Any Line of Immuno Therapy”, but exclude them from specific line therapy analysis, because they indeed received some IO therapy.

Options explored

In whitepaper submission for this NDA, the initial plan was to perform analysis of OS (Overall Survival) and Best Response. The vendor had difficulties cleaning OS data and waiting for it was obviously not an option.

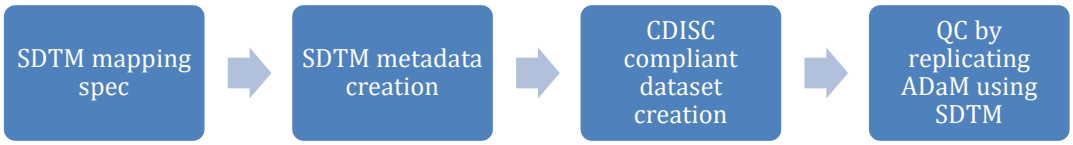
What did we choose and why

In order to meet timelines, the team eventually chose a progressive submission. In Chapter 1 of the Whitepaper, we provided Overall Survival analysis on RWE. Within one month, we provided Chapter 2, which included analysis of response. In Chapter 3, we pooled clinical study data with RWE and performed comparison of both OS and response on the biomarker specific population under study. This gave us the ability to submit the data from the first vendor fairly quickly, and follow-up with another vendor and the newly request response data, and a pooled analyses before

the review period completed.

MAPPING TO SDTM

Overview of the Process for SDTM mapping



SDTM domain specialist would provide dataset one to one specs, based on DTA and source data;
Data experts prepare excel sheets like below to correlate RAW to SDTM, dataset by dataset, variable to variable.

A	B	C	D	E	F	G
Raw Dataset	**Raw Variable**	**Raw Variable Value**	**SDTM Domain**	**SDTM TESTCD**	**TESTCD Value**	**TEST Value**
surv_stat	DLKA	Date last known alive	SUPPSS	QVAL	SSLKADTC	Last Date Known to be Alive
surg	SURG_PE_SITE	Site of biopsy	SUPPPR	QVAL	PRBIOS	Biopsy Site
syst_th	SYST_TH_CTP	Current therapeutic phase	SUPPCM	QVAL	CMTRTSET	Treatment Setting
syst_th	SYST_TH_OTH	Other type of therapy	SUPPCM	QVAL	CMSYSO	Other Systemic Therapy
pd_l1	ANTIBOD_KIT	Description of antibody or kit used for staining	SUPPMI	QVAL	MIMRK	Marker Details
pd_l1	PDL1_DATA_AB_22C3	Is IHC data available-Antibody 22c3?	SUPPMI	QVAL	MIMTHDDS	Method Description
syst_th	SYST_DTR	Date of response	FA	FATESTCD	STDTC	Start Date
syst_th	SYST_BR	specify response if available	FA	FATESTCD	DESC	Description
syst_th	SYST_PERC	Best percent change from baseline	FA	FATESTCD	PERC	Percentage
syst_th	SYST_DTDC	Date of decision to stop treatment	FA	FATESTCD	DENDTC	Decision End Date

For some datasets, we can see straight correlation from raw to SDTM, therefore straight forward steps take place like variables be renamed, labels be added, variable length reset.
For values that need 'codelist', experts would study raw data very carefully and understand it fully to provide accurate code lists.

