

A Data Manager's Experience with AI/ML Adoption and Efficiency

Diane Lacroix

PRE_ET01

PHUSE US Connect



Poll Question #1

Have you ever used Chat GPT to prepare a presentation for your boss?

1. Yes
2. No
3. They're sitting next to me



Poll Question #2

What best describes your sentiment on how AI/ML will impact Biometrics in the next 2-3 years?

1. Excited for enhanced productivity and increased ability to focus on high value tasks.
2. Concerns about patient safety.
3. Fear of loss of human control.
4. Concerns about job displacement.
5. All of the above.
6. None of the above.



The State of AI/ML Adoption

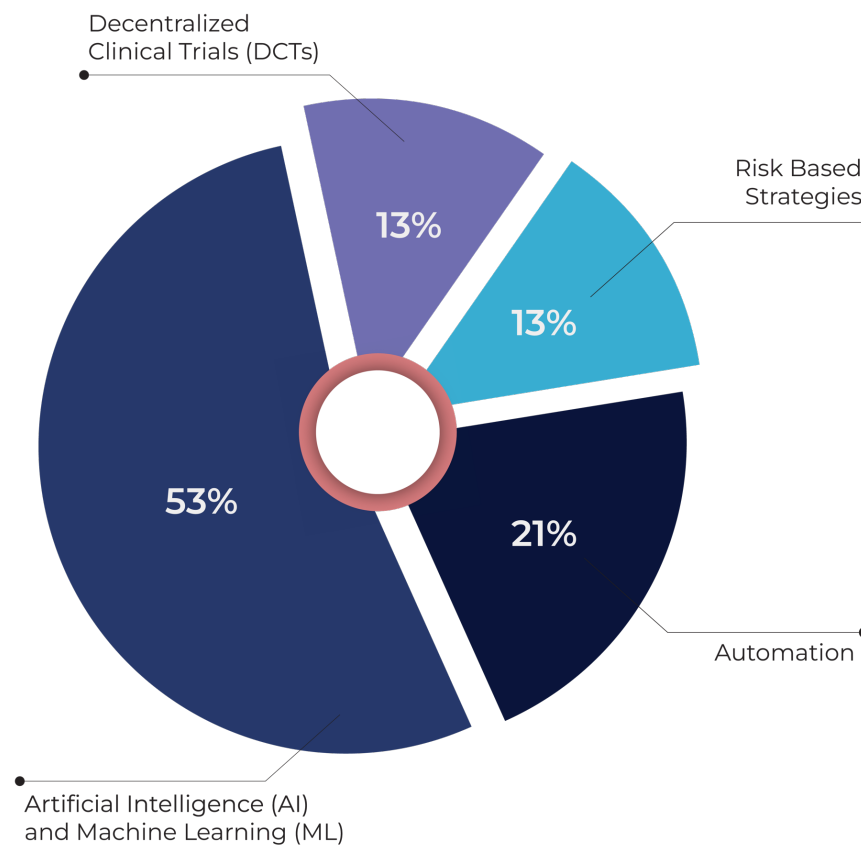
Survey Approach

- Builds on insights from Industry Outlook 2023
- Aims to understand how professionals are experiencing clinical data transformation
- Responses from 77 professionals working across clinical operations, data management, statistical programming, and biometrics functions
- Over 50 sponsor organizations



The Top Industry Priority

Which of these life science industry trends do you believe will have the greatest impact on efficiency and outcomes over the next 12 months?

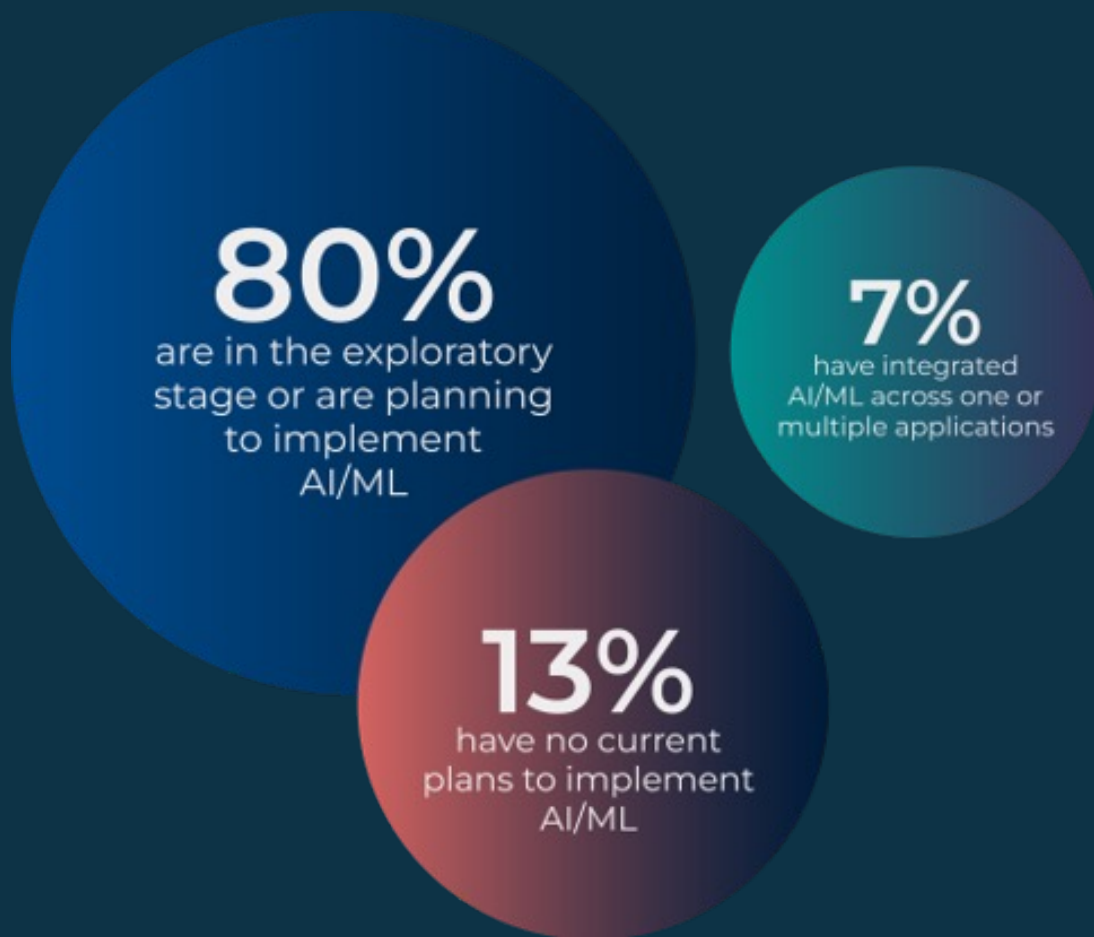


Which are the top 3 most effective strategies your organization is currently using to handle greater trial and data complexity?



Process and
Skills
Alongside
Technology

To what extent has your organization integrated AI and ML approaches into clinical data workflows?



Majority

In exploratory stages

Key Insights



Organizations are transforming across technology, processes and skills and not relying on technology alone. The 'humans in the loop' are critical.

