

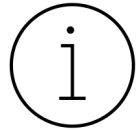
iCDM

interactive dashboards that innovate central
data monitoring at Danone Nutricia Research

Paul Vervuren & Dennis Menkveld
PHUSE EU CONNECT 2022 - AR05



agenda



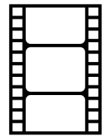
the project



dataflow

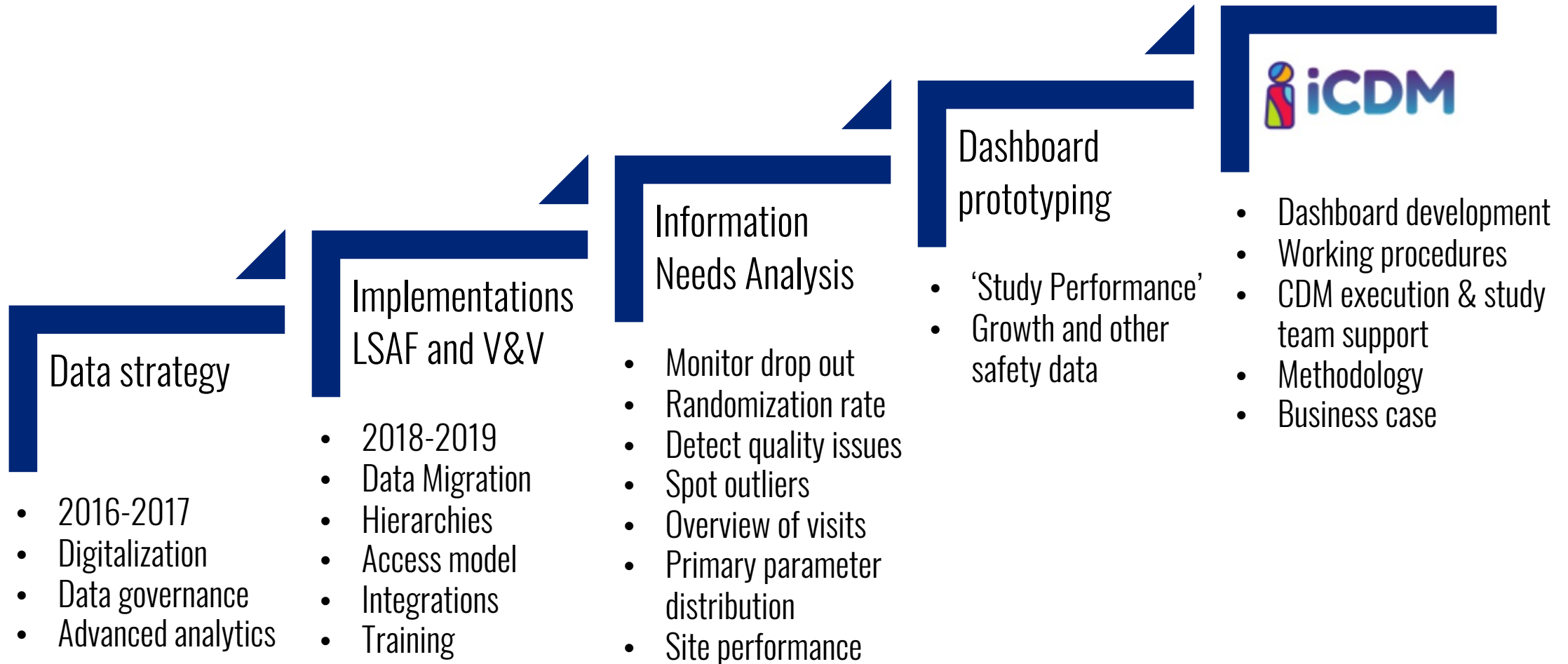


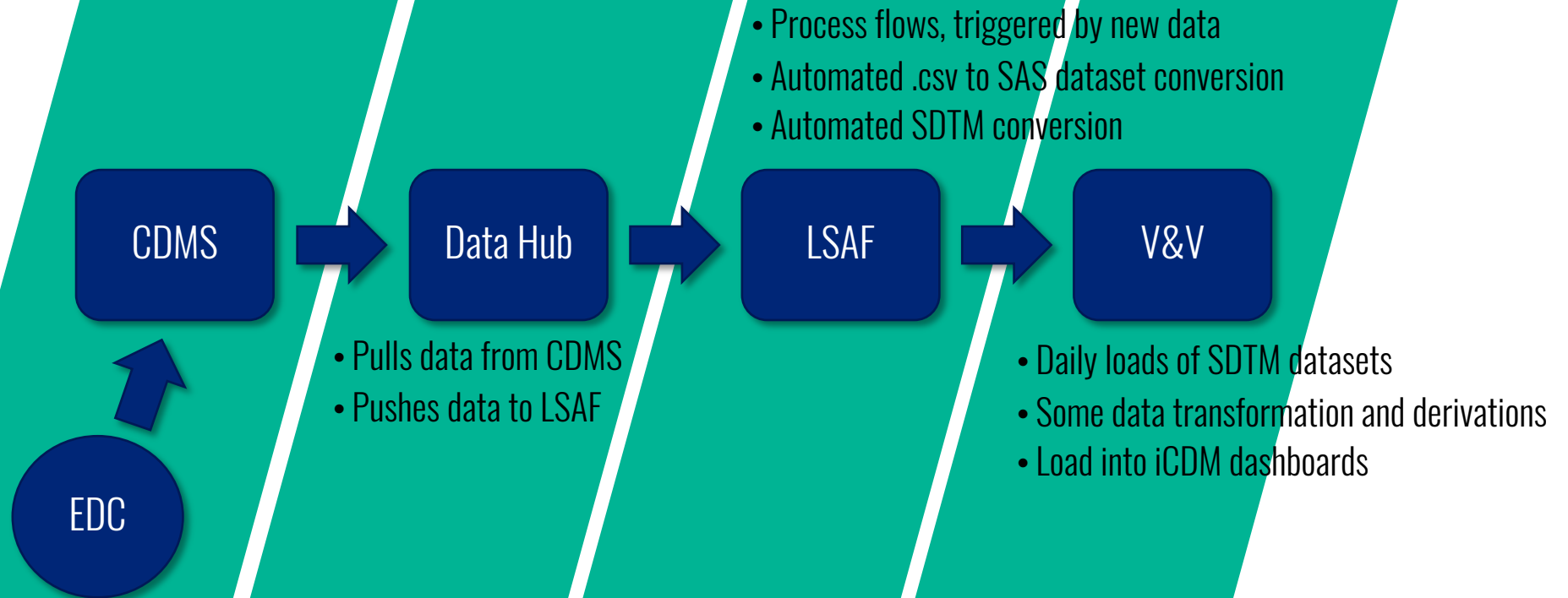
return on investment



demo

i the project





€ return on investment

Savings

- Data Review Meeting
- On-site monitoring
- Periodic Medical Review
- Data cleaning
- CAPA handling/resolution
- SDV

