Analyzing Data Missing Due to COVID-19: from Raw Data to ADaM and Beyond

Yuliia Bahatska, Roche

Yuliia Bahatska has 9 years of experience in statistical programming for clinical trials. She has been an active PHUSE member since 2016, and the co-chair of the Poster stream since 2019. Yuliia holds a master's degree in Applied Mathematics and a bachelor's degree in Foreign Languages.

Agenda

- Study Overview
- Analysis Requested
- Process Overview
  - Raw data to SDTM
  - SDTM to ADaM
- Shiny App Demo
- Conclusions

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Study Overview

- Phase III, randomized, double-controlled, double-blind, multicenter clinical study to evaluate efficacy, safety, PK and biomarker effects of intrathecally administered Tominersen in patients with manifest HD.

- Primary efficacy endpoint:
  - absolute change from baseline in the composite Unified Huntington's Disease Rating Scale score at Week 101.
  - For U.S. FDA - change from baseline in the Total Functional Capacity Scale score at Week 101.
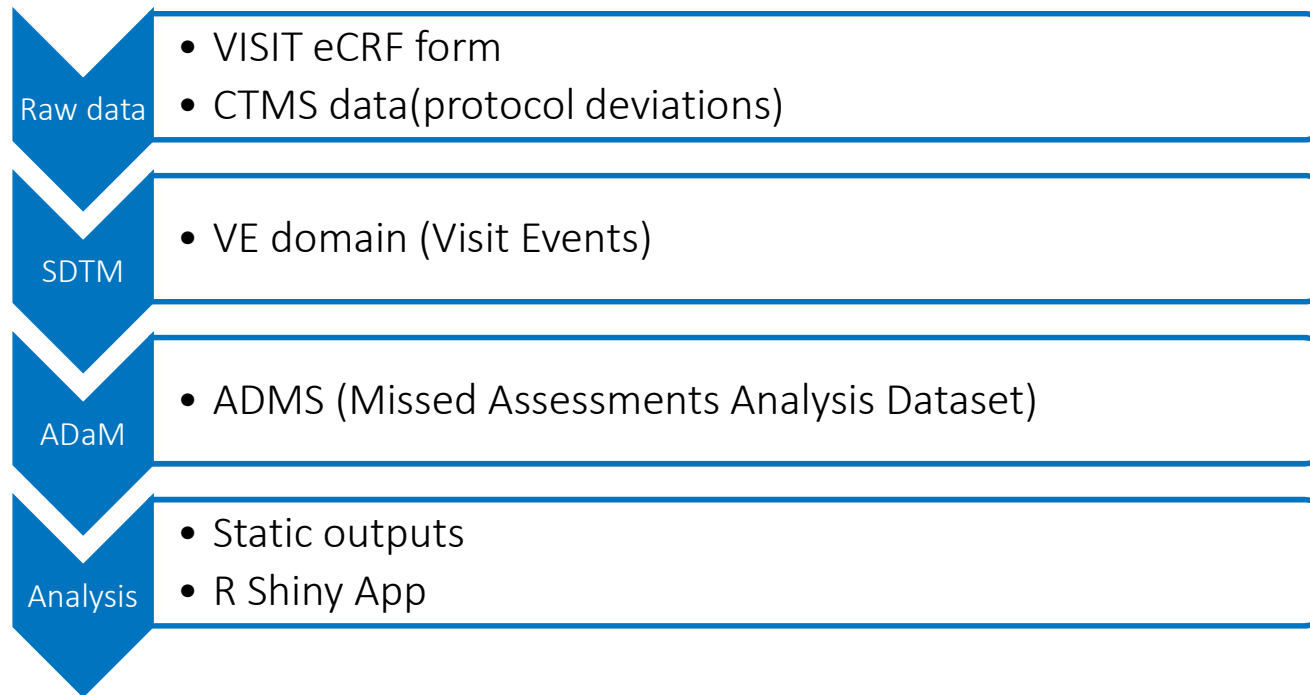
Changes to Study Conduct

- Many missed visits were replaced with phone calls/Video calls with patients and study partner
  - Collection of AEs and Con Meds was the scope of these calls
- Outcome measures collected remotely
  - FA (Functional Assessment)
  - TFC (Total Functional Capacity)
  - C-SSRS (Columbia-Suicide Severity Rating Scale)
  - CGI (Clinical Global Impression)
  - HD-DAS (Huntington's Disease Daily Activities Scale)

Analysis

- Summary of missed visits due to any COVID-19 related reasons

- Summary of missed doses due to any COVID-19 related reasons

- Summary of missed cUHDRS assessments due to any COVID-19 related reasons

- Summary of the duration of not being treated due to any COVID-19 related reasons

Process Overview

Raw data
- VISIT eCRF form
- CTMS data(protocol deviations)

