

The finding is a date

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- All presenters are employees of Novo Nordisk A/S.
- Views and opinions expressed are those of the presenters and not necessarily Novo Nordisk A/S.

Disclaimer

Is the event occurring more or less frequent?

Summarise findings to address

potential impact on

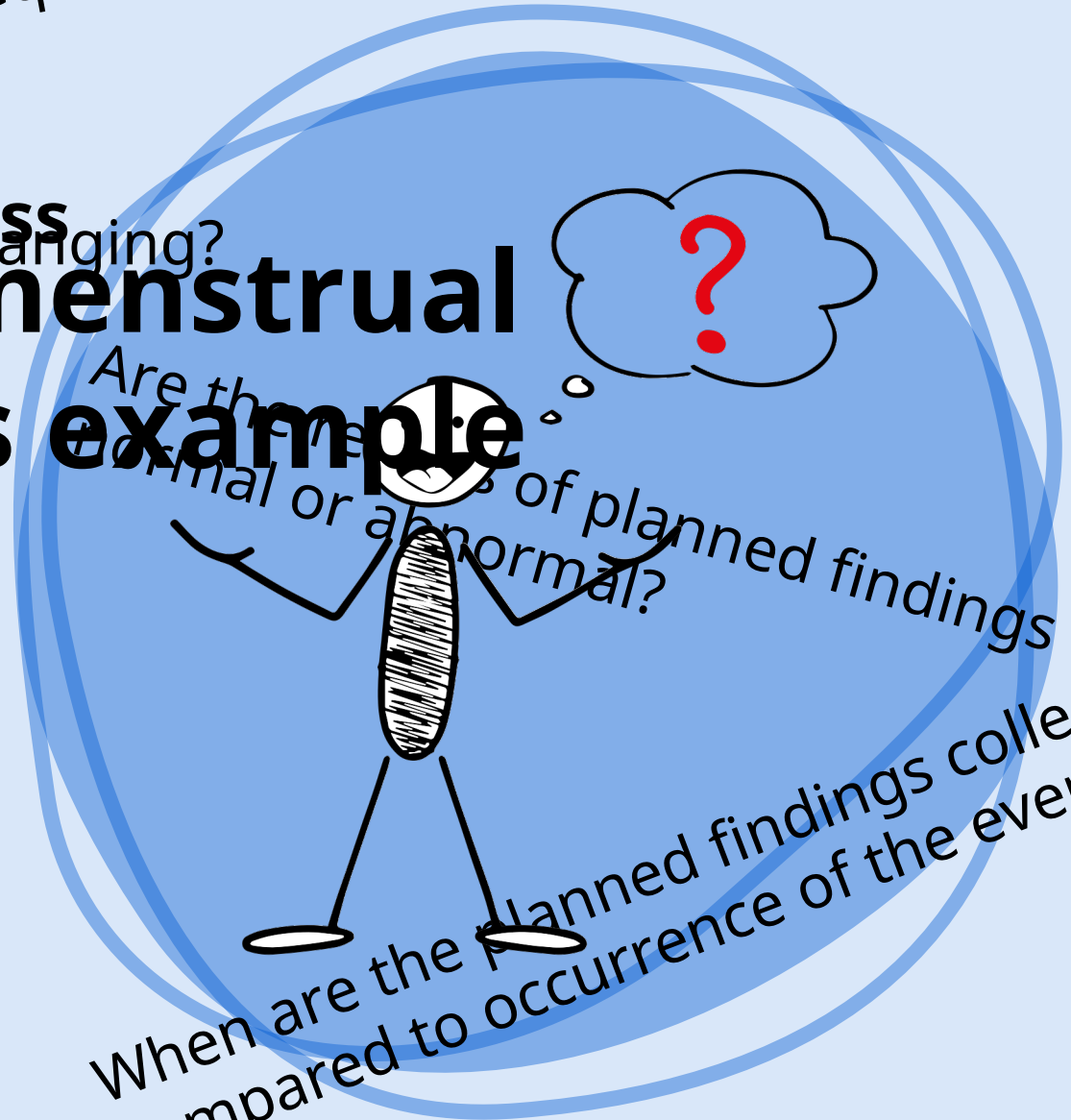
parameters!

Have other characteristics changed?