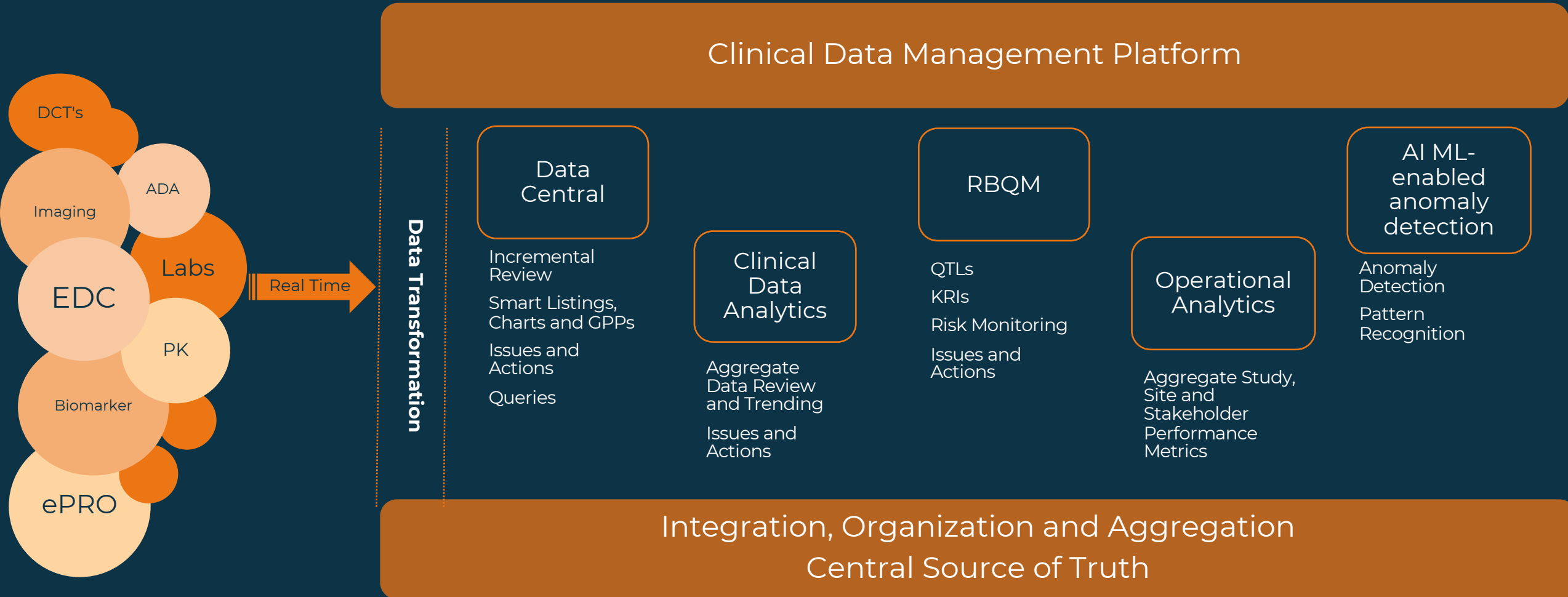


AI is the hot topic, but the expectation to see ROI within a short timeframe is optimistic given that most companies are in exploration stage.



Bridging the gap from exploration to value will require commitment, foundations and hard work- no magic bullet.

Technology Focus- Foundation for AI/ ML



Demystifying the Hype

Traditional Data Review

Methods

- Time Consuming
- Error Prone
- Low accuracy
- Resource Intensive

Manual Reviews

DM Initiated Queries

Decision Making

Action



AI Augmented Data Review

Methods

AI ML Review of Focused Output

Automation of Proposed Query Text

Human in the Loop

Action

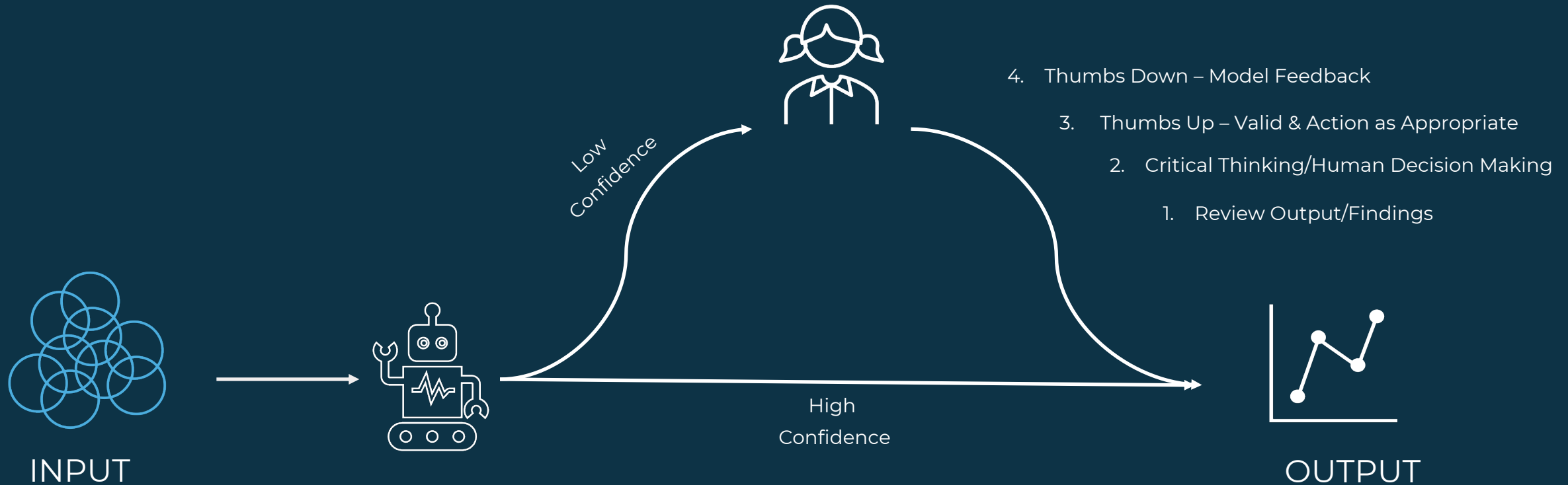


- Time Saving
- Higher Accuracy
- Higher efficiency and productivity

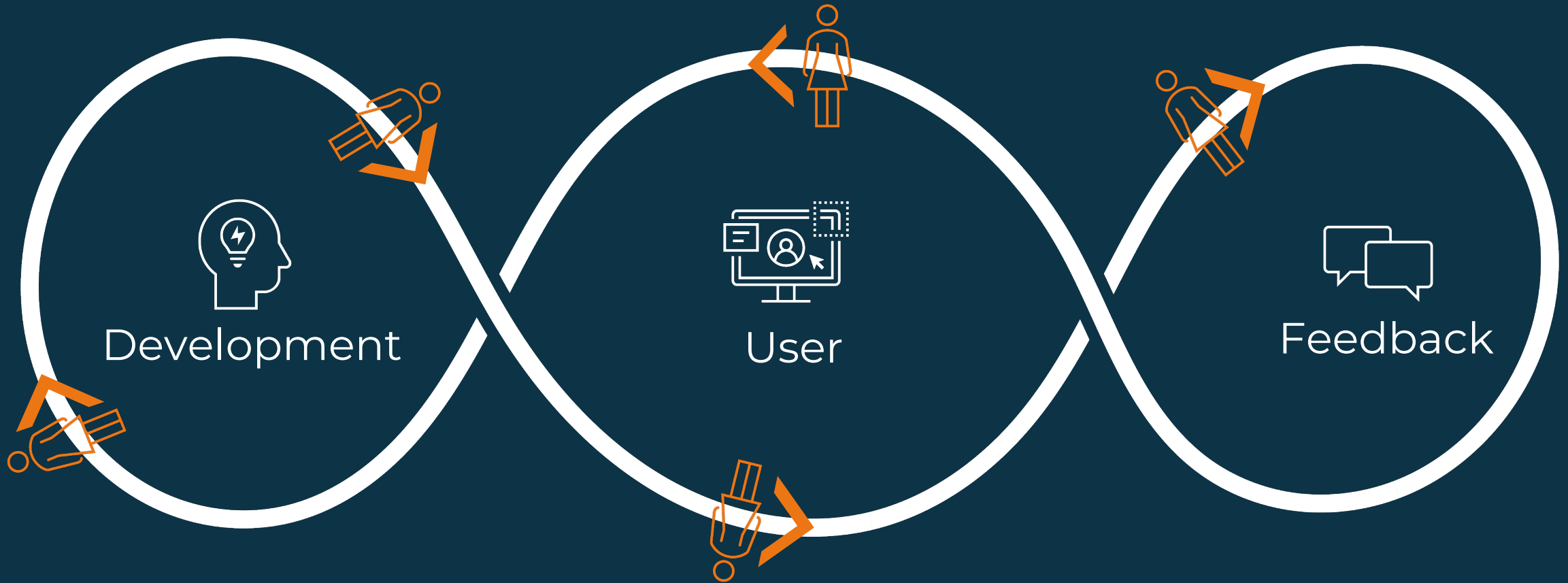


Data Manager as the Human in
the Loop – collaborating to bring
AI ML from ideation to reality

Human in the Loop (HITL) - Concept



Data Managers as the “Human in the Loop”