SDTM
- VE domain (Visit Events)

ADaM
- ADMS (Missed Assessments Analysis Dataset)

Analysis
- Static outputs
- R Shiny App

VE Domain

ve.xpt

Row	STUDYID	DOMAIN	USUBJID	VESEQ	VETERM	VEDECOD	VEPRESP	VEOCCUR	VISITNUM	VISIT	VISTDY	VEDTC	VESTDTC	VEDY	VESTDY	VEREASOC	VEEPCHGI	VECNTMOD
1	CVD-3	VE	301	1	ONSITE VISIT	PLANNED VISIT	Y	Y	1	BASELINE	1	2020-03-04	2020-03-04	1	1			
2	CVD-3	VE	301	2	ONSITE VISIT	PLANNED VISIT	Y	Y	2	WEEK 1	8	2020-03-11	2020-03-11	8	8			
3	CVD-3	VE	301	3	REPEAT VISIT FOR ABNORMAL LAB	UNSCHEDULED VISIT			2.5			2020-03-13	2020-03-13	10	10			
4	CVD-3	VE	301	4	ONSITE VISIT	PLANNED VISIT	Y	Y	3	WEEK 2	15	2020-03-19	2020-03-19	16	16			
5	CVD-3	VE	301	5	ONSITE VISIT	PLANNED VISIT	Y	N	4	WEEK 3	22	2020-03-25		22		Subject lacked transportation		
6	CVD-3	VE	301	6	ONSITE VISIT	PLANNED VISIT	Y	N	5	WEEK 4	29	2020-04-01		29		Subject refused due to fear of epidemic	Y	
7	CVD-3	VE	301	7	ONSITE VISIT	PLANNED VISIT	Y	N	6	WEEK 5	26	2020-04-08		36		Hospital restricted access to clinic	Y	
8	CVD-3	VE	301	8	VIRTUAL VISIT	PLANNED VISIT	Y	Y	7	WEEK 6	43	2020-04-15	2020-04-15	43	43		Y	REMOTE AUDIO

VE Domain

ve.xpt

Row	STUDYID	DOMAIN	USUBJID	VESEQ	VETERM	VEDECOD	VEPRESP	VEOCCUR	VISITNUM	VISIT	VISTDY	VEDTC	VESTDTC	VEDY	VESTDY	VEREASOC	VEEPCHGI	VECNTMOD
1	CVD-3	VE	301	1	ONSITE VISIT	PLANNED VISIT	Y	Y	1	BASELINE	1	2020-03-04	2020-03-04	1	1			
2	CVD-3	VE	301	2	ONSITE VISIT	PLANNED VISIT	Y	Y	2	WEEK 1	8	2020-03-11	2020-03-11	8	8			
3	CVD-3	VE	301	3	REPEAT VISIT FOR ABNORMAL LAB	UNSCHEDULED VISIT			2.5			2020-03-13	2020-03-13	10	10			
4	CVD-3	VE	301	4	ONSITE VISIT	PLANNED VISIT	Y	Y	3	WEEK 2	15	2020-03-19	2020-03-19	16	16			
5	CVD-3	VE	301	5	ONSITE VISIT	PLANNED VISIT	Y	N	4	WEEK 3	22	2020-03-25		22		Subject lacked transportation		
6	CVD-3	VE	301	6	ONSITE VISIT	PLANNED VISIT	Y	N	5	WEEK 4	29	2020-04-01		29		Subject refused due to fear of epidemic	Y	
7	CVD-3	VE	301	7	ONSITE VISIT	PLANNED VISIT	Y	N	6	WEEK 5	26	2020-04-08		36		Hospital restricted access to clinic	Y	
8	CVD-3	VE	301	8	VIRTUAL VISIT	PLANNED VISIT	Y	Y	7	WEEK 6	43	2020-04-15	2020-04-15	43	43		Y	REMOTE AUDIO