Using menstrual cycle as example

Are there any of planned findings normal or abnormal?

When are the planned findings collected compared to occurrence of the event?

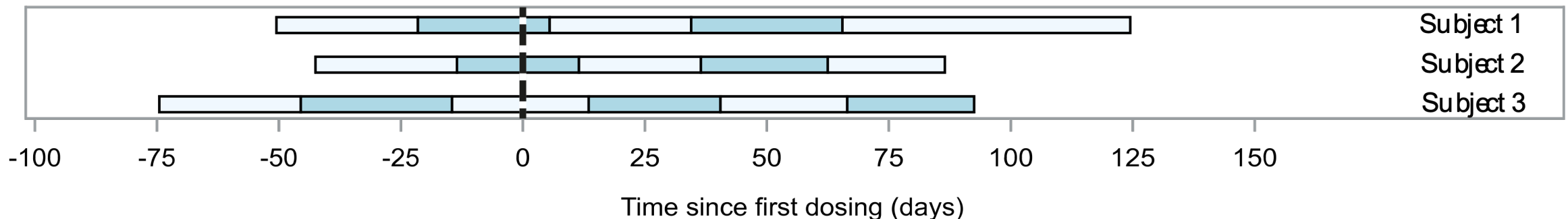


Setting the scene

The occurrence based data

Data collected at all planned visit

- "Previous Menstrual Period Start Date"
- "Last Menstrual Period Start Date"
- "Investigator's Evaluation of Menses"

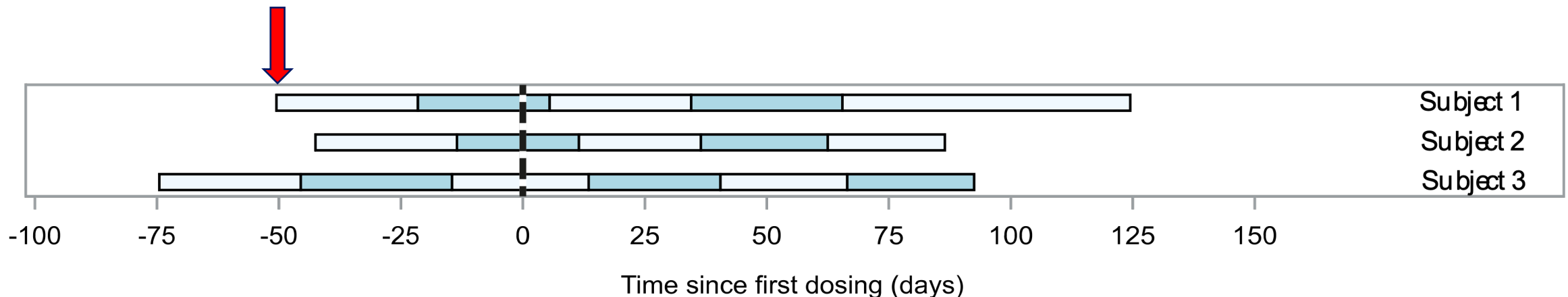


The occurrence based data

Data collected at all **planned visit**

- **"Previous Menstrual Period Start Date"**
- "Last Menstrual Period Start Date"
- "Investigator's Evaluation of Menses"

Holds start date of the second most recent menstrual cycle prior to the screening visit.

