CTDataHub: An Application that Extracts and Consolidates Adverse Events (AE), Concomitant Medication (ConMed), and Laboratory Results Data from Clinical Systems to Increase Clinical Trial Data Entry Efficiency, Trust, and Satisfaction

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Background

Clinical Research Coordinators (CRC) play a critical role in the completion of clinical trials, conducting extensive data work to support the clinical research team. The manual abstraction of data for clinical trials from a site's various clinical systems to biopharmaceutical firm's electronic data capture (EDC) systems is labor intense, open to errors and inefficient, and can risk delaying the completion of a trial. The volume of data collected in oncology trials has an average number of 10,000 data points entered per patient.

Archetype

Using human-centered design thinking methodology in partnership with CRCs at MSK, we created a web application, CTDataHub, to reduce the time and effort associated with this process for clinical research coordinators (CRCs). CTDataHub extracts and consolidates AEs and conmed data from clinical systems and displays it in a user-friendly view for easy entry into EDCs. CTDataHub was launched and rolled-out to CRCs to 313 CRCs between July - December 2023.

Archetype

Key Characteristics
- In charge of abstracting patient data from MSK tools to input into several sponsor EDCs
- Works on 4 - 8 protocols simultaneously
- Interacts with CRAs/RPAs, CTNs, PIs, Sponsor Monitors and Auditors
- Usually works with double screen and self-organizes her workflow and follow up the data-entry process.

Goals
- Enter patient data in an accurate and timely manner
- Solve queries as quick as possible
- Effectively communicate with other professionals to gather the information that is missing

Needs
- Normalized patient information (right after visit)
- 100% populated fields in both HIS and EMR
- Clear query instructions
- Time-saving hacks or shortcuts for recurrent data entry fields
- Quick, effective communication channels

Time Allocation (Weekly)
- Data entry 50.0%
- Query resolution 30.0%
- Communication 20.0%

Tools
- EMR / HIS
- CIS
- CARS
- Teams:
  - Shared Drive
  - Email
  - Calendar

Sponsor EDC&CTMS: Medidata, Datalabs EDC, REDCap, viedoc, ORACLE Health Sciences, Pfizer, ICON, Google

Clinical Research Coordinator
The Data Detective

"Data entry often feels like a clinical decision."

Experience level
1.5 years

Data Abstraction Experience

Stages	Prepare Data entry	Check CRF requirements	Search for data	Insert data in CRF	Resolve doubts
Doing	Check data/cycle to be input. Access to EDC and MSK tools. Organize two windows on the screen(s). Identify patient in all platforms	Choose easiest / quickest CRF to fill out first. Understands data elements required to abstract	Look through MSK tools. Leaf through emails and docs on Shared Drive. Identify the data element [OR] Contact CTN / PI if data is missing	Manually type in values and texts. Select correct unit of measurement for each data element	Answer queries. Reply to questions about the data entered. Check with Clinic team
			Research Team		Research Team
Thinking	A patient has visited the clinic recently. I will inform the sponsor about his progress.	How can I progress most fastest?	Will I find all the data asked for?	This is quick and easy.	I provide clarifications the best and fastest I can.
Feeling	Clear / Unclear (line chart)				
Experience	Preparation is easy and clear, CRCs organize themselves to have an overview of their tasks.	Creating a workflow of doing easy things first and leaving time-consuming for the end.	Frustrations and annoyance occur if data is not clearly stated or has to be leafed for.	Once identified the data element, entering it is quick and easy.	Some queries are easy to reply, those who require trial team feedback last longer.