Use Cases: AI Enabled Data Review

Anomaly Detection: Incorrect item type



Anomalous Records for ANALYTEVALUE - **Neutrophils** - 16

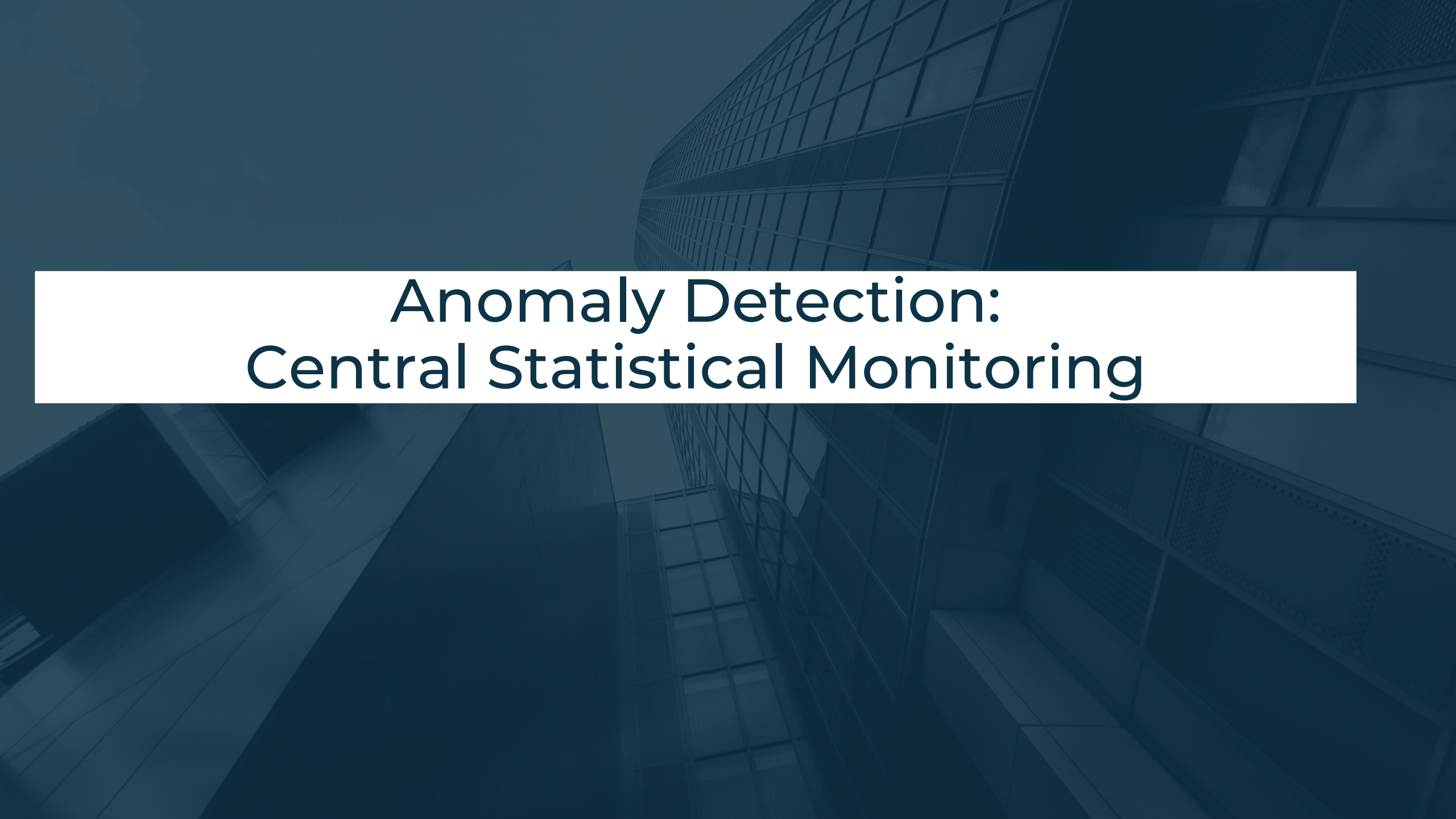
Review

☐	MDR	Record ID	Value	Subject ID
☐		4436		10293
☐		25973	NR	10528
☐		25974	NR	10528
☐		25978	NR	10528
☐		25979	NR	10528
☐		25250	ND	10874
☐		25306	ND	10874
☐		25145	ND	10874
☐		25386	ND	10874
☐		25424	ND	10874
☐		25449	ND	10874
☐		25619	ND	10874
☐		25203	ND	11051
☐		17581		11673
☐		25656	ND	6193
☐		25329	ND	9328

Anomalous Records for CMDSTXT - CMTRT_PT - POTASSIUM - 1

Review

☐	MDR	Record ID	Value	Subject ID
☐		25123	20-50	10681



Anomaly Detection: Central Statistical Monitoring

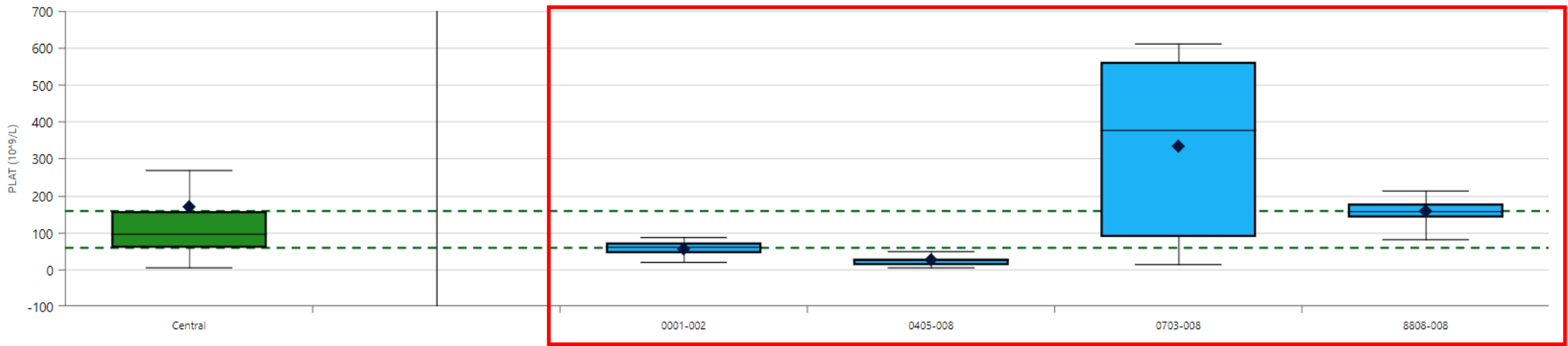
Lab and Vitals Tests Containing Anomalies 32

Domain	Test Category	Test Type	Units	# of Analyzed Subjects	# of Reviewed Subjects / # of Anomalous
LB	CHEMISTRY	GLUC	mmol/L	16	0 / 2
LB	HEMATOLOGY	HGB	g/L	16	0 / 8
VS	VS	HR	BEATS/MIN	15	0 / 4
LB	CHEMISTRY	K	mmol/L	15	0 / 2
LB	CHEMISTRY	LDH	ukat/L	16	0 / 7
LB	HEMATOLOGY	LYM	10^9/L	16	0 / 6
LB	HEMATOLOGY	MCH	pg/cell	16	0 / 7
LB	HEMATOLOGY	MCHC	g/L	16	0 / 5
LB	HEMATOLOGY	MCV	fL	16	0 / 6
LB	HEMATOLOGY	MONO	10^9/L	16	0 / 3
LB	HEMATOLOGY	NEUT	10^9/L	16	0 / 4
LB	HEMATOLOGY	NEUTB	10^9/L	6	0 / 3
LB	HEMATOLOGY	PLAT	10^9/L	16	0 / 4

Anomalous Subjects for PLAT 4

☐	DM	MDR	Subject ID	# of Analyzed Measurements	Site ID
☐			CLINTEK-011-0001-002	8	080-0001
☐			CLINTEK-011-0405-008	5	080-0405
☐			CLINTEK-011-0703-008	6	080-0703
☐			CLINTEK-011-8808-008	13	080-8808

Central Subject vs Anomalous Subjects



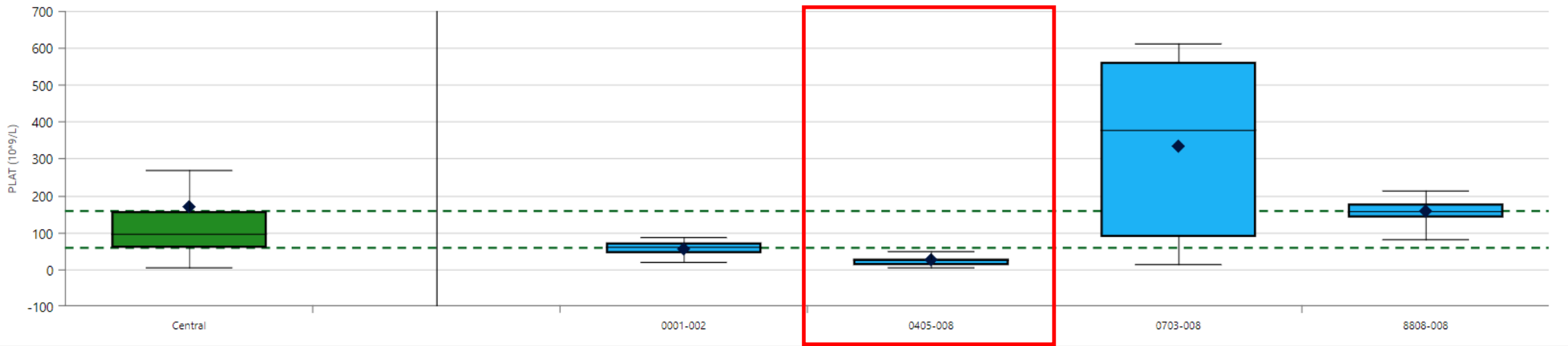
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LB	CHEMISTRY	LDH	ukat/L	16	0 / 7
LB	HEMATOLOGY	LYM	10^9/L	16	0 / 6
LB	HEMATOLOGY	MCH	pg/cell	16	0 / 7
LB	HEMATOLOGY	MCHC	g/L	16	0 / 5
LB	HEMATOLOGY	MCV	fL	16	0 / 6
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LB	HEMATOLOGY	NEUT	10^9/L	16	0 / 4
LB	HEMATOLOGY	NEUTB	10^9/L	6	0 / 3
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☐			CLINTEK-011-0703-008	6	080-0703
☐			CLINTEK-011-8808-008	13	080-8808