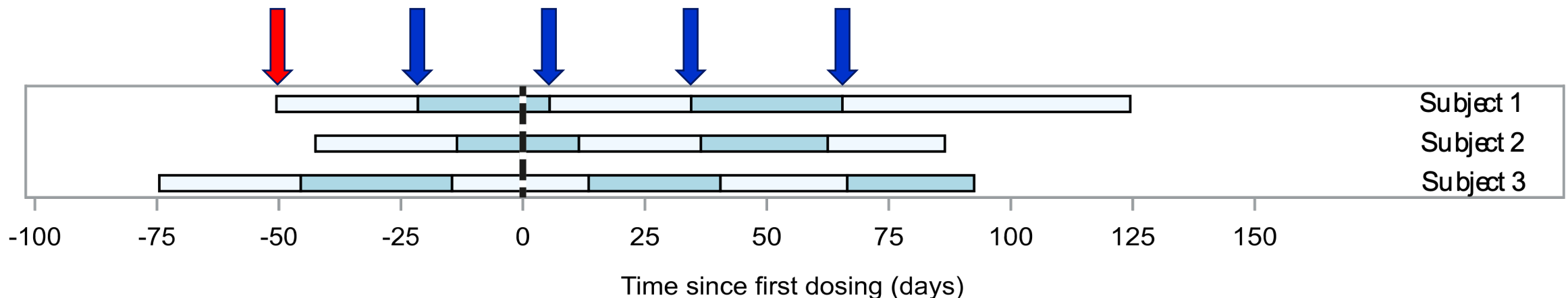


The occurrence based data

Data collected at all planned visit

- "Previous Menstrual Period Start Date"
- "Last Menstrual Period Start Date"
- "Investigator's Evaluation of Menses"

Holds start date of the latest menstrual cycle prior to the current visit. Records are event-driven and only exists if a menstrual cycle has started in the period between the current visit and preceding visit.

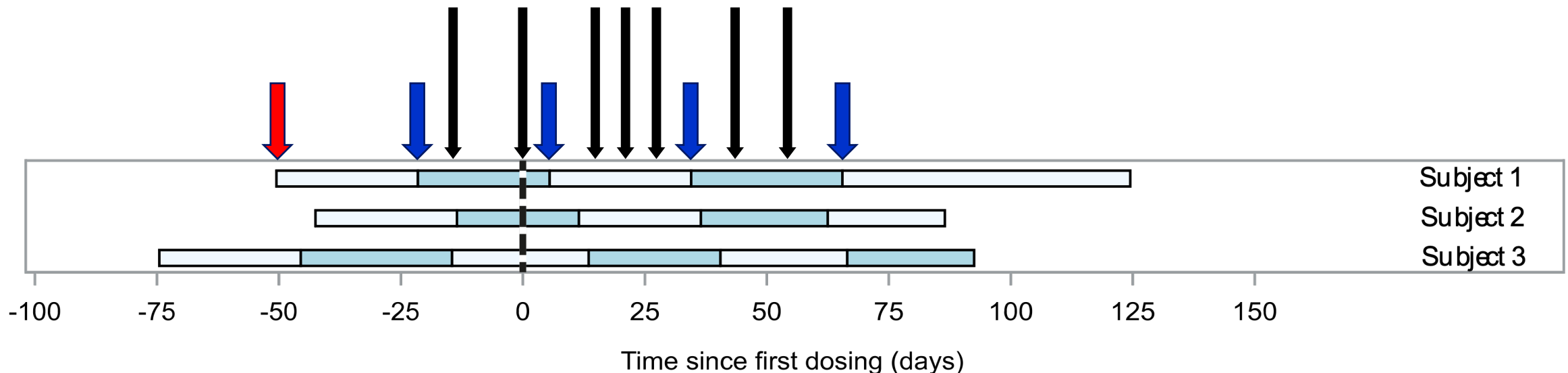


The occurrence based data

Data collected at all planned visit

- "Previous Menstrual Period Start Date"
- "Last Menstrual Period Start Date"
- "Investigator's Evaluation of Menses"

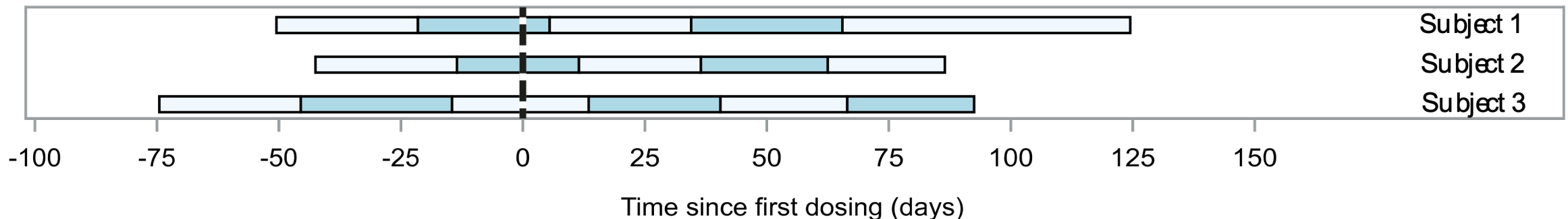
Holds investigator's evaluation of menstrual cycle as REGULAR or IRREGULAR based on the last occurrence of menses prior to the current visit.