Table	Field	Description	Codelist
syst_th	SIC	Subject Identifier Code	
syst_th	SYST_TH	Did the subject receive any systemic therapy?	yes, no
syst_th	SYST_TH_CTP	Current therapeutic phase	Neoadjuvant, Adjuvant, Palliative
syst_th	SYST_TH_NEOADJ	Did the subject receive neoadjuvant systemic therapy?	yes, no
syst_th	SYST_TH_NEOADJ_TH	Type of neoadjuvant therapy	DDMVAC/MVAC, Gem_cis, Gem_carbo, Gem,
syst_th	SYST_TH_ADJ	Did the subject receive adjuvant systemic therapy?	yes, no
syst_th	SYST_TH_PALL	Did the subject receive palliative systemic therapy?	yes, no
syst_th	SYST_TH_CLN	Current line of treatment	1st line of treatment, 2nd line of treatment,
syst_th	SYST_TH_LN1	1st line therapy	DDMVAC/MVAC, Gem_cis, Gem_carbo, Gem,
syst_th	SYST_TH_LN1_START	Start 1st line therapy	
syst_th	SYST_TH_LN1_END	End 1st line therapy	
syst_th	SYST_TH_LN2	2nd line therapy	DDMVAC/MVAC, Gem_cis, Gem_carbo, Gem,
syst_th	SYST_TH_LN2_START	Start 2nd line therapy	

For some variables, one can't match to one. We do detailed homework to fully understand the relationships of variables to map one variable. For example variable CM.CMGRDID pulls in info from 3 raw variables:

The mapping of CMGRPID comes from 3 raw variables: syst_th.SYST_TH_CLN, syst_th.SYST_TH_OTH and syst_th.SYST_TH_IO_CM_SPEC.
In the mockup 3 examples explain how to map CMGRPID.

Case 1: syst_th.SYST_TH_CLN
USUBJID Bridge-2OvHzCps has 2 rows with CMGRPID=2ND LINE OF TREATMENT
because mapping spec for raw variable syst_th.SYST_TH_CLN indicates 'Direct copy & uppercase'
In this case, each CMTRT comes from raw variables syst_th.SYST_TH_**LN1** to syst_th.SYST_TH_**LN6**
CMGRPID is assigned in case 1 only if syst_th.SYST_TH_CLN is empty.

Case 2: syst_th.SYST_TH_OTH
USUBJID Bridge-2OvHzCps has 6 rows with CMGRPID=PEMBROLIZUMAB + GEMCITABINE + CARBO-PLATINUM
because mapping spec for raw variable syst_th.SYST_TH_OTH indicates 'Direct copy and uppercase in CMGRPID and create rows for each treatment seperated by '+ ; ,' sign in CMTRT'
In this case, each CMTRT comes from raw variable syst_th.SYST_TH_OTH

Case 3: syst_th.SYST_TH_IO_CM_SPEC
USUBJID Bridge-2OvHzCps has 7 rows with CMGRPID= THLN2: RCT 54 GY/6 MAL CISPLATIN;THLN 3 RCT 45 GY + CISPLATIN; THLN5: GEMCITABINE/TRASTUZUMAB; THLN 6 TRASTUZUMAB; THLN7 ATEZOLIZUMAB; THLN 8 GEM/CIS; THLN 9 GEM
because mapping spec for raw variable syst_th.SYST_TH_IO_CM_SPEC indicates 'Direct copy and uppercase in CMGRPID and create rows for each treatment separated by '+ ; ,' sign in CMTRT'
In this case, each CMTRT comes from raw variable syst_th.SYST_TH_IO_CM_SPEC

So, for described subject in the email below here is the correct representation of SDTM datasets for CM:

	STUDYID	DOMAIN	USUBJID	CMSEQ	CMGRPID	CMTRT	CMCAT	CMSCAT	CMDTC	CMSTDTC	CMENDTC
Case 1	Bridge	CM	Bridge-YkSJhwfU	1	2ND LINE OF TREATMENT	PACLITAXEL	SYSTEMIC THERAPY		2018-0110	2017-07-01	2017-09-01
Case 1	Bridge	CM	Bridge-YkSJhwfU	2	2ND LINE OF TREATMENT	OTHER	SYSTEMIC THERAPY		2018-0110	2017-09-01	2018-01-10
Case 2	Bridge	CM	Bridge-YkSJhwfU	3	NIVOLUMAB	NIVOLUMAB	SYSTEMIC THERAPY		2018-0110	2017-09-01	2018-01-10
Case 3	Bridge	CM	Bridge-YkSJhwfU	4	NIVOLUMAB	NIVOLUMAB	SYSTEMIC THERAPY	PD1 INHIBITOR	2018-0110	2017-09-01	2018-01-10

For complex dataset like FGFR to MI, we even need to reference to analysis dataset (which was an advantage); Linking related domains CM/SUPPCM, CM/FA for IO treatments is also a big challenge.