VE NSV Metadata

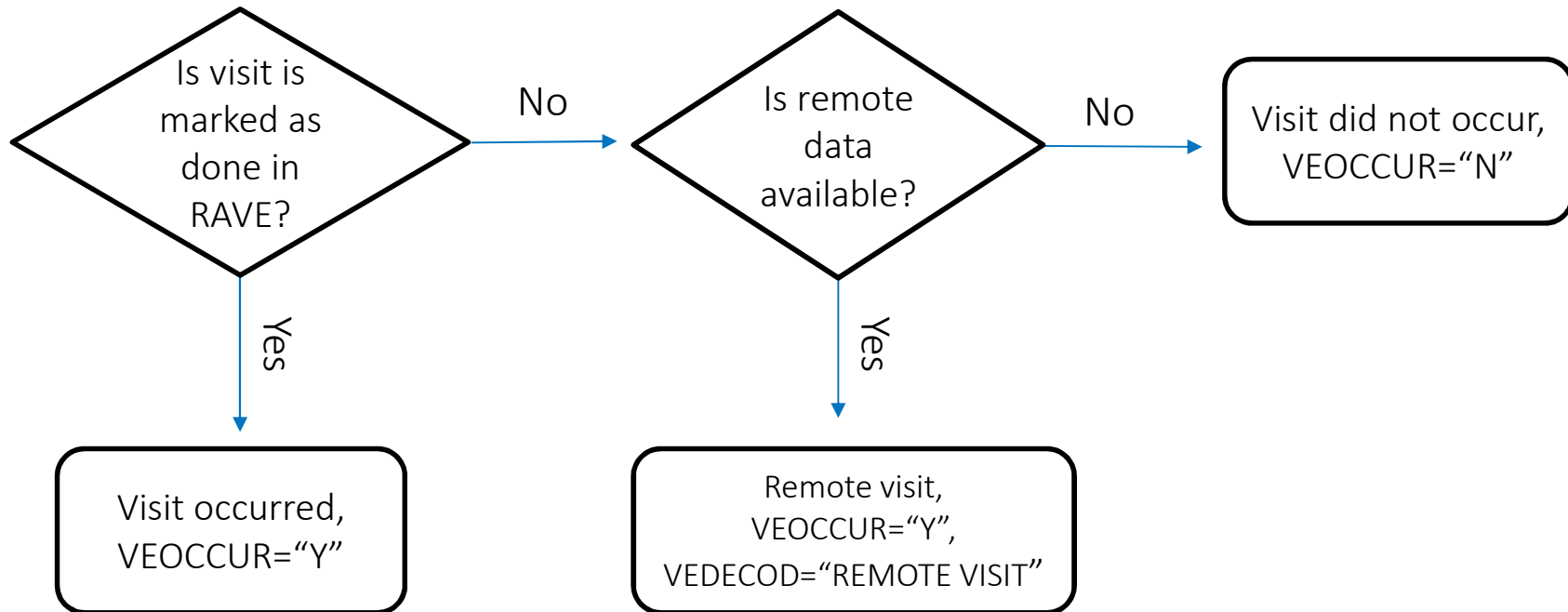| Variable	Label	Type	Codelist	Role	Origin	Comment
VEREASOC	Reason for Occur Value	text		Non-Standard Record Qualifier	CRF	
VEEPCHGI	Epi/Pandemic Related Change Indicator	text	NY	Non-Standard Record Qualifier	CRF	
VECNTMOD	Contact Mode	text	CNTMODE	Non-Standard Record Qualifier	CRF	CNTMODE is a sponsor-defined codelist.

Protocol Deviations

- Deviations recorded in CTMS(sites instructed to start with COVID-19)

- Assess whether the deviation is COVID-19 related based on DVDESC (contains "COVID")

- Combine with VISIT eCRF form

- If there is a deviation related to COVID-19, flag the visit as Epi/Pandemic Related (VEEPCHGI="Y")

Visit form in RAVE

ADMS (Missed Assessments Analysis Dataset)

- Expected parameters : Overall visit, dose, uHDRS components
  - Based on assessment schedule and subject's study status create records for assessments expected for subject
  - If record is not expected, populate the reason in ARSND(COVID-19 and other reasons)
  - If date of assessment is not available, derive planned date (PDT) based on date of Day 1 visit (SV) and planned day of visit(TV)
- Completed parameters: Overall visit, dose, uHDRS components
  - For all records where parameter is expected indicate whether assessment was performed, if not, populate reason in ARSND(COVID-19 and other reasons)
- Duration of dosing missed due to COVID-19
  - Difference in days between date or planned date of dose of the last dose prior to missed dose due to COVID-19 and the first dose after dose missed due to COVID-19 or the planned date of the dose missed not due to COVID-19

ADMS, Expected Parameters

- For all planned visits can use TV, for specific endpoints will need to subset based on the protocol schedule

```sas
proc sql noprint;
    create table EXPECTED_VISITS as select a.*, b.VISIT, b.VISITNUM,b.VISITDY from ADSL a, TV b
    order by a.USUBJID, b.VISITNUM;
quit;
```

- Derive date of DAY 1 visit, actual date of visit or planned date of visit:

```sas
data DAY1;
    set SV(where=(VISIT="DAY 1"));
    if not missing(SVSTDTC) then DAY1DT=input(SVSTDTC,yymmdd10.);
    keep USUBJID DAY1DT;
run;
```

...

```sas
if not missing(VESTDTC) then ADT=input(VESTDTC,yymmdd10.);     For visits that occurred
else PDT=DAY1DT+VISITDY-(VISITDY>0);                    For visits that did not occur
```