The planned findings

Hormone levels related to menstrual cycle assessed at **planned visits**

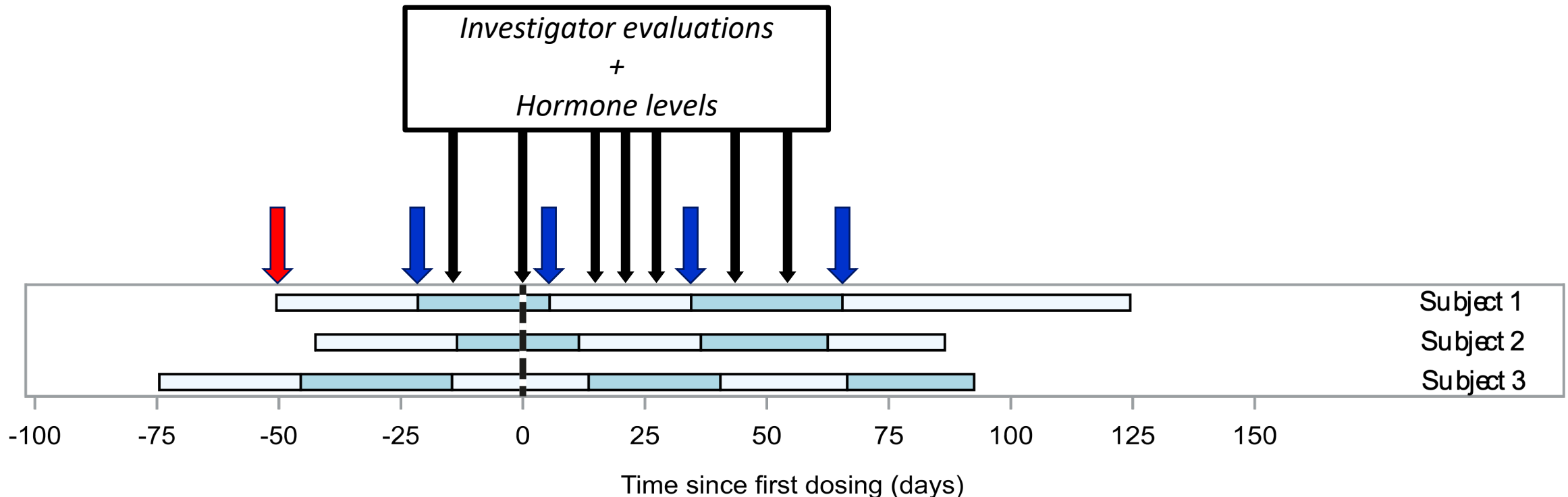
- Progesterone
- Estradiol Serum



The planned findings

Hormone levels related to menstrual cycle assessed at **planned visits**

- Progesterone
- Estradiol Serum



Summary of data (SDTM)

Occurrence based data

DOMAIN	USUBJID	RPTEST	RPORRES	RPORRESU	RPSTRESC	RPSTRESN	RPSTRESU	VISIT	VISITDY
RP	Subject 10	Previous Menstrual Period Start Date	yyyy-mm-dd		yyyy-mm-dd			VISIT 1 (SCREENING)	-28
RP	Subject 10	Last Menstrual Period Start Date	yyyy-mm-dd		yyyy-mm-dd			VISIT 1 (SCREENING)	-28
RP	Subject 10	Investigator's Evaluation of Menses	REGULAR		REGULAR			VISIT 1 (SCREENING)	-28
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RP	Subject 10	Investigator's Evaluation of Menses	REGULAR		REGULAR			VISIT 2 (DAY -1)	-1
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Summary of data (SDTM)

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RP	Subject 10	Investigator's Evaluation of Menses	REGULAR		REGULAR			VISIT 2 (DAY 2)	2

