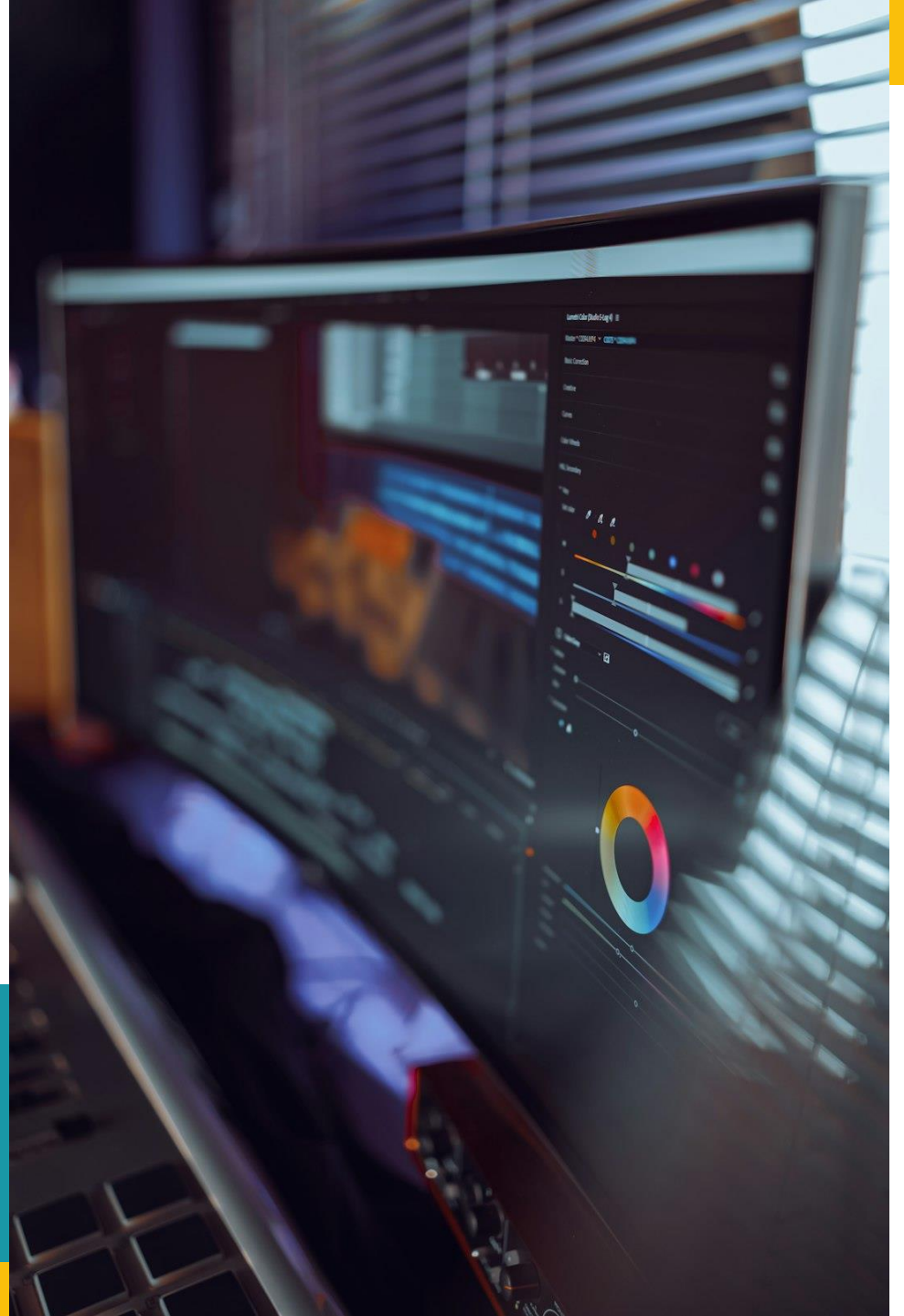
PACT
Partnership for Advancing Clinical Trials

Results from the PACT Consortium Year One Data on DCT Usage and Experience

Summary Report

September 2024



About the PACT Consortium

Launched summer 2023 with funding from Reagan-Udall Foundation and Medable

Hosted at, and facilitated by, Tufts CSDD (Tufts University School of Medicine)