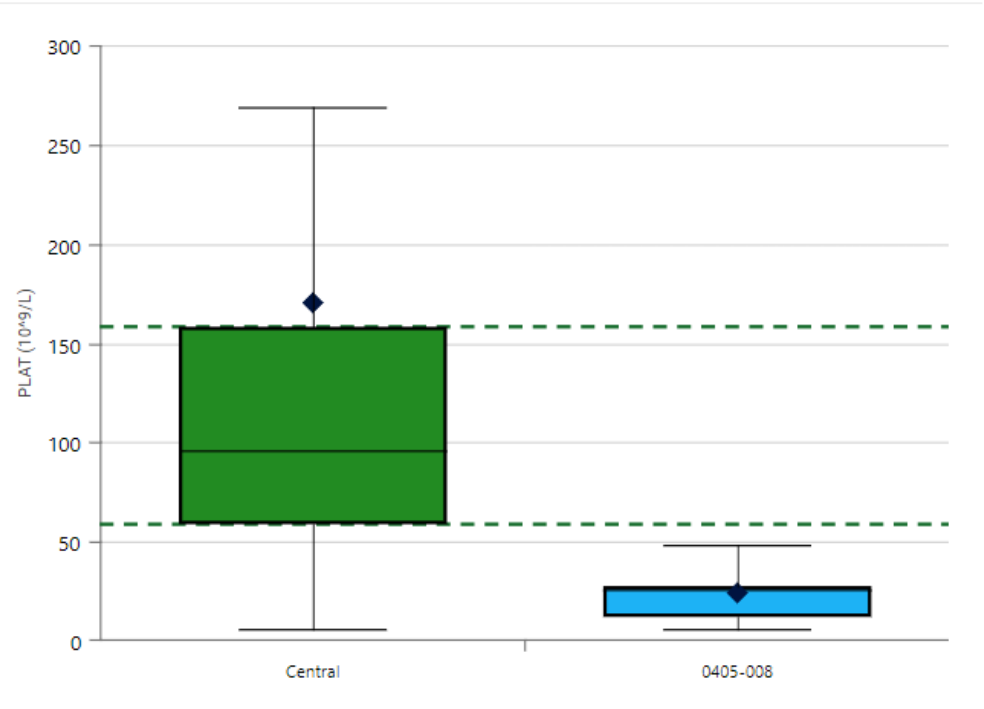
Central Subject vs Anomalous Subjects



Anomalous Subjects for PLAT 4

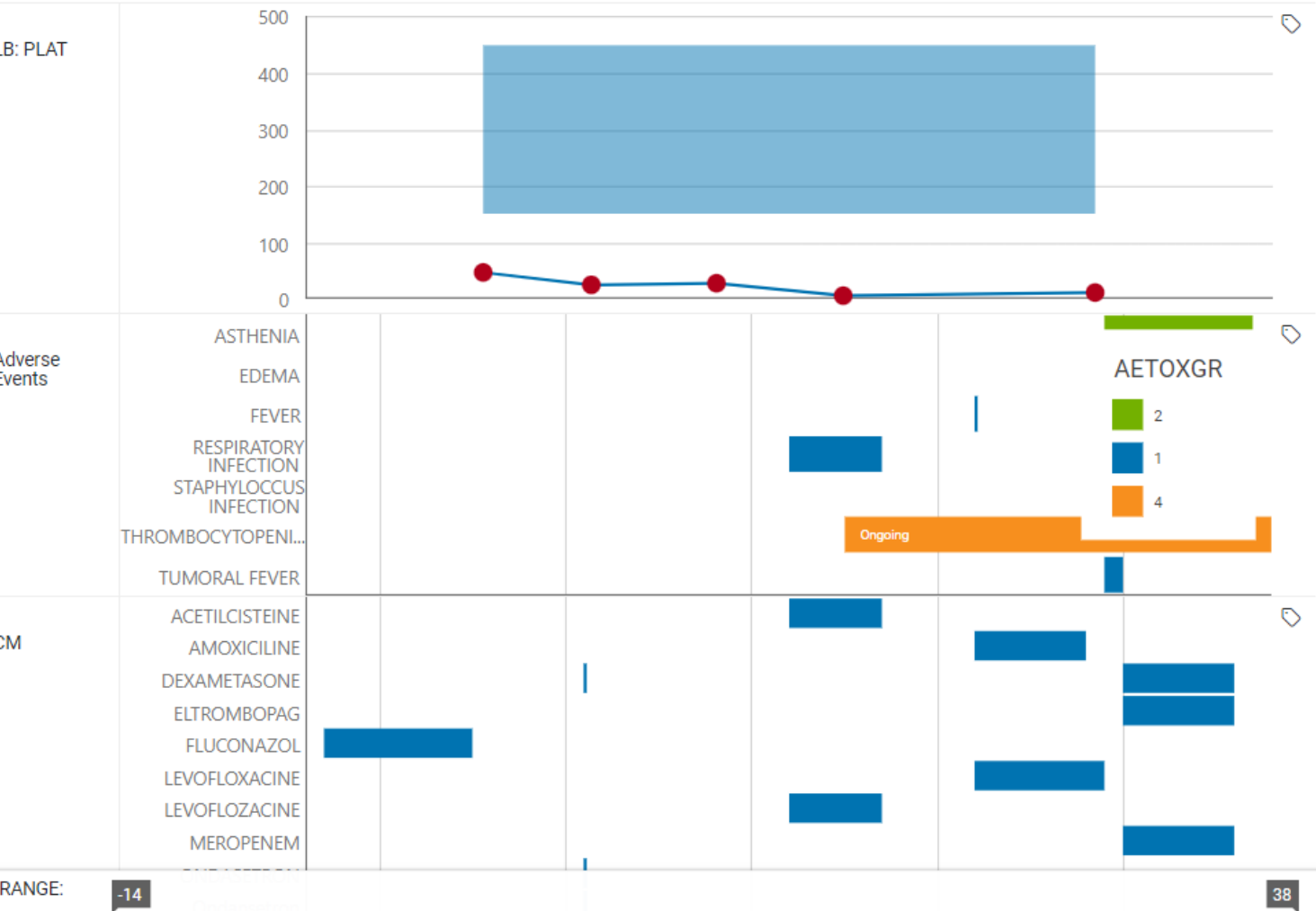
☐	DM	MDR	Subject ID	# of Analyzed Measurements	Site ID
☐			CLINTEK-011-0001-002	8	080-0001
☒			CLINTEK-011-0405-008	5	080-0405
☐			CLINTEK-011-0703-008	6	080-0703
☐			CLINTEK-011-8808-008	13	080-8808