Planned findings

DOMAIN	USUBJID	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSPEC	VISIT	VISITDY
LB	Subject 10	Estradiol	xx.x	ng/L	xx.x	xx.x	ng/L	SERUM	VISIT 1 (SCREENING)	-28
LB	Subject 10	Estradiol	xx.x	ng/L	xx.x	xx.x	ng/L	SERUM	VISIT 2 (DAY 1)	1
LB	Subject 10	Progesterone	xx.x	ug/L	xx.x	xx.x	ug/L	SERUM	VISIT 1 (SCREENING)	-28
LB	Subject 10	Progesterone	xx.x	ug/L	xx.x	xx.x	ug/L	SERUM	VISIT 2 (DAY 1)	1

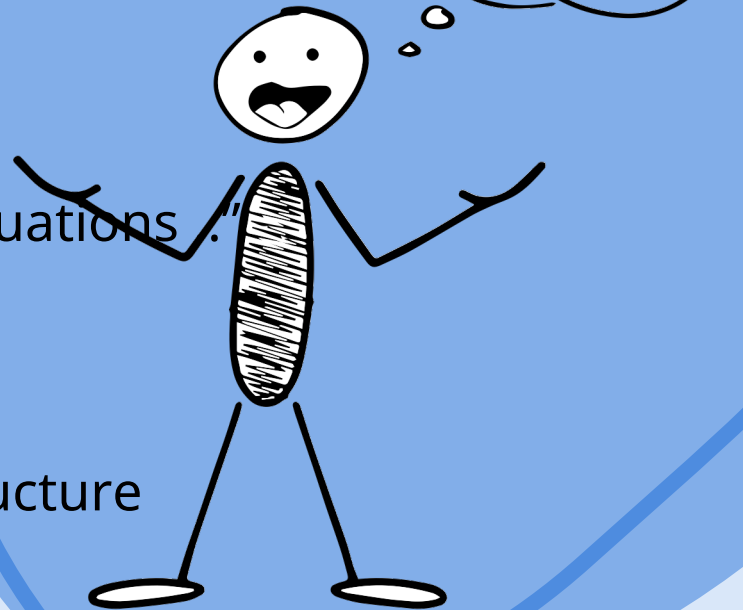
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RP	Subject 10	Investigator's Evaluation of Menses	REGULAR		REGULAR			VISIT 2 (DAY2)	2

Reflections

- Two parameters with different characteristics
- BDS structure best suited for "Investigator's evaluations"

Action

- Use BDS structure
- Fit "Menstrual cycle start date" data into BDS structure



ADaM data model for the occurrence based data

Generating ADRP

SUBJID	AVISIT	PARAM	AVAL	AVALU	AVALC	AVALDT	RPSTRESC	PM PSTDT
Subject 10	Visit 1 (screening)	Investigators Evaluation of Menses			REGULAR		REGULAR	
Subject 10	Visit 1 (screening)	Menstrual cycle duration (day)	34	day	34d	dd-mm-yyyy	yyyy-mm-dd	dd-mm-yyyy
Subject 10	Visit 2 (day -2)	Investigators Evaluation of Menses			REGULAR		REGULAR	
Subject 10	Visit 2 (day -2)	Menstrual cycle duration (day)	31	day	31d	dd-mm-yyyy	yyyy-mm-dd	
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Subject 10	Visit 2 (day 1)	Investigators Evaluation of Menses			REGULAR		REGULAR	
Subject 10	Visit 2 (day 2)	Investigators Evaluation of Menses			REGULAR		REGULAR	

Generating ADRP

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Subject 10	Visit 2 (day 2)	Investigators Evaluation of Menses			REGULAR		REGULAR	

Timing variables

- Time from first dose to visit (ARELTM1(U), ARLTM1RF, AR1RFDTM)

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Timing variables

- Time from first dose to visit (ARELTM1(U), ARLTM1RF, AR1RFDTM)
- Time from most recent menses to visit (ARELTM2(U), ARLTM2RF, AR2RFDTM)

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SUBJID	AVISIT	PARAM	AVAL	AVALU	AVALC	AVALDT	RPSTRESC	PMPSTDT
Subject 10	Visit 1 (screening)	Investigators Evaluation of Menses			REGULAR		REGULAR	
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Timing variables