ADMS, Expected Parameters

- If planned date of visit is in the future, then visit is not reached and not expected
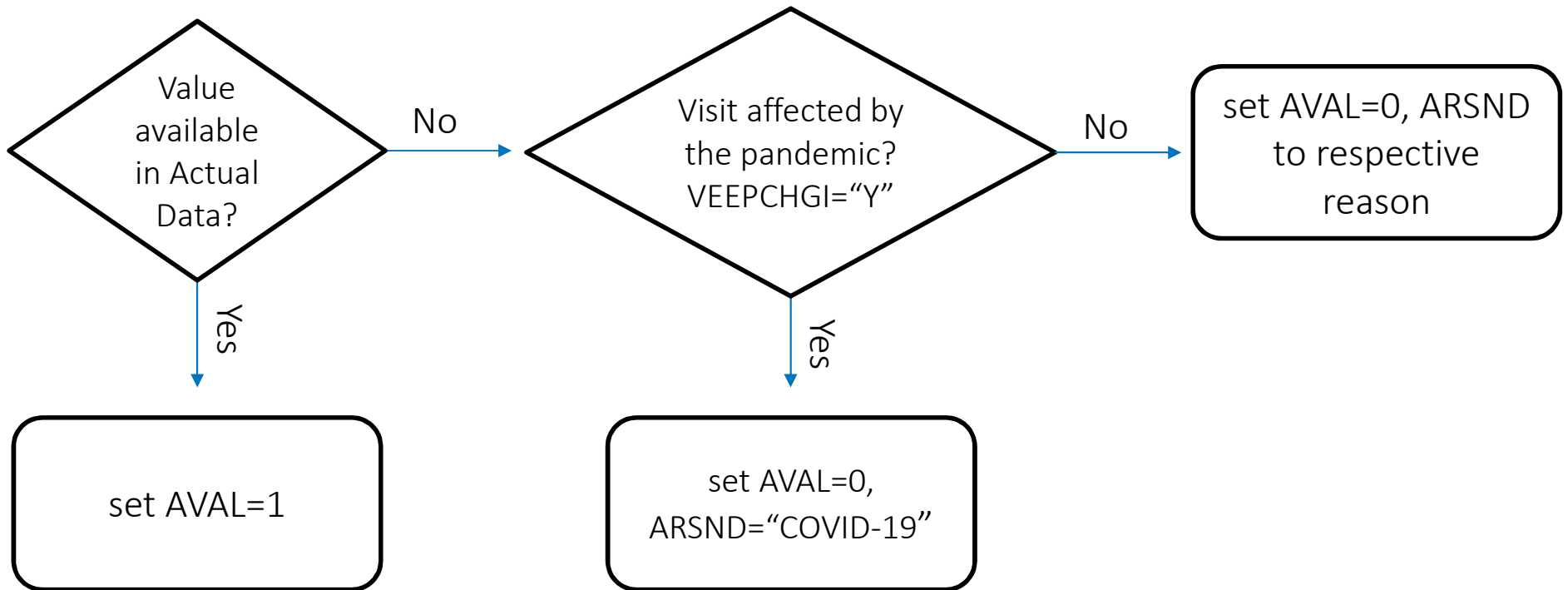
```
if PDT>today() then do;
    AVAL=0;
    ARSND="VISIT NOT REACHED";
end;
```

- If planned date of visit is after study discontinuation date, then the visit will never occur:

```
if PDT>EOSDT and EOSSTT="DISCONTINUED" then do;
    AVAL=0;
    ARSND=DCSREAS;
end;
```