Start-up costs

- Project costs
- Standards implementation
 - adaptations for ongoing studies

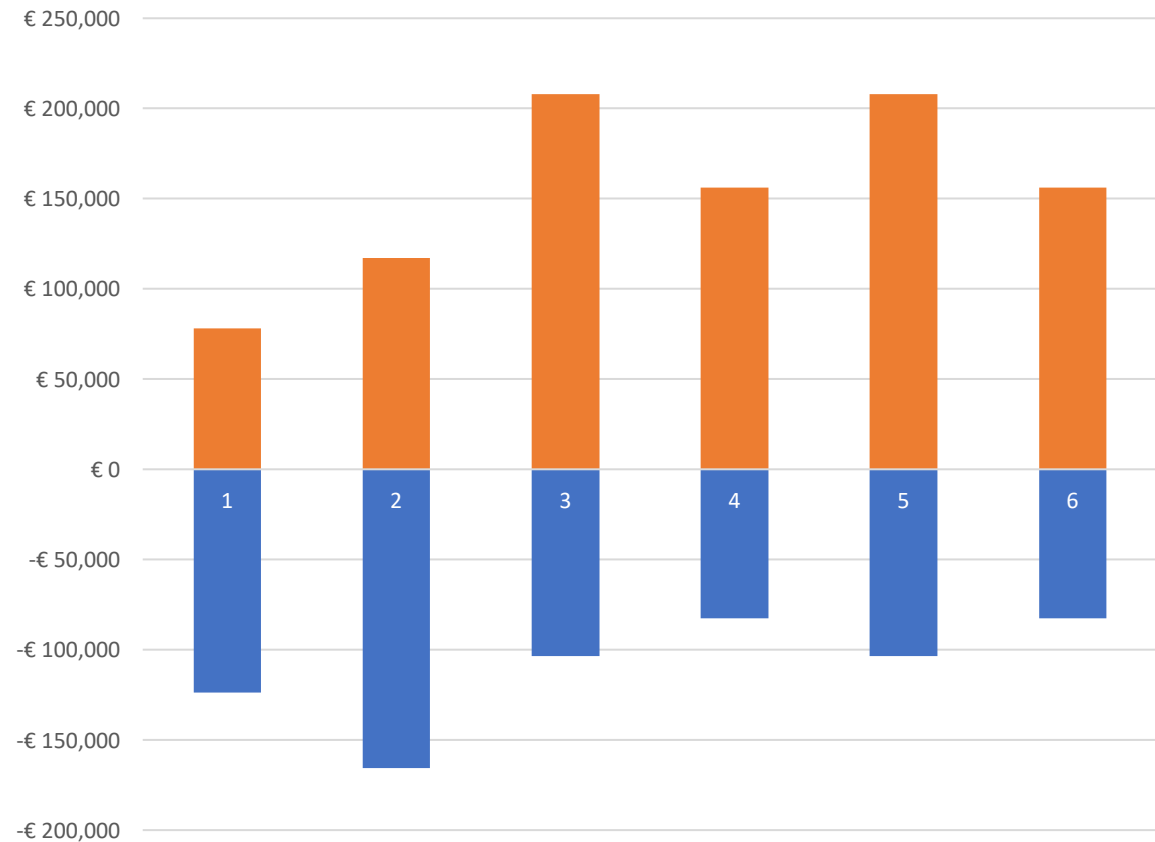
Recurring costs

- Software costs
- Dashboard development
- Data preparations
- Continuous improvements

€ return on investment

Six-year scenario

- Start-up phase two years
 - Three to four studies per year
 - Mix of studies running one or two years
 - Costs always in year one
 - Savings split (for two-year studies)
 - Savings set to 50% and 75% respectively in year one and two.
- Break-even after 2-3 years

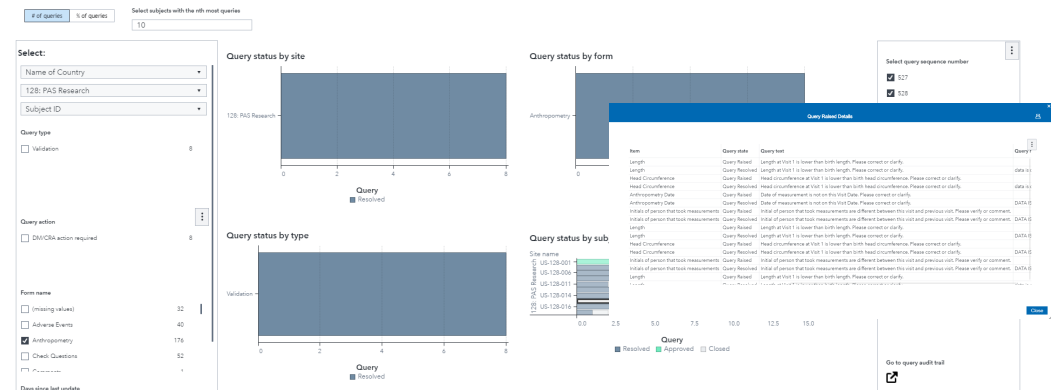


DEMO

This 10-min demo will show the design, technical functionalities of the iCDM dashboards, and will highlight the added value for study team members in different functions (e.g. clinical study manager, data manager, medical monitor, researcher/clinician)



- Anthropometrics: find outlier
- Growth curve: check individual
- Queries: check pending query: no
- Visit planning: check when visit
- Action: inform CRO/sites, investigators