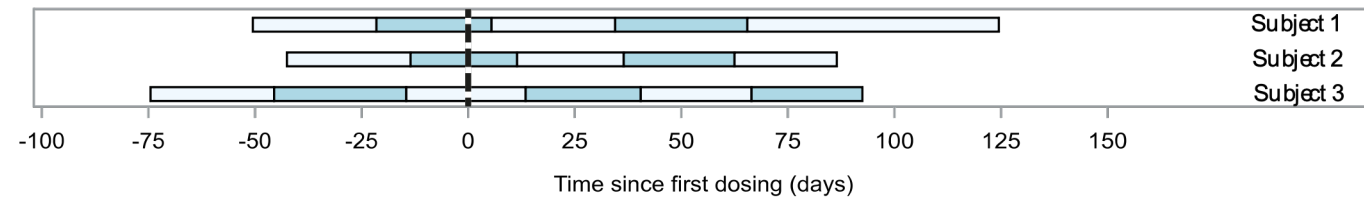
- Time from first dose to visit (ARELTM1(U), ARLTM1RF, AR1RFDTM)
- Time from most recent menses to visit (ARELTM2(U), ARLTM2RF, AR2RFDTM)
- Time from first dose to most recent menses (ARELTM3(U), ARLTM3RF, AR3RFDTM)