<u>Lessons learned</u>
Issues we encountered

- a lot of raw variables described in DTA document are misspelled, variables with NO proper labels, making it difficult to be sure of their meaning and hence difficult to map.
- Understanding how data were collected from patient charts to fully align with vendor's database documentation before we make decision what raw maps to which SDTM.
- Understanding medication start dates (e.g. how these were derived from patient charts), the algorithm for response and other fields was not well understood up front when the data was received.
- Compliance checks on the SDTM had significant errors because much of the information required in SDTM is just not available.

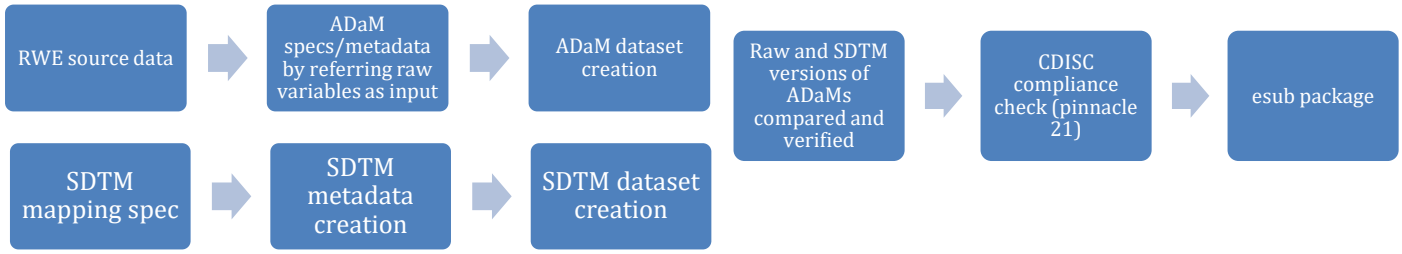
These required multiple phone calls with the vendor, and explanation of the dataset to the FDA required provision of some of vendor's database documentation.
Solutions we explored

- develop draft specifications to outline what analysis can be done using the available data,
- make sure up-front alignment in cross functional team on the data limitations,
- prioritize end points,
- prepare metadata directly from source;

ADaM CREATION

<u>Overview of the process for ADaM creation</u>
The process of data resolution delayed the data transfers, in order to overcome the delay and to meet submission timeline, team decided to generate both SDTM conversion and ADaM datasets in parallel. i.e. just like SDTM, ADaMs were directly created from source raw datasets and but later regenerated using mapped SDTM datasets and validated/verified against raw ADaM version.

Below diagram describes the data flow from RAW to esub package



Lessons Learned

The above parallel approach was lengthy, redundant and it took more resources and time, but this was a best feasible solution at that point.

As stated earlier we had multiple meetings with our vendor to resolve data issues even though, we left with hand full of partial dates and inconsistent data points, so team decided to handle them at analysis level. Example day and month of birth dates were imputed, and specimen reported dates were proposed as entry timepoint to handle the time lag issue by using a delayed entry model (left truncation model).

ADaM STRUCTURE AND SUBMISSION

STRATEGY FOR AD DESIGN AND LIST OF ADS

The following ADaM datasets were created to address endpoints (overall survival and response) related analysis by following analysis data model v2.1 and implementation guide v1.0

Dataset Dataset Label	Class	Efficacy	Safety	Baseline or other subject characteristics	Primary Objective	Structure
ADSL Subject Level Analysis Dataset	ADSL			X		One observation per subject
ADBIO Biomarkers Analysis Dataset	OTHER			X		One record per subject per parameter category per parameter
ADCM Concomitant Medications	OTHER	X				One record per subject per each medication per timepoint
ADTTE Time-to-Event Analysis Dataset	BDS	X			X	One record per subject per parameter
ADEFF Efficacy Analysis Dataset	BDS	X				One record per subject per parameter

ADSL dataset contains one record per subject. It contains all subjects in the raw demographic dataset and subject variables such as subject-level population flags, planned and actual treatment variables, demographic, baseline disease information, factors, subgrouping variables and important dates.