Central Subject vs Anomalous Subjects



Graphical Patient Profile

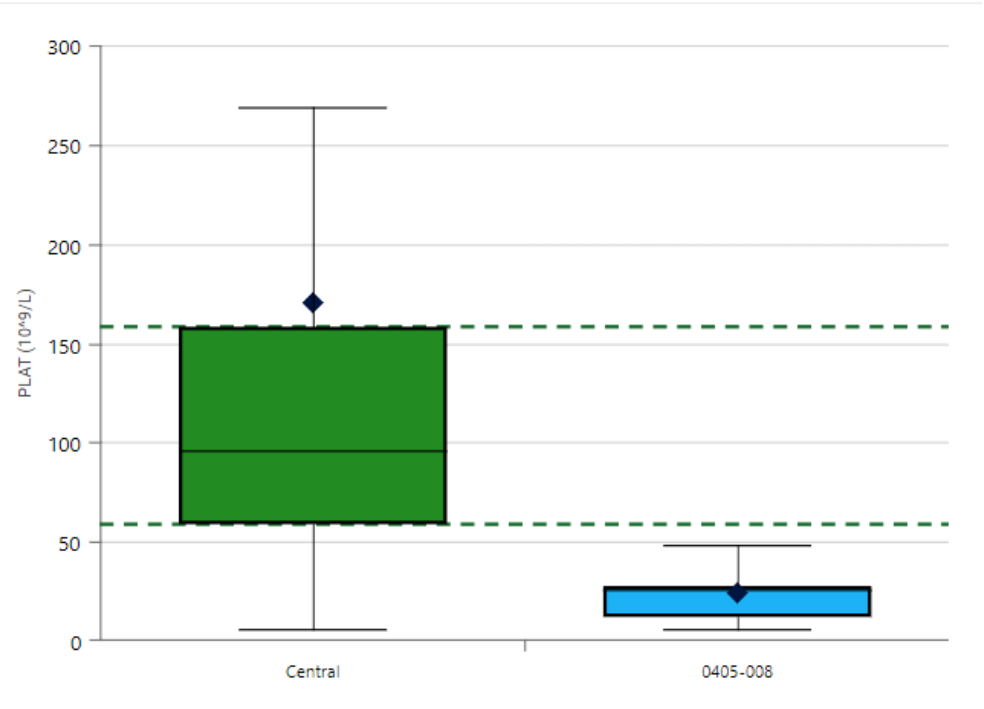
USUBJID	CLINTEK-011-0405-008
AGE	68
SEX	M
RACE	WHITE
ARM	COHORT 1



Anomalous Subjects for PLAT 4

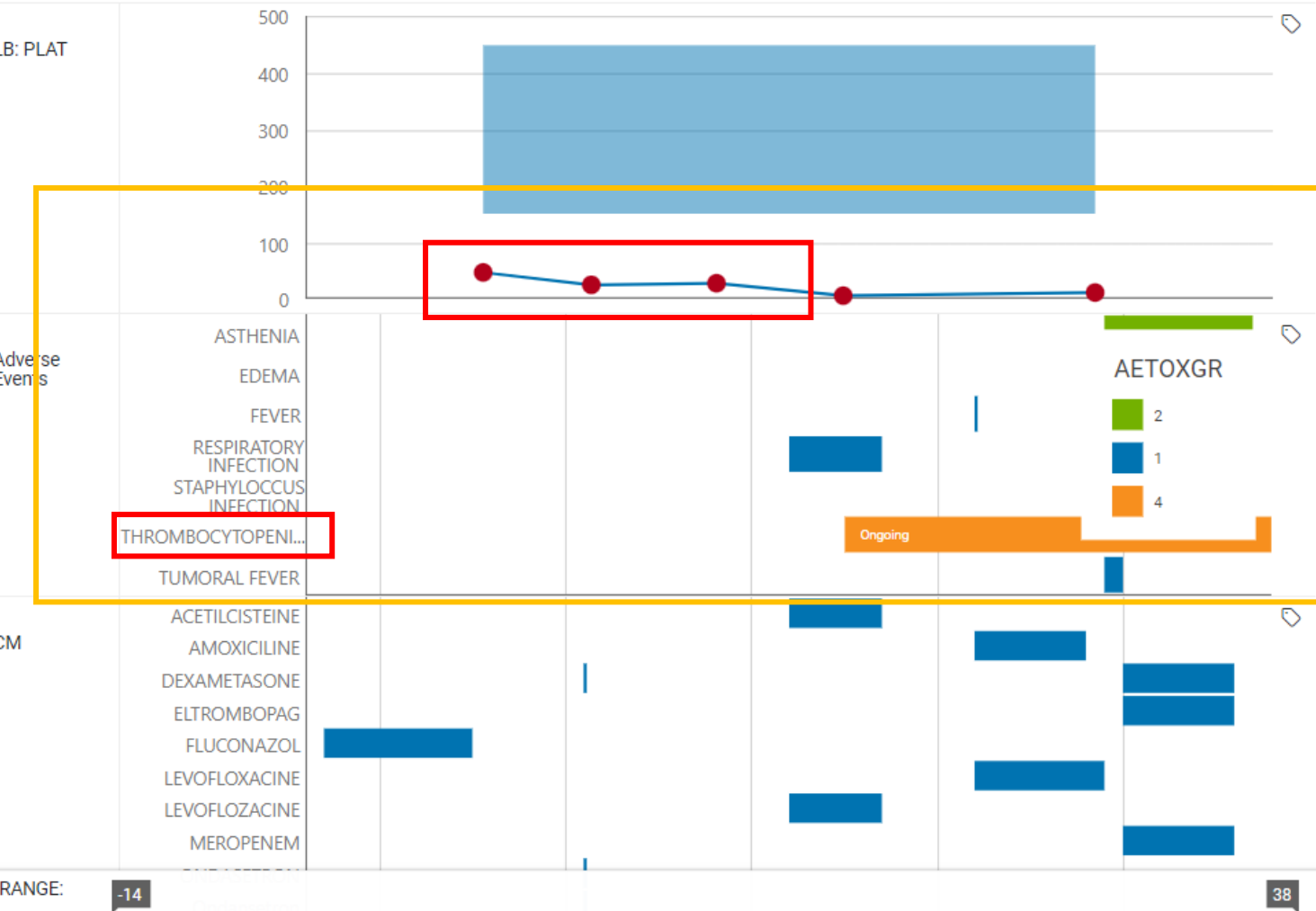
☐	DM	MDR	Subject ID	# of Analyzed Measurements	Site ID
☐			CLINTEK-011-0001-002	8	080-0001
☒			CLINTEK-011-0405-008	5	080-0405
☐			CLINTEK-011-0703-008	6	080-0703
☐			CLINTEK-011-8808-008	13	080-8808

Central Subject vs Anomalous Subjects



Graphical Patient Profile

USUBJID	CLINTEK-011-0405-008
AGE	68
SEX	M
RACE	WHITE
ARM	COHORT 1



Anomalous AE durations



Anomalous Subjects for Urinary tract infection 2

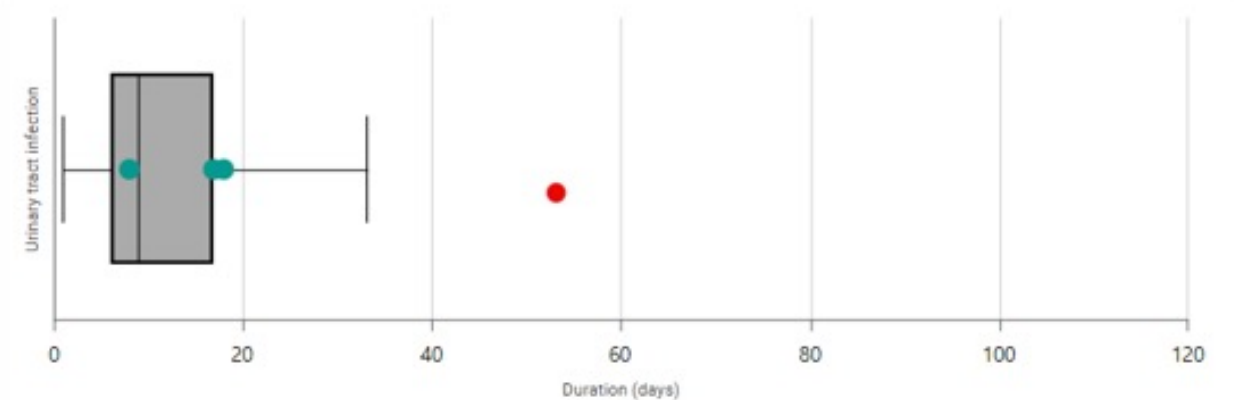
Review

☐	MDR	Subject ID	# of Events	# of Anomalous Events	Site ID
☒		CLINTEK-061-0789-808R	4	1	0789
☐		CLINTEK-061-8030-807R	1	1	8030