- Otherwise visit is expected
- Same logic applies for specific endpoints

ADMS, Completed Parameters

ADMS, Example: ongoing subject

USUBJID	VISIT	VISITNUM	VEDECOD	VEEPCHGI	PARAM	ADT (format...	PDT (for...	AVAL	ARSND
BN40423-001	DAY 1	1	PLANNED VISIT	N	Visit Overall Expected	15JUL2019	.	1	
BN40423-001	SCREENING	-1	PLANNED VISIT	N	Visit Overall Expected	24JUN2019	.	1	
BN40423-001	WEEK 13	4	PLANNED VISIT	N	Visit Overall Expected	30SEP2019	.	1	
BN40423-001	WEEK 21	6	PLANNED VISIT	N	Visit Overall Expected	03DEC2019	.	1	
BN40423-001	WEEK 29	8	PLANNED VISIT	N	Visit Overall Expected	28JAN2020	.	1	
BN40423-001	WEEK 37	10	PLANNED VISIT	Y	Visit Overall Expected	10MAR2020	.	1	
BN40423-001	WEEK 45	12	PLANNED VISIT	N	Visit Overall Expected	19MAY2020	.	1	
BN40423-001	WEEK 5	2	PLANNED VISIT	N	Visit Overall Expected	12AUG2019	.	1	
BN40423-001	WEEK 53	14	PLANNED VISIT	N	Visit Overall Expected	14JUL2020	.	1	
BN40423-001	WEEK 61	16	PLANNED VISIT	N	Visit Overall Expected	15SEP2020	.	1	
BN40423-001	WEEK 69	18	PLANNED VISIT	N	Visit Overall Expected	03NOV2020	.	1	
BN40423-001	WEEK 77	20	PLANNED VISIT	N	Visit Overall Expected	04JAN2021	.	1	
BN40423-001	WEEK 85	22			Visit Overall Expected	.	22FEB2021	0	VISIT NOT REACHED
BN40423-001	WEEK 93	24			Visit Overall Expected	.	19APR2021	0	VISIT NOT REACHED
BN40423-001	DAY 1	1	PLANNED VISIT	N	Visit Overall Completed	15JUL2019	.	1	
BN40423-001	SCREENING	-1	PLANNED VISIT	N	Visit Overall Completed	24JUN2019	.	1	
BN40423-001	WEEK 13	4	PLANNED VISIT	N	Visit Overall Completed	30SEP2019	.	1	
BN40423-001	WEEK 21	6	PLANNED VISIT	N	Visit Overall Completed	03DEC2019	.	1	
BN40423-001	WEEK 29	8	PLANNED VISIT	N	Visit Overall Completed	28JAN2020	.	1	
BN40423-001	WEEK 37	10	PLANNED VISIT	Y	Visit Overall Completed	10MAR2020	.	1	
BN40423-001	WEEK 45	12	PLANNED VISIT	N	Visit Overall Completed	19MAY2020	.	1	
BN40423-001	WEEK 5	2	PLANNED VISIT	N	Visit Overall Completed	12AUG2019	.	1	
BN40423-001	WEEK 53	14	PLANNED VISIT	N	Visit Overall Completed	14JUL2020	.	1	
BN40423-001	WEEK 61	16	PLANNED VISIT	N	Visit Overall Completed	15SEP2020	.	1	
BN40423-001	WEEK 69	18	PLANNED VISIT	N	Visit Overall Completed	03NOV2020	.	1	
BN40423-001	WEEK 77	20	PLANNED VISIT	N	Visit Overall Completed	04JAN2021	.	1	

ADMS, Example: subject discontinued study

USUBJID	VISIT	VISITNUM	VEDECOD	VEEPCHGI	PARAM	AVAL	ADT (format...	PDT (format...	ARSND
BN40423-002	DAY 1	1	PLANNED VISIT	N	Dose Expected	1	16JUL2019	.	
BN40423-002	WEEK 5	2	PLANNED VISIT	N	Dose Expected	1	13AUG2019	.	
BN40423-002	WEEK 13	4	PLANNED VISIT	N	Dose Expected	1	15OCT2019	.	
BN40423-002	WEEK 21	6	PLANNED VISIT	N	Dose Expected	1	.	02DEC2019	
BN40423-002	WEEK 29	8			Dose Expected	0	.	27JAN2020	WITHDRAWAL BY SUBJECT
BN40423-002	WEEK 37	10			Dose Expected	0	.	23MAR2020	WITHDRAWAL BY SUBJECT
BN40423-002	WEEK 45	12			Dose Expected	0	.	18MAY2020	WITHDRAWAL BY SUBJECT
BN40423-002	WEEK 53	14			Dose Expected	0	.	13JUL2020	WITHDRAWAL BY SUBJECT
BN40423-002	WEEK 61	16			Dose Expected	0	.	07SEP2020	WITHDRAWAL BY SUBJECT
BN40423-002	WEEK 69	18			Dose Expected	0	.	02NOV2020	WITHDRAWAL BY SUBJECT
BN40423-002	WEEK 77	20			Dose Expected	0	.	28DEC2020	WITHDRAWAL BY SUBJECT
BN40423-002	WEEK 85	22			Dose Expected	0	.	22FEB2021	WITHDRAWAL BY SUBJECT
BN40423-002	WEEK 93	24			Dose Expected	0	.	19APR2021	WITHDRAWAL BY SUBJECT
BN40423-002	DAY 1	1	PLANNED VISIT	N	Dose Completed	1	16JUL2019	.	
BN40423-002	WEEK 5	2	PLANNED VISIT	N	Dose Completed	1	13AUG2019	.	
BN40423-002	WEEK 13	4	PLANNED VISIT	N	Dose Completed	1	15OCT2019	.	
BN40423-002	WEEK 21	6	PLANNED VISIT	N	Dose Completed	0	.	02DEC2019	NOT SPECIFIED