Few key date variables

Variable Name	Variable Description	Note
ARFSTDT	Analysis Reference Start Date	Advanced diagnosis date was used as analysis reference start
DTHDT	Date of Death	
LSTALVDT	Date Last Known Alive	
SPRPTDT	Specimen Reported Date	Was used for entry point in delayed entry model (left truncation)
BRTHDT	Date/Time of Birth	Day and month were imputed

Few key baseline and disease characteristics variables

Variable Name	Variable Description	Note
AGE	Age	These variables were used as factors in cox model
SEX	Sex	
ECOGBL	Baseline ECOG	
LOCPTTYP	Primary Tumor Location Type	
TUMSTAGE	Tumor Stage	
SMOKSTFL	Smoking Status Flag	

Few key population variables:
Systemic therapy treatment taken on or after advanced diagnosis dates are considered for below variables

Variable Name	Variable Description	Note
AIOFL	Any IO treatment	Most of the key analysis are based on Any IO
AIOLxFL	Any IO at Line x Flag	x takes value 1, 2, 3, i.e. 1 is for line 1, 2 is for line 2 and 3 is for line 3 or higher
ACHFL	Any Chemo treatment	
ACHLxFL	Any Chemo at Line x flag	x takes value 1, 2, 3, i.e. 1 is for line 1, 2 is for line 2 and 3 is for line 3 or higher

ADBIO dataset contains biomarker, mutation and fusion related parameters i.e. FGFR mutation/fusion status, FGFR alterations, PDL IHC testing with antibodies like SP142, 22C3, 28-8. Mutation variants like G370C, R248C, Y373C, S249C and Fusion variants like TACC3, BAIAP2L1, CASP7, BICC1.

ADCM dataset contains all prior medications and concomitant medications from source Lineoftherapy dataset. It contains Prior and Concomitant medication flag variables and it also contains flag variables for IO/Chemo mono and combo treatment received.

Few key variables:

Variable Name	Variable Description	Note
ACATx	Analysis Category x	x takes value 1 and 2
CQ0xNAM	Customized Query 0x Name	x takes value 1 to 4, i.e. 1 for CHEMOTHERAPY DRUG, 2 for LINE 1 CORE

Variable Name	Variable Description	Note
		CHEMO DRUG, 3 for LINE 2 CORE CHEMO DRUG and 4 for IMMUNOTHERAPY DRUG
PRMEDFL	Prior Medication Flag	Treatment/Therapy taken prior to Advanced diagnosis date (ADSL. ARFSTDT) are considered as prior
CMMEDFL	Concomitant Medication Flag	Treatment/Therapy taken on or after Advanced diagnosis date (ADSL. ARFSTDT) are considered as CM (ADSL. ARFSTDT)

ADTTE dataset contains OS endpoints related parameters for each treated subject and subjects without line of therapy were excluded. AVAL is the OS time. AVAL1 is the delay entry time, which is the time from the OS index date to the delay entry date (specimen reported date).