Medical History 29

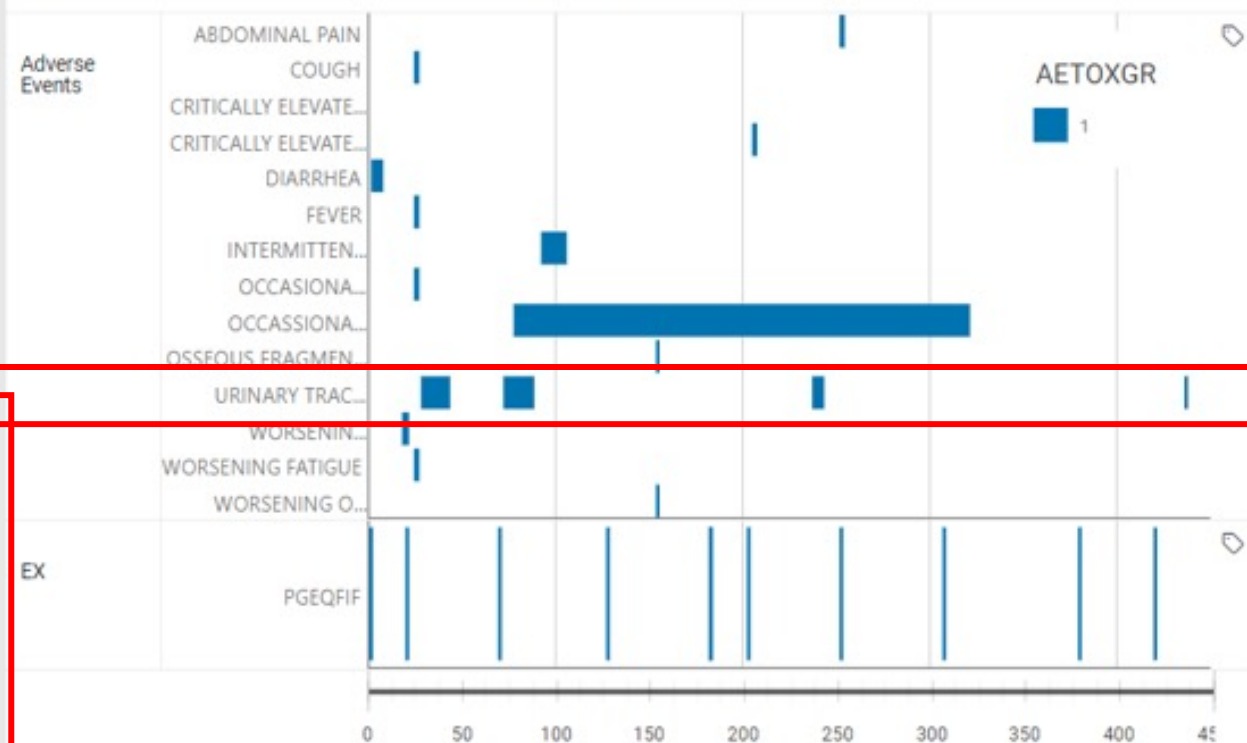
MHSEQ	MHTERM	MHDECOD	MHCAT	MHI
1	MYASTHENIA GRAVIS		MYASTHENIA GRAVIS MEDICAL ...	Y
2	RIGHT KNEE PAIN	Arthralgia	MEDICAL HISTORY	
3	LEFT BASILAR AIRSPACE DISEASE	Atelectasis	MEDICAL HISTORY	
4	ELEVATED GLUCOSE	Blood glucose increased	MEDICAL HISTORY	
5	BILATERAL CARPAL TUNNEL SY...	Carpal tunnel syndrome	MEDICAL HISTORY	

AE Durations



Graphical Patient Profile

USUBJID	CLINTEK-061-0789-808R
AGE	52
SEX	F
RACE	WHITE
ARM	COHORT 0



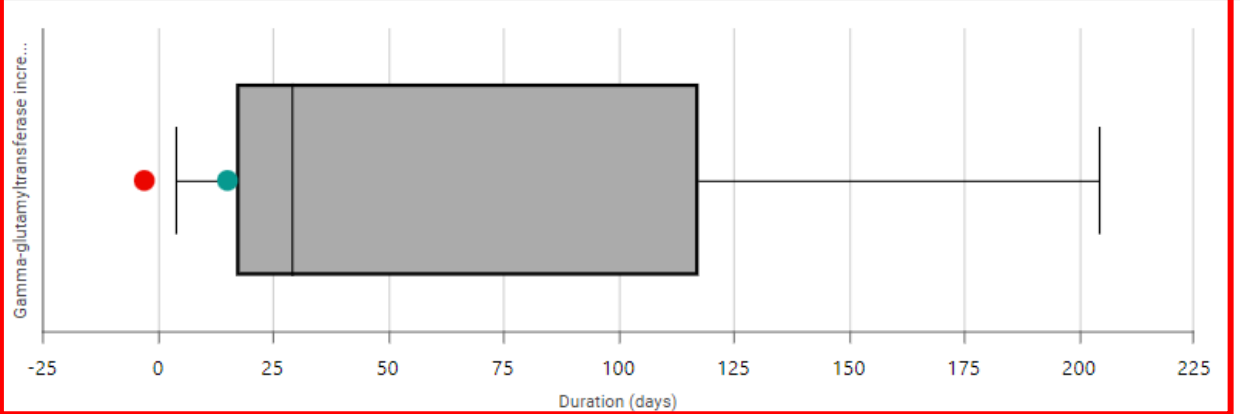
Anomalous Subjects for Gamma-glutamyltransferase increa: 1

☒	DM	MDR	Subject ID	# of Events	# of Anomalous Events	Site ID
☒			CLINTEK-011-0407-008	2	1	080-0407

Medical History 4

MHSEQ	MHSPID	MHTERM	MHLLT	MHLLTCD	MHDECOD	MHPTCD	MHHLT
1	MH-926631-2	ALLERGIC RHINITIS	Allergic rhinitis	10001723	Rhinitis allergic	10039085	Nasal congestic
2	DH-926634-0	CLL DIAGNOSIS					
3	MH-926631-1	MENINGITIS	Meningitis	10027199	Meningitis	10027199	Central nervous
4	DH-926634-0	RT DIAGNOSIS					

AE Durations



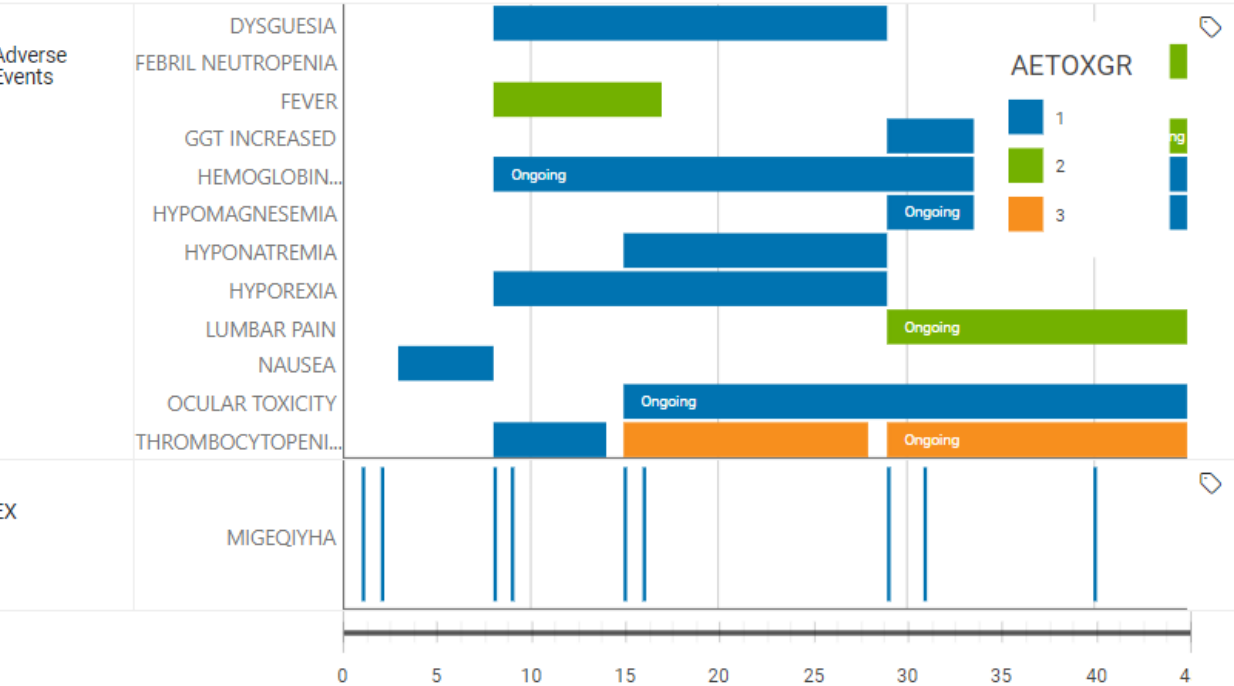
Summary of trained AEs for Gamma-glutamyltransferase increased