ADMS, Dosing missed due to COVID-19

USUBJID	VISIT	VISITNUM	ADT (formatted)	PDT (formatted)	AVAL	ARSND
BN40423-001	WEEK 21	6	03DEC2019	.	1	
BN40423-001	WEEK 29	8	28JAN2020	.	1	
BN40423-001	WEEK 37	10	10MAR2020	.	0	COVID-19
BN40423-001	WEEK 45	12	19MAY2020	.	1	
BN40423-001	WEEK 53	14	14JUL2020	.	1	

USUBJID	VISIT	VISITNUM	ADT (formatted)	PDT (formatted)	AVAL	ARSND
BN40423-003	WEEK 21	6	06JAN2020	.	1	
BN40423-003	WEEK 29	8	19FEB2020	.	0	DRUG HOLIDAY
BN40423-003	WEEK 37	10	16APR2020	.	0	COVID-19
BN40423-003	WEEK 45	12	09JUN2020	.	0	COVID-19
BN40423-003	WEEK 53	14	11AUG2020	.	0	DRUG HOLIDAY

USUBJID	VISIT	VISITNUM	ADT (formatted)	PDT (formatted)	AVAL	ARSND	EOSDT (formatt...
BN40423-004	WEEK 21	6	19DEC2019	.	1		29JUN2020
BN40423-004	WEEK 29	8	13FEB2020	.	1		29JUN2020
BN40423-004	WEEK 37	10	.	15APR2020	0	COVID-19	29JUN2020
BN40423-004	WEEK 45	12	.	10JUN2020	0	COVID-19	29JUN2020

ADMS, Dosing missed due to COVID-19

USUBJID	VISIT	VISITNUM	ADT (formatted)	PDT (formatted)	AVAL	ARSND
BN40423-001	WEEK 21	6	03DEC2019	.	1	
BN40423-001	WEEK 29	8	28JAN2020		1	
BN40423-001	WEEK 37	10	10MAR2020	.	0	COVID-19
BN40423-001	WEEK 45	12	19MAY2020	.	1	
BN40423-001	WEEK 53	14	14JUL2020	.	1	

USUBJID	VISIT	VISITNUM	ADT (formatted)	PDT (formatted)	AVAL	ARSND
BN40423-003	WEEK 21	6	06JAN2020	.	1	
BN40423-003	WEEK 29	8	19FEB2020		0	DRUG HOLIDAY
BN40423-003	WEEK 37	10	16APR2020	.	0	COVID-19
BN40423-003	WEEK 45	12	09JUN2020		0	COVID-19
BN40423-003	WEEK 53	14	11AUG2020	.	0	DRUG HOLIDAY

USUBJID	VISIT	VISITNUM	ADT (formatted)	PDT (formatted)	AVAL	ARSND	EOSDT (formatt...
BN40423-004	WEEK 21	6	19DEC2019	.	1		29JUN2020
BN40423-004	WEEK 29	8	13FEB2020		1		29JUN2020
BN40423-004	WEEK 37	10	.	15APR2020	0	COVID-19	29JUN2020
BN40423-004	WEEK 45	12	.	10JUN2020	0	COVID-19	29JUN2020

ADMS, Dosing missed due to COVID-19

```
data DOSE_DATES NOT_RESUMED;

    set DOSE; *dataset that contains only subjects with missed doses due to COVID (based on Dose Completed parameter);

    retain DATE_PREV ;

    by USUBJID VISITNUM;

…use lag of all the ARSND, ADT/PDT to get them from the previous record with suffix _PREV, for date, it is DATE_TEMP
and combines ADT and PDT

*set all variables to missing for the first record;

    if first.USUBJID then call missing(of DATE_TEMP DATE_PREV REAS_PREV);

*start of the interval of dosing missed due to COVID;

    if ARSND="COVID-19" and (REAS_PREV ne "COVID-19") then DATE_PREV=DATE_TEMP;

*stop of the interval of missed dosing;

    if REAS_PREV ne "COVID-19" and ARSND ne "COVID-19" then call missing(DATE_PREV);

    output DOSE_DATES;

    if last.USUBJID and ARSND="COVID-19" then output NOT_RESUMED;

run;
```

ADMS, Dosing missed due to COVID-19

USUBJID	VISIT ▲	ADT (for... ▲	AVAL	ARSND ▲	REAS_PREV	DATE_PRE...	DATE_TEMP (f...
BN40423-001	WEEK 29	28JAN2020	1			.	03DEC2019
BN40423-001	WEEK 37	10MAR2020	0	COVID-19		28JAN2020	28JAN2020
BN40423-001	WEEK 45	19MAY2020	1		COVID-19	28JAN2020	10MAR2020
BN40423-001	WEEK 53	14JUL2020	1			.	19MAY2020

```
*start of the interval of dosing missed due to COVID;
    if ARSND="COVID-19" and (REAS_PREV ne "COVID-19") then DATE_PREV =DATE_TEMP;
*stop of the interval of missed dosing;
    if REAS_PREV ne "COVID-19" and ARSND ne "COVID-19" then call missing(DATE_PREV);
    output DOSE_DATES;
    if last.USUBJID and ARSND="COVID-19" then output NOT_RESUMED;
run;
```