Few key parameters:

PARAMCD	PARAM	Note
OSAIO	Overall survival - any IO (months)	
OSAIOLx	Overall survival - any IO at line x (months	x takes value 1 and 2
OSAIOL3	Overall survival - any IO at line 3 or more (months)	
OSACH	Overall survival - any chemo (months)	
OSACHLx	Overall survival - any chemo at line x (months)	x takes value 1 and 2
OSACHL3	Overall survival - any chemo at line 3 or more (months)	

Few key parameters:

Variable Name	Variable Description	Note
ADT	Analysis Date	Death date for death subjects, Last known alive date for alive subjects
STARTDT	Time to Event Origin Date for Subject	Start date of respective treatment (i.e. Any IO, Line 1 IO, Line 2 IO, etc
SPRPTDT	Specimen Reported Date	
AVAL	Analysis Value	Duration in months from respective treatment start date to death or last know date. i.e. aval = max (0, adt - startdt) /30.4375;
AVAL1	Analysis Value 1	Duration in months from specimen reported date to respective treatment start date i.e. aval1 = max (0, sprptdt - startdt) / 30.4375;
CNSR	Censor	0 if subject dies; 1 Otherwise

ADEFF contains best overall response parameters for IO treated subjects, because source data captured only IO associated response.

Few key parameters:

PARAMCD	PARAM
BRANYIO	Best Response for Any Line of Immuno Therapy

PARAMCD	PARAM
BRIOL1	Best Response for 1st Line of Immuno Therapy
BRIOL2	Best Response for 2nd Line of Immuno Therapy
BRIOL2H	Best Response for 2nd or higher Line of Immuno Therapy
BRIOL3H	Best Response for 3rd or higher Line of Immuno Therapy

GUIDING PRINCIPLES FOR DESIGN AND CHALLENGES FACED

Data integrity, traceability, and dependency links related issues are very common in retrospective data collection models, but these are all the fundamental principles of submission data. So along with data cleaning and Adam specification activity we carefully verified these key principles and the data points, which were not meeting these key principles were escalated and resolved before analysis activity. Few unresolved data points were excluded from all our analysis.

Few examples of data integrity, traceability and dependency related issues.

- Many survival duration data points were transferred without respective treatment start and end date (death or last known date).
- Systemic line 1 treatment end date after line 2 start date
- Response and response date were transferred without treatment association and few response dates were before the treatment start date

It took more time and resource to understand, converted and impute the nonstandard data points to standard ADaM structure. Biostat and programming team were worked very closely to design and implement imputation, derivation algorithms. Due to the limitation of vendor's data disclosure agreement, we were directed to include only analysis required and respective dependent information in ADaMs, so cross functional team carefully reviewed and excluded all non-required data points from ADaMs

The pooled analysis of core clinical study and RWE was well planned hence the RWE team decided to adopt the same AD structures, attributes (variables, labels), parameters and it's naming conventions, which was followed in the core clinical study, so the data pooling activity was easy and fast. Due to this approach we reused wide range of reporting macros and programs for pooled analysis. As planned, required RWE ADaMs datasets (ADSL, ADTTE, ADEF) and parameters were directly pooled with core clinical study to compare the Overall survival and object response rate of clinical study drug with RWE drugs.

REGULATORY PROCESS

As each chapter of the RWE analyses was submitted, we had a round of regulatory requests and questions that followed, starting as stated previously with the request for data which came with quite a few privacy and contractual hurdles between Janssen, the FDA, and the RWE vendor. We had a privacy consultant from the vendor help evaluate the data for de-identification before even starting the analyses which caused some analysis issues as stated previously with partial dates and missing data. We also had several discussions with the agency about the use of this data beyond the purpose of this submission and ended with adding wording in the contract and agreements with respect to the freedom of information act claiming some exemptions and loosely agreeing to inform relevant parties before information can be used for other purposes.

FDA QUESTIONS

To give a flavor of the types of questions around RWE data we received you can see some of them listed below.