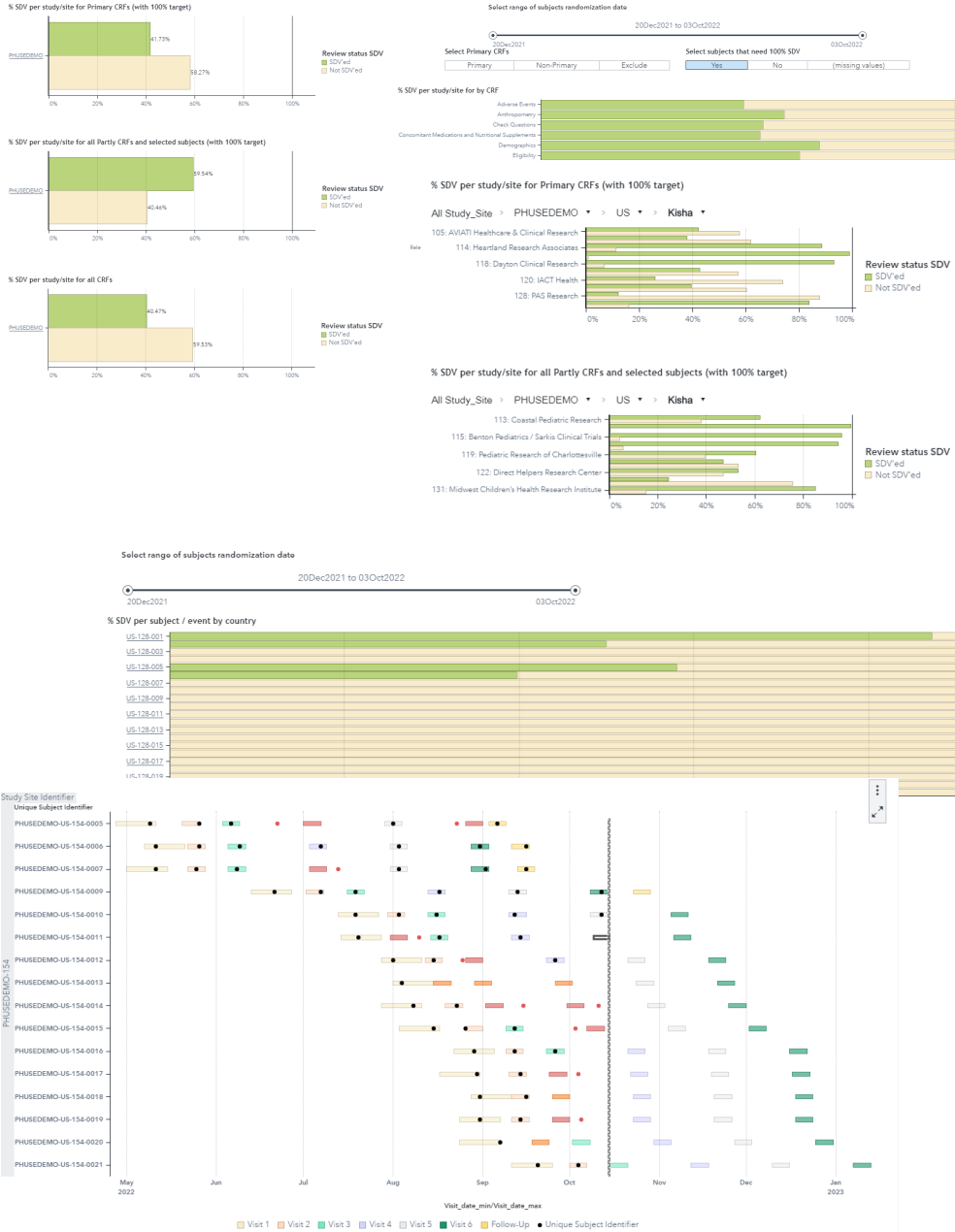
OVERALL CRO AND SITE MANAGEMENT

UNDER AND OVERSPEND OF SDV PER CRA/SITE

- SDV of items that is not necessary/approved
- Lack of SDV on items that are agreed upon, too late to notice issues?