30 Member Companies (sponsors and CROs)

Primary Objectives

- Establish consensus definitions and metrics for benchmarking DCT use and impact
- Gather hard data (dependent and independent variables) on actual DCT use cases
- Develop evidence-based insights to inform DCT deployment strategies and optimization

Year One Timeline

- October 2023: Establish governance, positioning, establish consensus definitions and metrics
- November-April 2024: Data warm-up/Data Collection
- May 2024: Analysis and reporting
- June-July 2024: Data cleaning, confirmation, and additional data collection

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Participating Organizations

Executive Summary

- Less than 20% of the trials in the Year One dataset have reached Database Lock or Primary Completion; roughly half of clinical trials in the dataset have planned end dates in 2024 or 2025

- Study visits are the most common activity supported by DCT solutions. eCOA are the most commonly deployed DCT Solution (80% of trials); portals, apps for data collection, apps for reminders, and home visits were each used in about half of clinical trials in the Year One dataset

- The effect of DCT solutions use is not uniform and cannot yet be generalized. Many outcomes analyzed are not showing a significant improvement or detriment compared to industry benchmarks

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Executive Summary *(continued)*

- Although in most cases the impact of DCT solutions compared to industry benchmarks do not show significant differences, for clinical trials that have deployed DCT solutions, actual cycle times are typically beating plan timelines

- Clinical trials with DCT solutions have a lower proportion of white participants and a higher proportion of Asian participants. Other racial demographics such as American Indian or Alaska Native, Native Hawaiian or Pacific Islander, Black or African American, and multiracial identities, as well as participants of Hispanic or Latino ethnicity, show modest increases compared to the benchmark

Tufts Center for the Study of Drug Development
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The Dataset Reflects Mostly Diverse TA, Phase III Trials

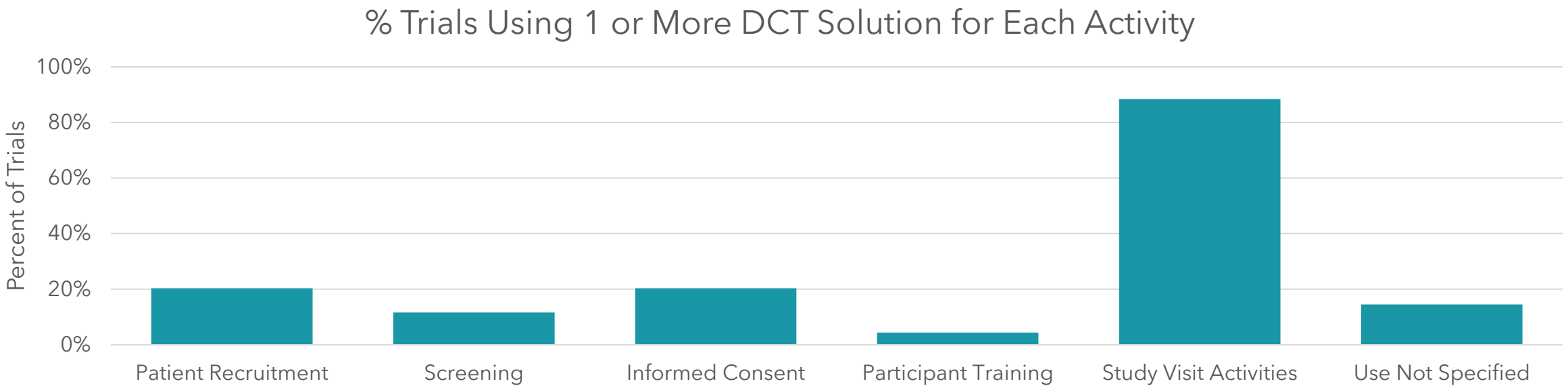
Characteristic	n	Percent
Phase		
Phase I	3	4.4%
Phase II	15	21.7%
Phase III	46	66.7%
Phase IV	5	7.3%