Request	Response
Multiple RWE Data Sources: FDA requested that data from multiple RWE data sources be submitted, where available	We collected information from 3 different data sources but were only able to complete the analyses in time for the submission on 2 of them. The second source coming into play in chapter 2 and a pooled analysis including our clinical trial data in chapter 3.
Response Data: FDA requested response data be provided. Janssen stressed response by RECIST not typically collected outside of clinical trials. RWE vendor developed Real-World Tumor Response (rwTR).	Since the original plan only included survival analysis, we reached out to the vendor to see if response data was available and stressed to the agency that it would not be response by RECIST and planned this data to

	be included in subsequent chapters.
Patient Narratives, Radiology Scans and Radiology Reports: Individual patient narratives requested; names of antineoplastic therapy; radiological assessment dates with reports (including baseline); and clinician assessment/plan. Radiology scans were also requested but were not available for provision to FDA.	We sent in listings by patient of all the requested data using the analysis datasets included in the submission along with a sampling of radiological scans and reports from the RWE vendor directly. The design of analysis datasets had tier 1 (ADSL, ADBIO, ADCM) with the necessary source data along with flags and tier 2 (ADTTE, ADEFF) further analyzed these for the endpoints used in outputs.
CDISC Formatting and analysis programs: FDA requested CDISC formatted data and analysis programs	As described above this was one of the first requests at the pre-NDA meeting and subsequent requests asked for the SAS and R programs that supported the analyses that we then sent up front with each chapter.
SAP Timelines: Assess timing of statistical analysis plan in relation to initiation of data analyses to ensure analyses were pre-planned and not post-hoc	We had very little organization to this (like we see currently in CSRs) so responses addressed the timelines of data, analysis plan, execution of analyses, and write ups.

FDA TECHINICAL WALKTHROUGH

After submission during the FDA review period they requested a technical walkthrough - to give you a flavor of the questions around RWE analyses and data see below. To maintain confidentiality the questions and responses are generalized.

1. **FDA:** In RWE, X patients have been treated, why Y in the analysis?
   Janssen: Reason is …. Patient flags to identify this population are located in the ADSL.xpt dataset. These are referenced in the ADRG.pdf document in 5.3.5.4 predictive value report which was previewed during the meeting with the FDA review team.
2. **FDA:** How reliable is the diagnosis information and line of therapy in the Electronic Health Records from the RWE vendor:
   Janssen: Electronic Health Records (EHR) recorded diagnosis dates and all therapies received. These captured both structured records in database and unstructured records from free text clinical notes, reviewer and abstractor reviewed these data and consolidate them into the database.
3. **FDA:** Are RWE patients representative of general disease under study patients?
   Janssen: The demographics seem to suggest they reflect the general disease under study patients. Note these are primarily patients from community practice and less reflective of clinical trial population.
4. **FDA:** Are there any of the disease under study patients in the RWE database excluded due to lack of determination of genomic data.
   Janssen: Possibly. Since the genetic status is a key analysis variable, we did not obtain any data from patients who did not have genomic results.

CONCLUSION

In conclusion this effort was a great learning experience, it allowed us to understand real world data, generated a lot of excitement at the FDA and in the clinical research community, and is continuing to help this compound plan for further research as well as support publications on top of the original intent of supplementing the NDA submission. The hardest issue to date is getting the data with the content we need that is also current and complete. The data is out there but gathering it seems to be the problematic and ensues a considerable cost. Finding quality vendors and sources will be key to success especially if it is to be used in a submission - as the traceability, reproducibility, and inclusion of the data and analyses seems to be required - as this experience has proven. The data requirements were the same as you would expect with clinical trial data. In looking back the step that seemed to add the least value and the most cost was mapping to SDTM so perhaps a better standardized format for this type of data is needed.

REFERENCES

ASCO GU paper here https://meetinglibrary.asco.org/record/169663

ACKNOWLEDGMENTS

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RECOMMENDED READING

https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Nicole Thorne
Janssen
1400 McKean Road
Springhouse, PA 19477
Work Phone: 215-793-7430
nthorne@its.jnj.com

Kathy Wu
Janssen
920, Route 202 South
Raritan, NJ 08869
908-927-6441 (office)
KWU8@its.jnj.com

Ramesh Sundaram
GCE Solutions, Inc
1408 E Empire St
Bloomington, IL 61701-3519
United States of America
416-802-5147 (office)
rsundar7@ITS.JNJ.com
ramesh.sundaram@gcesolutions.com