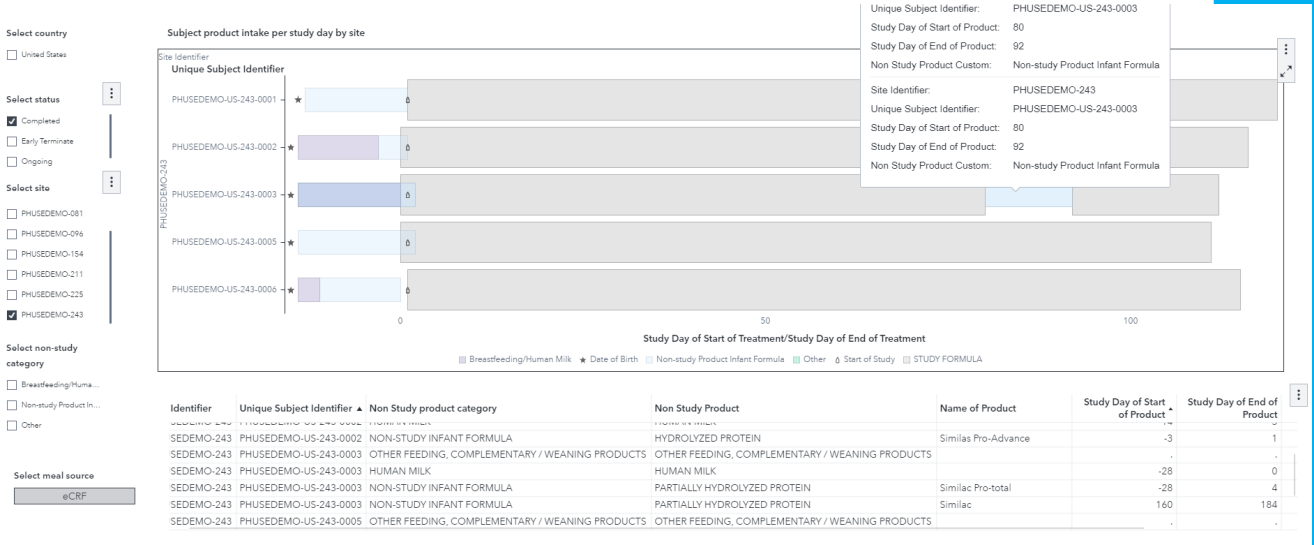
PLAN VISITS AND OUTSTANDING WORK FOR A REQUESTED VISIT DURATION:

- Notify that a site has a lot of SDV to do or the opposite
- Check visit planning for new visit to come up for this site
- Approval of visit



PRODUCT COMPLIANCE FOR AN INTERIM ANALYSIS