Not Anomalous

Anomalous

Graphical Patient Profile

USUBJID	CLINTEK-011-0407-008
AGE	41
SEX	F
RACE	WHITE
ARM	COHORT 1



Shift in labs and Vitals



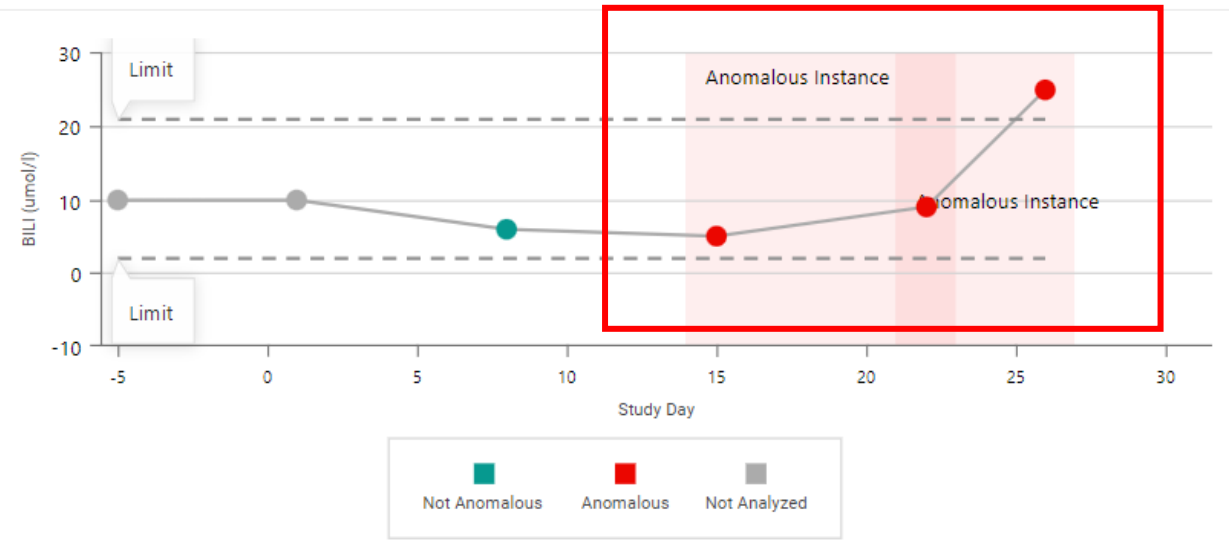
Anomalous Subjects for BILI 12

☐	DM	MDR	Subject ID	# of Analyzed Measurements	# of Anomalous Measurements	# of Anc
☐			CLINTEK-011-0007-007	4	4	3
☐			CLINTEK-011-0400-008	2	2	2
☒			CLINTEK-011-0703-008	4	3	2
☐			CLINTEK-011-0709-008	2	2	2
☐			CLINTEK-011-0001-002	7	2	1

Medical History 8

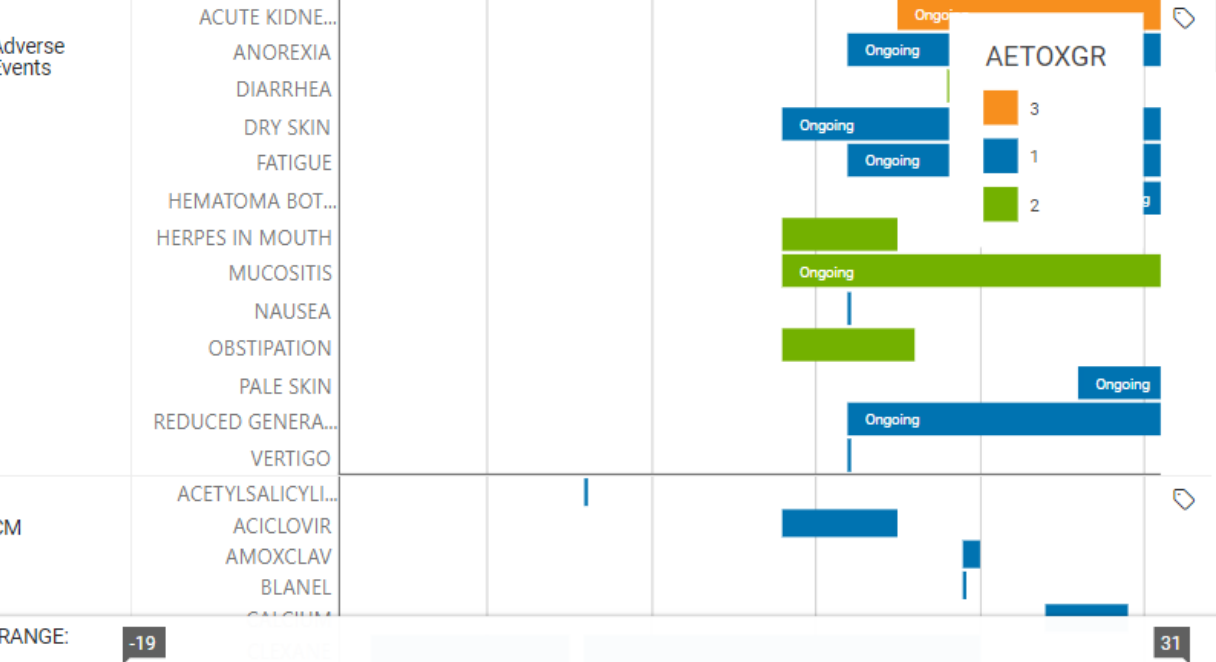
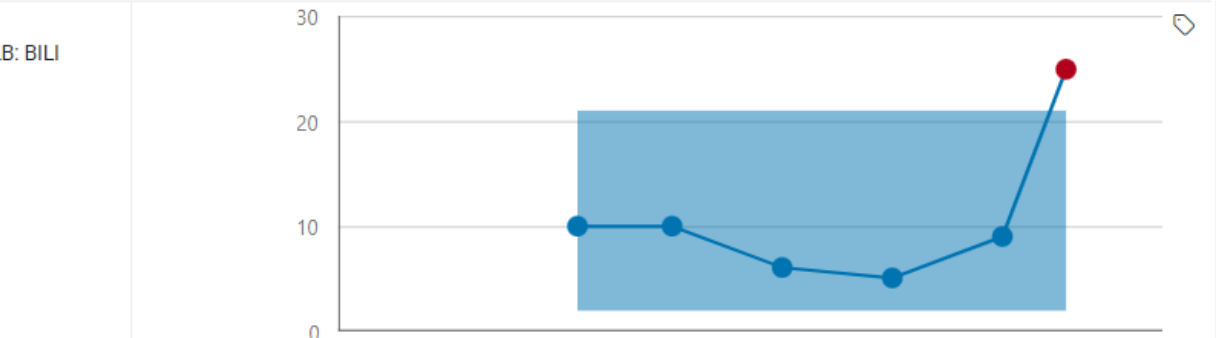
MHSEQ	MHSPID	MHTERM	MHLLT	MHLLTCD	MHDECOD
1	DH-802609-0	CLL DIAGNOSIS			
2	MH-802604-4	HYPERLIPOPROTEINAEMIA	Hyperlipoproteinaemia	10058221	Hyperlipidaemia
3	MH-802604-3	HYPERTENSION	Hypertension	10020772	Hypertension
4	MH-802604-2	HYPERURIKAEMIA	Hyperuricemia	10020907	Hyperuricaemia
5	MH-802604-5	LYMPHADENOPATHY	Lymphadenopathy	10025197	Lymphadenopathy

Measurements over time



Graphical Patient Profile

USUBJID	CLINTEK-011-0703-008
AGE	66
SEX	M
RACE	WHITE
ARM	COHORT 1



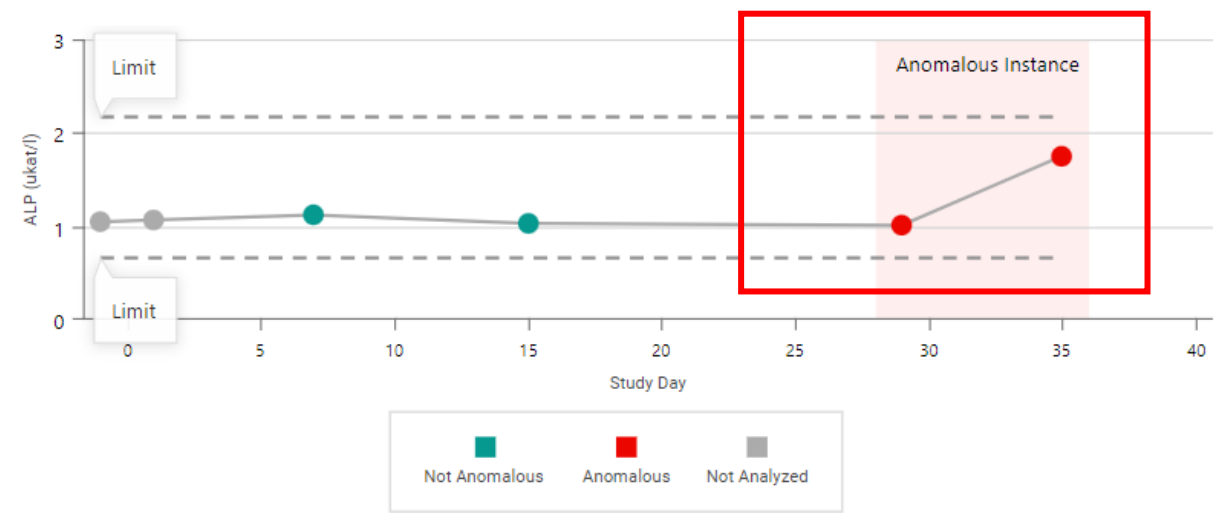
Anomalous Subjects for ALP 14

☒	DM	MDR	Subject ID	# of Analyzed Measurements	# of Anomalous Measurements	# of Anc
☐			CLINTEK-011-0703-008	4	4	4
☐			CLINTEK-011-0007-007	4	2	2
☐			CLINTEK-011-0400-008	2	2	2
☐			CLINTEK-011-0409-008	2	2	2
☐			CLINTEK-011-8808-008	7	4	2