Methods

To evaluate CTDataHub's impact on CRCs, we assessed: 1) CTDataHub usage, 2) data entry efficiency, 3) trust in data (data is correct to enter in sponsor EDC) assessed via a 5-point Likert attitudinal trust scale, and 4) satisfaction using Net Promoter Score (NPS) by comparing two surveys. Survey 1 (S1) was sent to 313 CRCs prior to receiving access to CTDataHub to establish a baseline of current clinical systems such as CIS, EMR, CTMS. Survey 2 (S2) was administered to 59 meaningful users of CTDataHub; those who used and viewed a patient data page at least 10 times between 09/01/23-10/31/23. S1 had a 72% response rate (n=225), and S2 had a 51% response rate (n=30); with all respondents of S2 completing S1. Behavioral usage on CTDataHub was tracked using Heap Analytics.
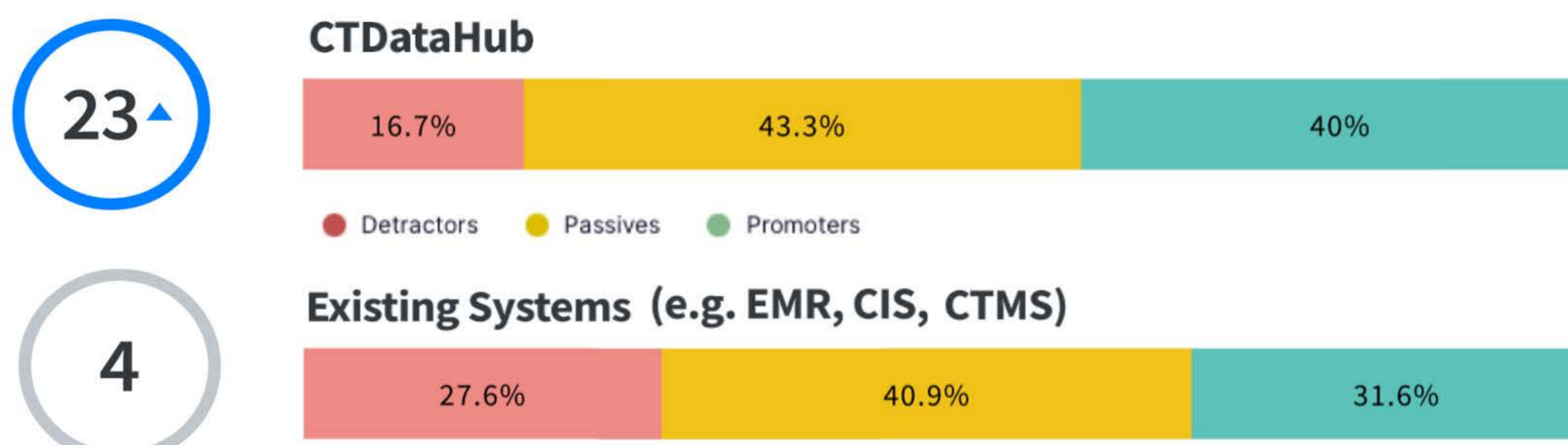
Results

🕐 Efficiency: CTDataHub is saving CRCs time on data entry.

Respondents reported an average decrease in time spent of 18% (2h/week). 70% of meaningful users reported that using CTDataHub decreased the time they spend on data related activities, 20% noted no impact, and 10% reported increased time. The decrease in time was greater with CRCs that had less than 12 months of experience in their role.
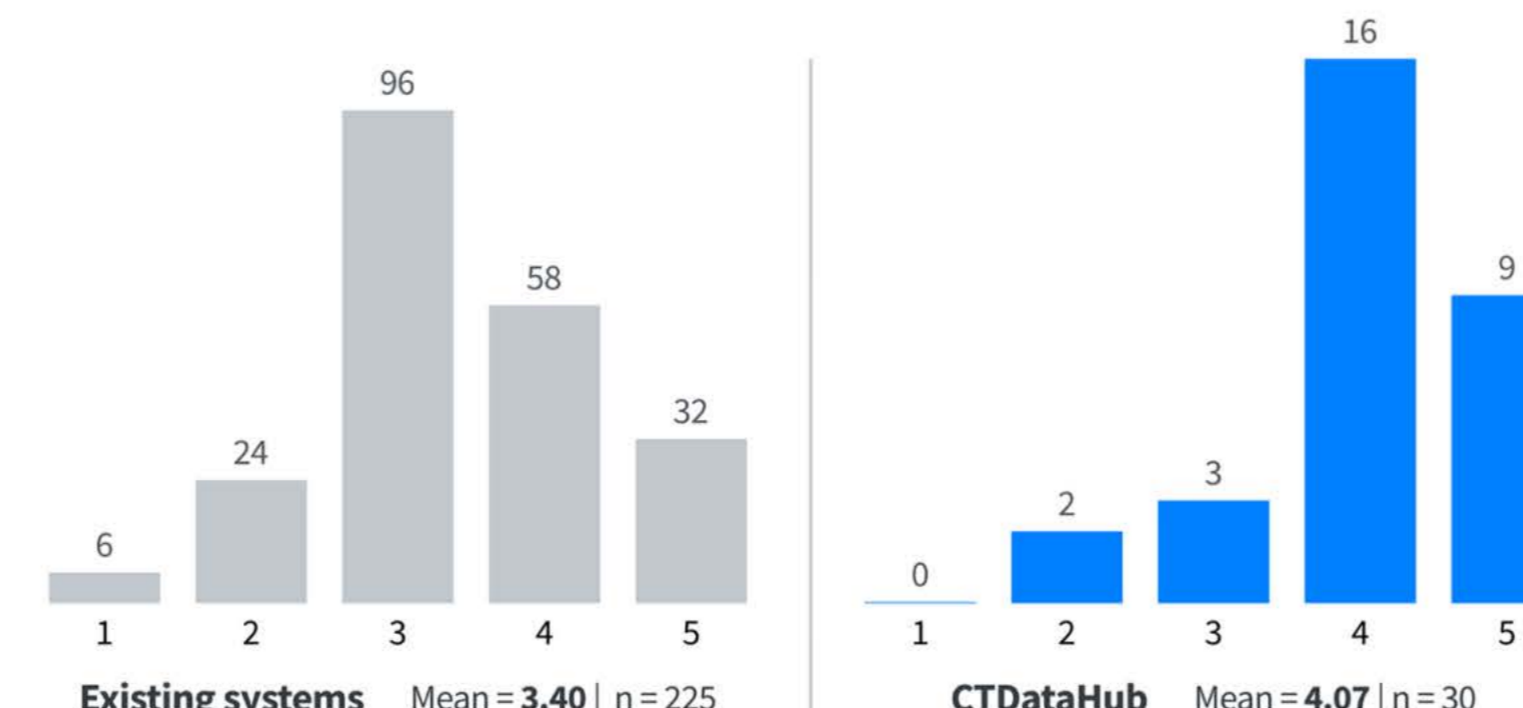
Total time spent on data entry using existing systems — **10 hrs/week**