- Product compliance: notify gap in study product at a glance, see details
- Check pending queries for actions
- Inform site if necessary
- Action: retrain sites if occurs is often
- Action: still evaluable subject for interim?

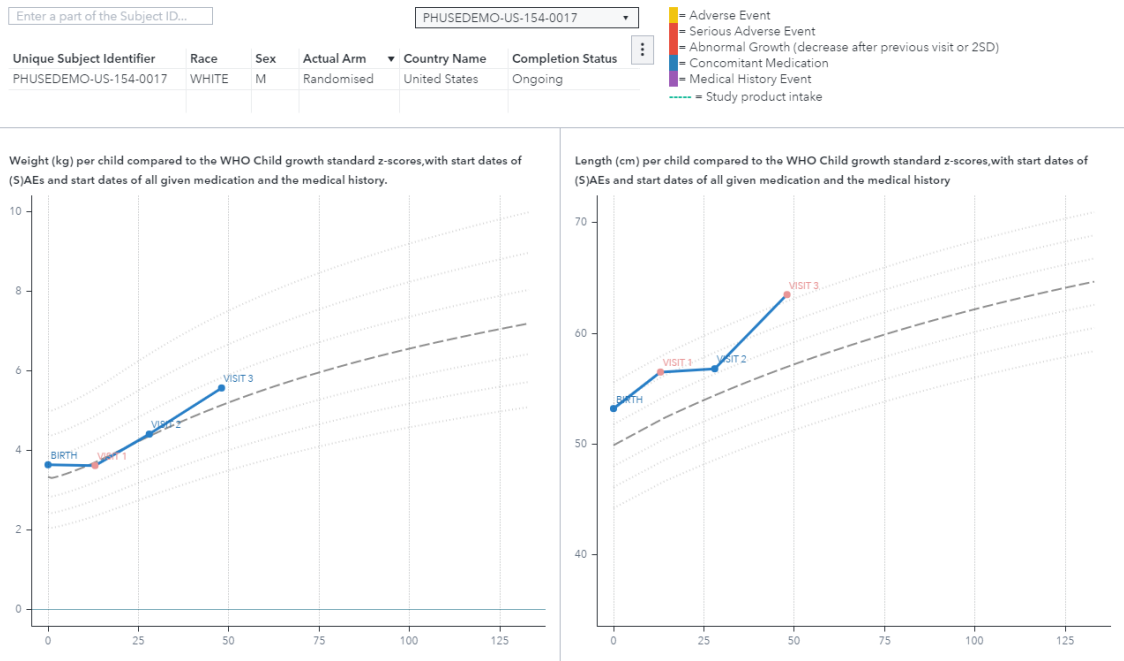
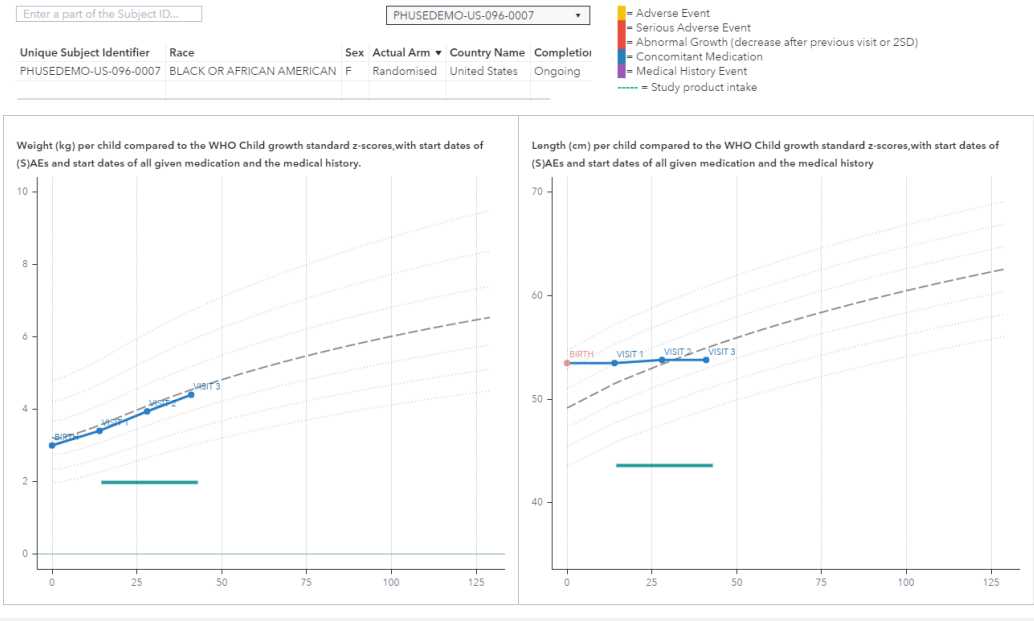