ADMS, Dosing missed due to COVID-19

USUBJID	VISIT ▲	ADT (for... ▲	AVAL	ARSND ▲	REAS_PREV	DATE_PRE...	DATE_TEMP (f...
BN40423-001	WEEK 29	28JAN2020	1			.	03DEC2019
BN40423-001	WEEK 37	10MAR2020	0	COVID-19		28JAN2020	28JAN2020
BN40423-001	WEEK 45	19MAY2020	1		COVID-19	28JAN2020	10MAR2020
BN40423-001	WEEK 53	14JUL2020	1			.	19MAY2020

USUBJID	VISIT	ADT (format...	AVAL	ARSND	REAS_PREV	DATE_PREV (...	DATE_TEMP (f...
BN40423-003	WEEK 29	19FEB2020	0	DRUG HOLIDAY		.	06JAN2020
BN40423-003	WEEK 37	16APR2020	0	COVID-19	DRUG HOLIDAY	19FEB2020	19FEB2020
BN40423-003	WEEK 45	09JUN2020	0	COVID-19	COVID-19	19FEB2020	16APR2020
BN40423-003	WEEK 53	11AUG2020	0	DRUG HOLIDAY	COVID-19	19FEB2020	09JUN2020
BN40423-003	WEEK 61	13OCT2020	0	DRUG HOLIDAY	DRUG HOLIDAY	.	11AUG2020
BN40423-003	WEEK 69	30NOV2020	0	DRUG HOLIDAY	DRUG HOLIDAY	.	13OCT2020
BN40423-003	WEEK 77	25JAN2021	0	DRUG HOLIDAY	DRUG HOLIDAY	.	30NOV2020

```
*stop of the interval of missed dosing;
    if REAS_PREV ne "COVID-19" and ARSND ne "COVID-19" then call missing(DATE_PREV);
    output DOSE_DATES;
    if last.USUBJID and ARSND="COVID-19" then output NOT_RESUMED;
run;
```

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ADMS, Dosing missed due to COVID-19

USUBJID ▲	VISIT	ADT (form...	PDT (formatted)	ARSND	REAS_PREV	DATE_PREV (...	DATE_TEMP (f...
BN40423-004	WEEK 29	13FEB2020	.			.	19DEC2019
BN40423-004	WEEK 37	.	15APR2020	COVID-19		13FEB2020	13FEB2020
BN40423-004	WEEK 45	.	10JUN2020	COVID-19	COVID-19	13FEB2020	15APR2020

```
if last.USUBJID and ARSND="COVID-19" then output NOT_RESUMED;
run;
```

Dosing Missed Due to COVID-19

- If dosing was resumed, calculate the difference between two dates

```
_AVAL=coalesce(ADT,PDT)-DATE_PREV-(coalesce(ADT,PDT)>=DATE_PREV);
```

- If dosing was not resumed, use either end of study date or if subject still on study, today's date

```
if not missing(EOSDT) then _AVAL=EOSDT-DATE_PREV-(EOSDT>=DATE_PREV);
else _AVAL=today()-DATE_PREV-(today()>=DATE_PREV);
```
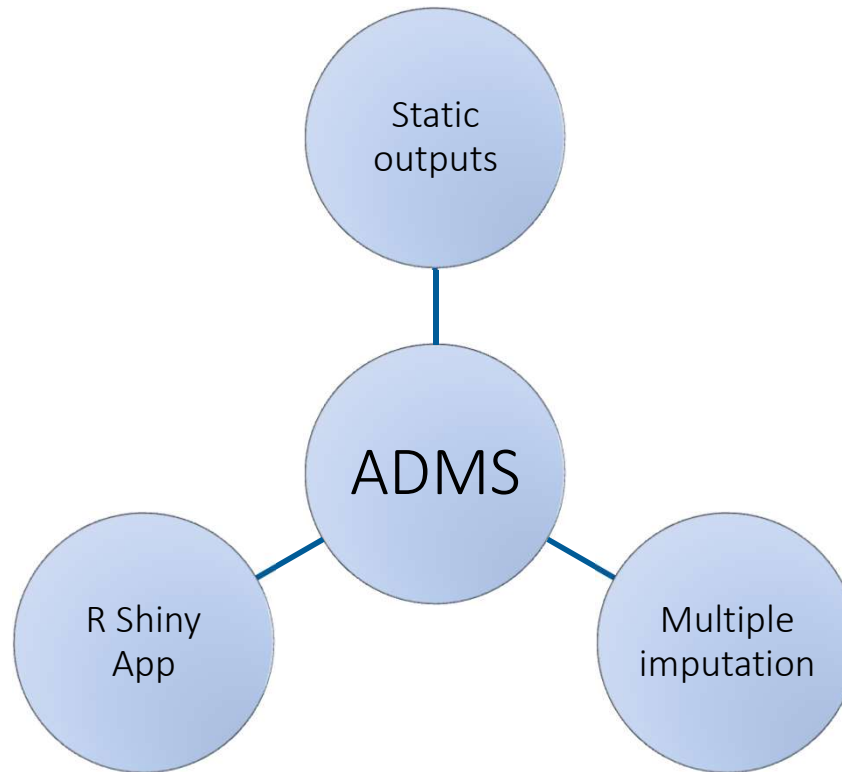
- Sum up all the intervals of missed dosing by subject

```
proc sql noprint;
    create table COVID_DOSE_SUM as select distinct USUBJID, sum(_AVAL) as AVAL
        from COVID_DOSE group by USUBJID;
quit;
```