Medical History 5

MHSEQ	MHSPID	MHTERM	MHLLT	MHLLTCD	MHDECOD	MHP
1	MH-1042705-3	CATARACT	Cataract	10007739	Cataract	1000
2	DH-1042702-0	CLL DIAGNOSIS				
3	MH-1042705-2	PERIPHERA POLYNEUROPATHY	Polyneuropathy	10036105	Polyneuropathy	1003
4	MH-1042705-1	PSEUDOPHAKIE	Pseudophakia	10048867	Intraocular lens implant	1006
5	DH-1042702-0	RT DIAGNOSIS				

Measurements over time



Graphical Patient Profile

USUBJIDCLINTEK-011-0703-009

AGE63

SEXM

RACEWHITE

ARMCOHORT 1

LB: ALP

Adverse Events

CONSTRAINED MOVEMENT

Ongoing

HAEMATOMA

NAUSEA

RESPIRATORY INSUFFICIENCY

CM

ACICLOVIR

CIPROFLOXACIN

CLEXANE

COTRIM FORTE

DIPIDOLOR

EUGALAC

FUROSEMID

LYRICA

METOCLOPRAMID

MOVICOL

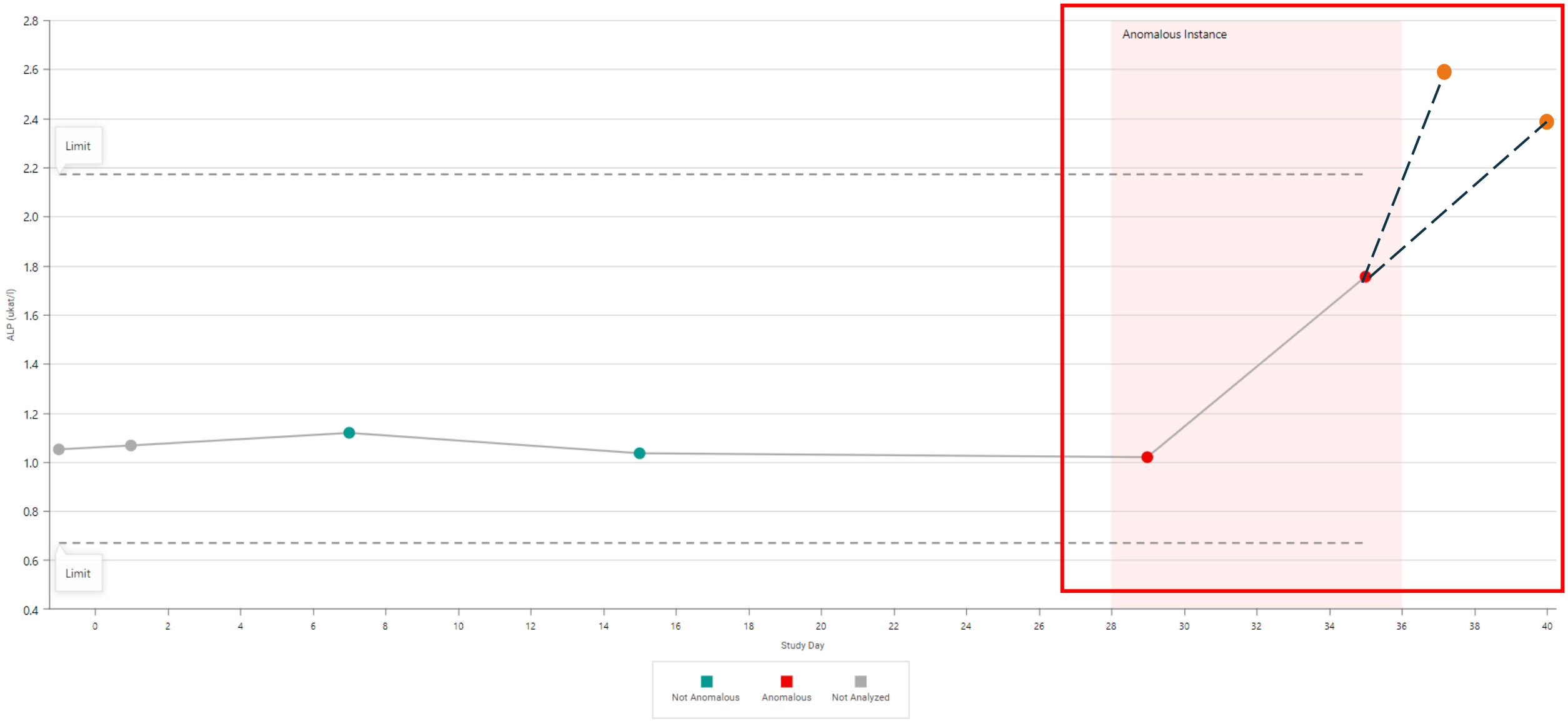
NACL 0.9%

NOVAIGI

RANGE:

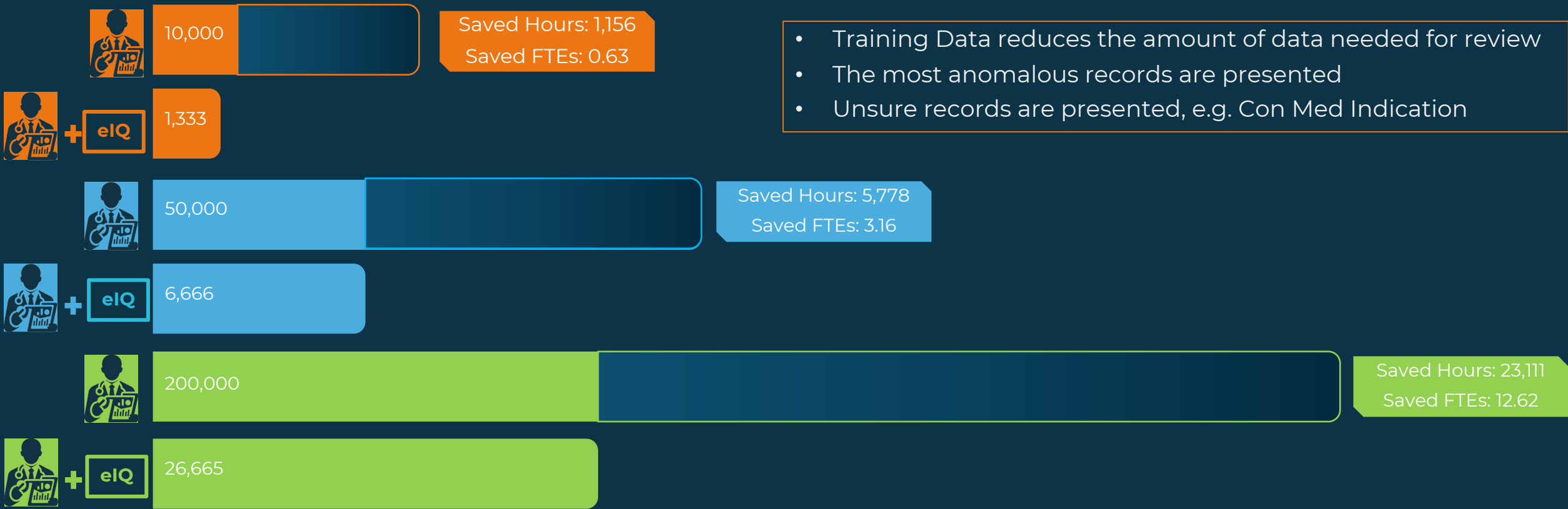
-4

Measurements over time



Traditional vs AI-Enhanced Data Review: Savings

AI-enhanced data review reduces the number of records requiring review by 87%.



*est. 8min/record

Questions/ Get in Touch

Diane Lacroix
VP, Clinical Data Management
eClinical Solutions
dlacroix@eclinicalsol.com



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