Visualisation of data

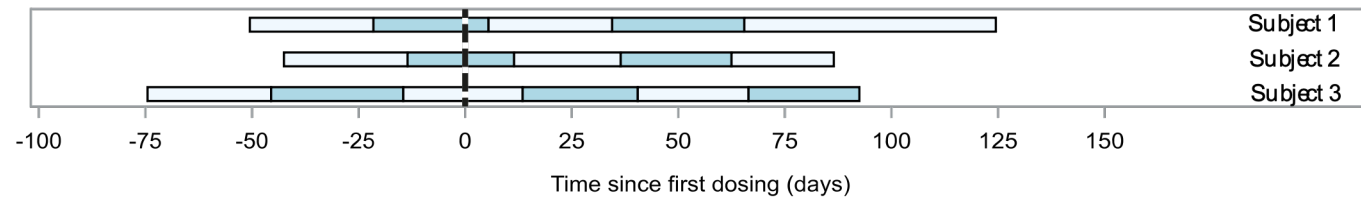
Plots

Timing and duration of menstrual cycle relative to treatment start

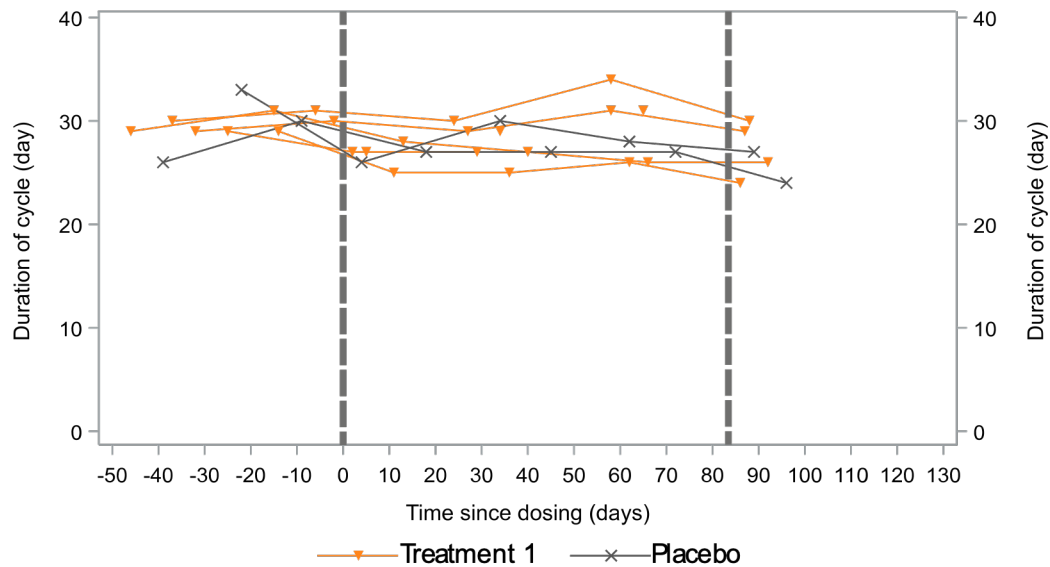


Plots

Timing and duration of menstrual cycle relative to treatment start



Comparison of menstrual cycle duration between treatment groups

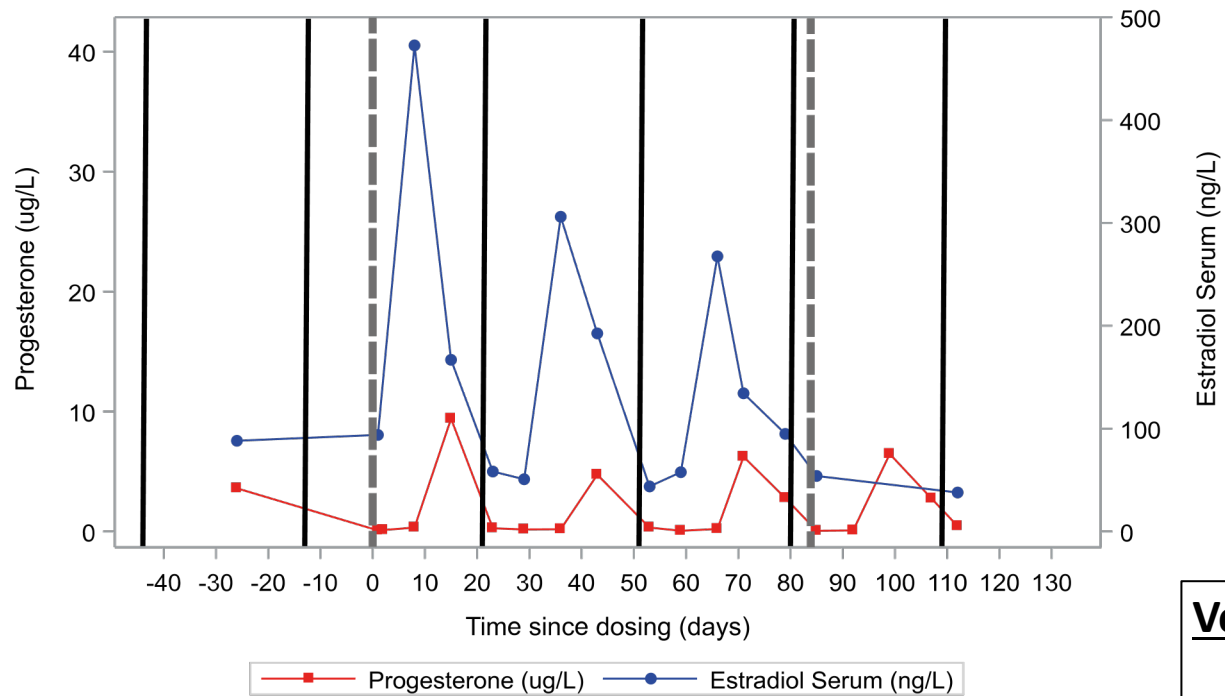


Vertical lines

- Dotted grey lines represent first and last dosing

Plots

Hormone levels relative to treatment and menstrual start date



Vertical lines

- Dotted grey lines represent first and last dosing
- Black lines represents beginning of menstrual cycle

Table

Menstrual cycle presence

	Treatment 1 N (%)	Treatment 2 N (%)	Treatment 3 N (%)	Treatment 4 N (%)	Treatment 5 N (%)	Placebo N (%)
Number of female subjects	7	6	4	3	0	6
Visit 14 (day 85)						
N	5 (71.4)	4 (66.7)	2 (50.0)	1 (33.3)	0 (0.0)	5 (83.3)
Regular	5 (100.0)	4 (100.0)	2 (100.0)	1 (100.0)	0 (0.0)	5 (100.0)
Irregular	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Visit 18 (follow-up, day 1)						
N		5 (83.3)	3 (75.0)	2 (66.7)	0 (0.0)	3 (50.0)
Regular		4 (80.0)	3 (100.0)	2 (100.0)	0 (0.0)	3 (100.0)
Irregular		1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Visit 18 (follow-up, day 2)						
N	7 (100.0)	5 (83.3)	2 (50.0)	0 (0.0)	0 (0.0)	6 (100.0)
Regular	5 (71.4)	4 (80.0)	2 (100.0)	0 (0.0)	0 (0.0)	6 (100.0)
Irregular	2 (28.6)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