Time decreased since using CTDataHub — **20%↓**

🖤 Satisfaction: CTDataHub scored higher than other clinical systems.

CTDataHub has proved to be an easier, more satisfying data entry experience relative to previous methods. The NPS for CTDataHub versus other clinical systems (on average 2.5 systems) was 23 compared to 4.
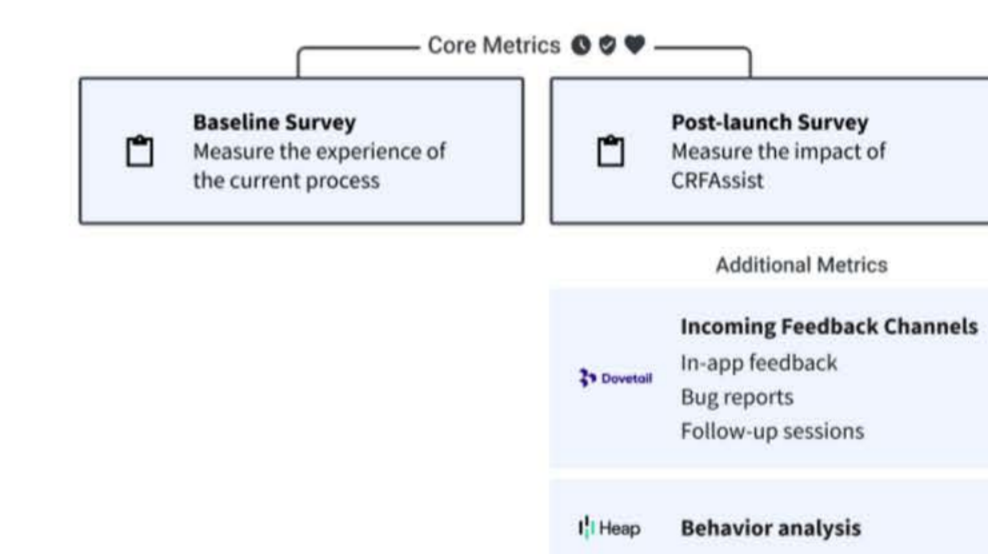
CTDataHub — 23
| Detractors 16.7% | Passives 43.3% | Promoters 40% |