ADMS, Example: subject discontinued study

USUBJID	VISIT	VEDECOD	VEEPCHGI	PARAM ▾	ADT (format...	PDT (format...	AVAL	ARSND
BN40423-003				Dosing Missed Due to COVID-19 (days)	.	.	174	
BN40423-003	DAY 1	PLANNED VISIT	N	Dose Expected	13AUG2019	.	1	
BN40423-003	WEEK 5	PLANNED VISIT	N	Dose Expected	12SEP2019	.	1	
BN40423-003	WEEK 13	PLANNED VISIT	N	Dose Expected	04NOV2019	.	1	
BN40423-003	WEEK 21	PLANNED VISIT	N	Dose Expected	06JAN2020	.	1	
BN40423-003	WEEK 29	PLANNED VISIT	N	Dose Expected	19FEB2020	.	1	
BN40423-003	WEEK 37	PLANNED VISIT	Y	Dose Expected	16APR2020	.	1	
BN40423-003	WEEK 45	PLANNED VISIT	Y	Dose Expected	09JUN2020	.	1	
BN40423-003	WEEK 53	PLANNED VISIT	N	Dose Expected	11AUG2020	.	1	
BN40423-003	WEEK 61	PLANNED VISIT	N	Dose Expected	13OCT2020	.	1	
BN40423-003	WEEK 69	PLANNED VISIT	N	Dose Expected	30NOV2020	.	1	
BN40423-003	WEEK 77	PLANNED VISIT	N	Dose Expected	25JAN2021	.	1	
BN40423-003	WEEK 85			Dose Expected	.	23MAR2021	0	VISIT NOT REACHED
BN40423-003	WEEK 93			Dose Expected	.	18MAY2021	0	VISIT NOT REACHED
BN40423-003	DAY 1	PLANNED VISIT	N	Dose Completed	13AUG2019	.	1	
BN40423-003	WEEK 5	PLANNED VISIT	N	Dose Completed	12SEP2019	.	1	
BN40423-003	WEEK 13	PLANNED VISIT	N	Dose Completed	04NOV2019	.	1	
BN40423-003	WEEK 21	PLANNED VISIT	N	Dose Completed	06JAN2020	.	1	
BN40423-003	WEEK 29	PLANNED VISIT	N	Dose Completed	19FEB2020	.	0	DRUG HOLIDAY
BN40423-003	WEEK 37	PLANNED VISIT	Y	Dose Completed	16APR2020	.	0	COVID-19
BN40423-003	WEEK 45	PLANNED VISIT	Y	Dose Completed	09JUN2020	.	0	COVID-19
BN40423-003	WEEK 53	PLANNED VISIT	N	Dose Completed	11AUG2020	.	0	DRUG HOLIDAY
BN40423-003	WEEK 61	PLANNED VISIT	N	Dose Completed	13OCT2020	.	0	DRUG HOLIDAY
BN40423-003	WEEK 69	PLANNED VISIT	N	Dose Completed	30NOV2020	.	0	DRUG HOLIDAY
BN40423-003	WEEK 77	PLANNED VISIT	N	Dose Completed	25JAN2021	.	0	DRUG HOLIDAY

What's Next?

Conclusions

- Structure allows for further parameters to be added
- Combination of ADT/PDT variables enables to look at a specific time interval, i.e. "first wave"
- Non-CRF data needs to be reconciled vs. RAVE data
- Code might need to be adapted in case of a more complicated study design, i.e. if the study has SFUP after treatment discontinuation

Thank you!

Contact Information
yuliia.bahatska@roche.com