Query Raised Details

Query study sequence number	Subject ID	Event name	Date & time (UTC)	Site name	Query type	Form name	Raised on	Item
115	US-113-003	Visit 1	2022-03-23 13:42	113: Coastal Pediatric Research	Manual	Subject Characteristics	Item	Birth leng
115	US-113-003	Visit 1	2022-03-23 13:43	113: Coastal Pediatric Research	Manual	Subject Characteristics	Item	Birth leng
115	US-113-003	Visit 1	2022-03-28 18:48	113: Coastal Pediatric Research	Manual	Subject Characteristics	Item	Birth leng
116	US-113-003	Visit 1	2022-03-23 13:43	113: Coastal Pediatric Research	Manual	Subject Characteristics	Item	Birth hea
116	US-113-003	Visit 1	2022-03-28 18:48	113: Coastal Pediatric Research	Manual	Subject Characteristics	Item	Birth hea
117	US-113-003	Visit 1	2022-03-23 13:48	113: Coastal Pediatric Research	Manual	Study Product Intake	Item	Start Date
117	US-113-003	Visit 1	2022-03-28 18:53	113: Coastal Pediatric Research	Manual	Study Product Intake	Item	Start Date
118	US-113-003	Visit 2	2022-03-23 13:51	113: Coastal Pediatric Research	Manual	Check Questions	Item	Any Adv
118	US-113-003	Visit 2	2022-03-23 13:51	113: Coastal Pediatric Research	Manual	Check Questions	Item	Any Adv
148	US-113-003	Visit 4	2022-03-28 17:41	113: Coastal Pediatric Research	Validation	Anthropometry	Item	Initials of
148	US-113-003	Visit 4	2022-03-28 17:41	113: Coastal Pediatric Research	Validation	Anthropometry	Item	Initials of
220	US-113-003	Visit 5	2022-05-04 17:57	113: Coastal Pediatric Research	Validation		Event date	
220	US-113-003	Visit 5	2022-05-04 17:57	113: Coastal Pediatric Research	Validation		Event date	
252	US-113-003	Visit 6	2022-05-24 18:31	113: Coastal Pediatric Research	Validation	Anthropometry	Item	Initials of
949	US-113-003	Visit 6	2022-05-24 18:31	113: Coastal Pediatric Research	Validation	Anthropometry	Item	Initials of

SAFETY MONITORING

- Review infant growth
-
- Drill down from aggregated overview to subject details.
- observe trends in specific Adverse events
- assess impact on individual subjects



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THANKS TO

iCDM team

V&V team

SDTM team

Danone Nutricia Research