Existing Systems (e.g. EMR, CIS, CTMS) — 4
| 27.6% | 40.9% | 31.6% |

● Detractors ● Passives ● Promoters

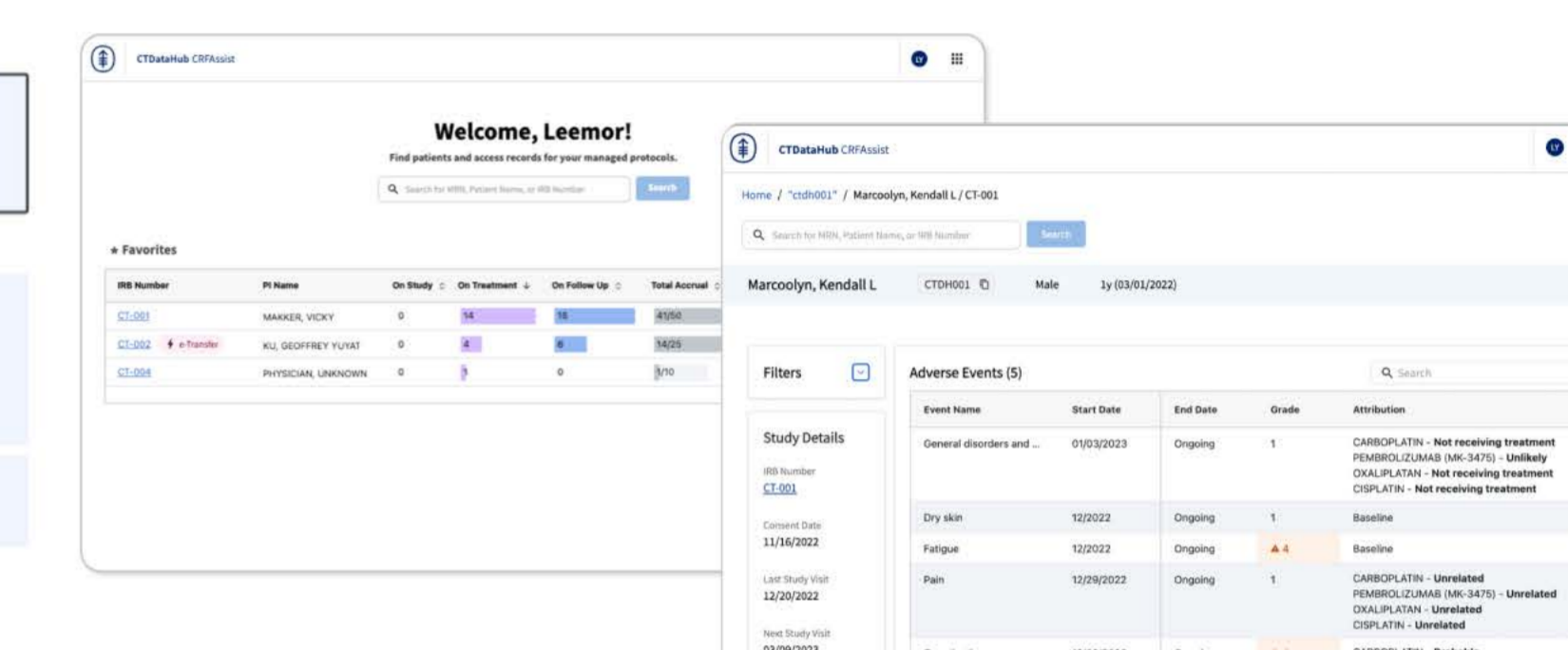### 🛡 Trust: CTDataHub scored higher than other clinical systems.

CRCs responded that CTDataHub was more likely to correctly retrieve ConMed and AE data when compared to other clinical systems. One possible reason is that CTDataHub provides a holistic and transparent view of what data is available and what data is missing. This enables CRCs to uncover potential issues with the data quality more quickly.

Existing systems — Mean = 3.40 | n = 225
(1: 6, 2: 24, 3: 96, 4: 58, 5: 32)

CTDataHub — Mean = 4.07 | n = 30
(1: 0, 2: 2, 3: 3, 4: 16, 5: 9)

Measuring Impact

Core Metrics
- Baseline Survey — Measure the experience of the current process
- Post-launch Survey — Measure the impact of CRFAssist

Additional Metrics
- Incoming Feedback Channels: In-app feedback, Bug reports, Follow-up sessions
- Behavior analysis

CTDataHub

CRC Quotes

"Nobody gives us attention as much. We have to work with what the clinicians and nursing do, so **it's nice to be getting attention** on how to make our lives easier so I appreciate that."

"CTDataHub definitely **helps to consolidate** a lot of the information very well! Makes it easier to retrieve medications off **of first glance.**"

"I have previously worked as a CCI in Rad Onc for 2.5 years so I was familiar with where to access this information but **having it all in one spot that is easy to use** is a great improvement. I love the copy and paste feature and the ability to search for a specific conmed or AE."

Conclusion

Our preliminary data shows that CTDataHub has decreased data abstraction and entry time for AEs and ConMeds for 70% of meaningful users by an average of 2h/week relative to other clinical systems. CTDataHub increased trust in data being abstracted, and user satisfaction increased. As meaningful usage increases, we will continue to compare how CTDataHub use versus traditional workflows impact CRC efficiency, trust in data, user satisfaction, and accuracy. CTDataHub will be enhanced with additional data sets (site local labs, vitals, tumor response) and automated EHR2EDC capabilities in 2024.

Existing Systems
- Is this data in system 1?
- Is this data in system 2?
- Why is the data different in 1 and 2?
- Why is this data missing? I need to contact the CTN...

CTDataHub
A one-stop hub for clinical data