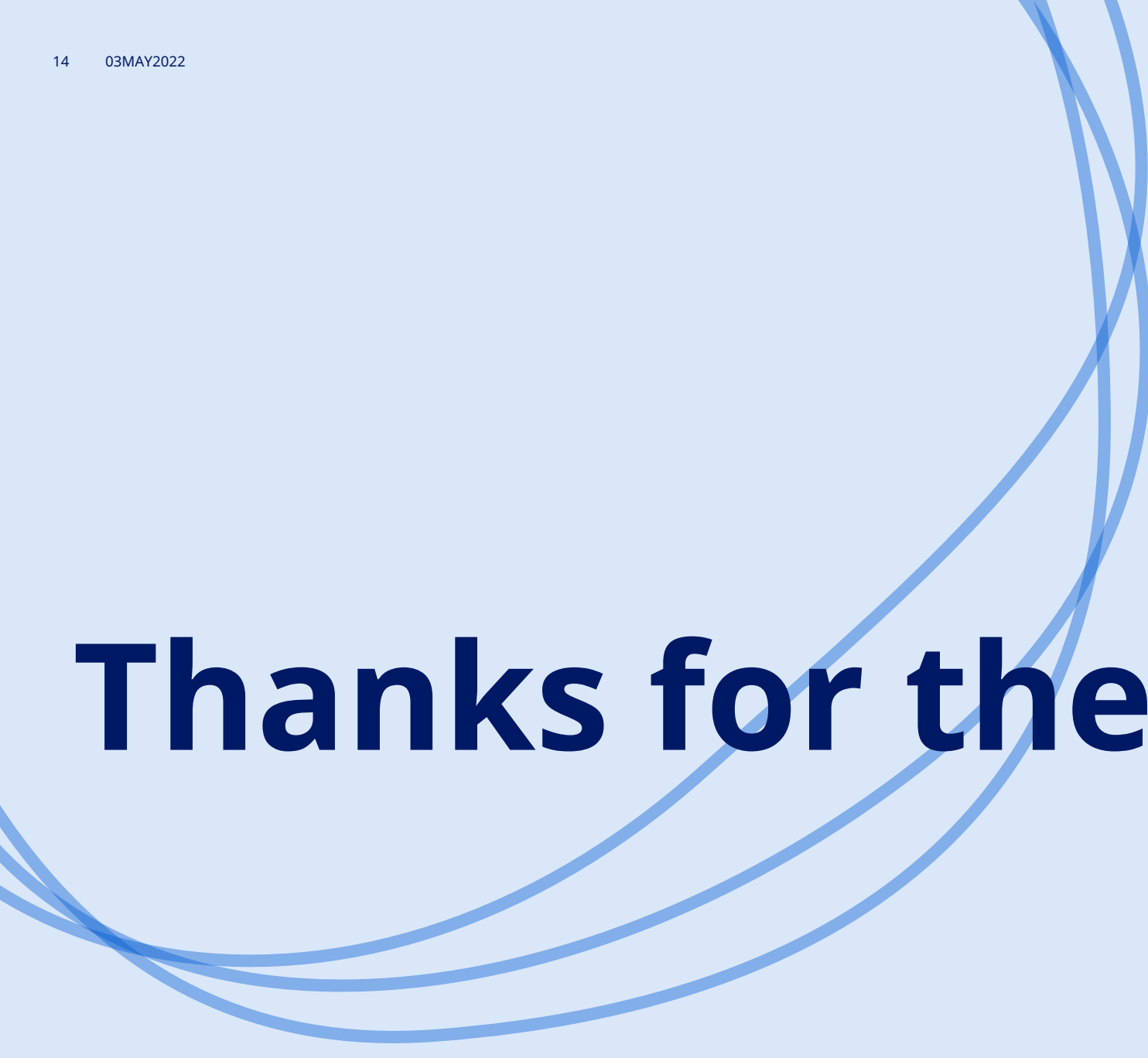
Integrating records in one ADaM dataset

- Increases overview and transparency
- Eases output programming

Using the BDS structure

- Allows for having several different parameters in dataset
- We have variables intended to hold visit information and timing information
- Easy to combine data with related data from other BDS datasets (e.g. ADLB)

Conclusion



Thanks for the attention