Characteristic	n	Percent
Therapeutic Area		
Anti-Infective	8	11.6%
Cardiovascular	2	2.9%
Central Nervous System	14	20.3%
Endocrine	4	5.8%
Gastrointestinal	4	5.8%
Immunologic	13	18.8%
Oncology	8	11.6%
Respiratory	2	2.9%
Other	14	20.3%

Source: Tufts CSDD | PACT Consortium 2024; *n* = 69

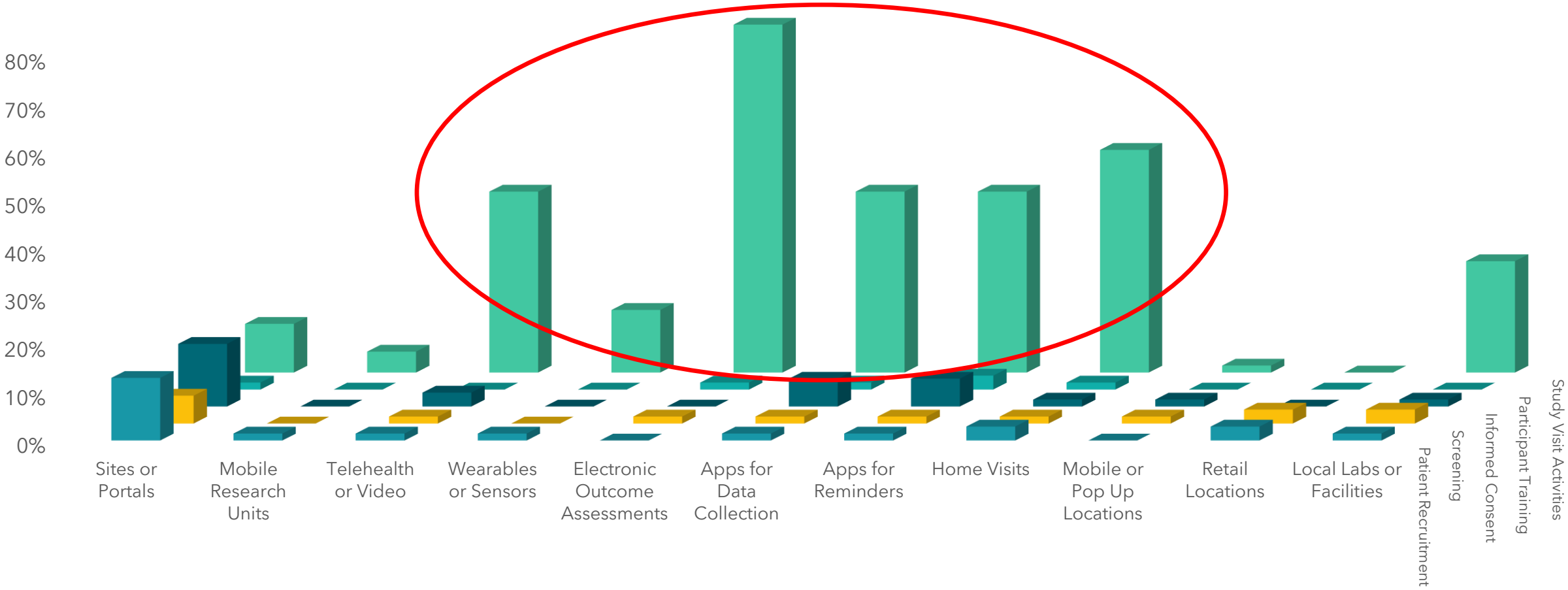
How Much Can be Conducted Remotely?

	n	Mean (CoV)	Median	Range
Total Number of DCT Solutions Used	68	3.8 (0.48)	4	1 – 9
Percent of **Procedures** that Could be Performed Remotely	39	35.6% (0.84)	20.0%	0.0% – 100.0%
Percent of **Study Visits** that Could be Conducted Remotely	47	41.0% (0.78)	33.3%	0.0% – 100.0%



Source: Tufts CSDD | PACT Consortium 2024; *n* = 69

How DCT Solutions Are Being Used



Source: Tufts CSDD | PACT Consortium 2024; *n* = 69

Actual Cycle Times for Trials with DCT Solutions Typically Beat Plan

Planned to Actual (days)	n	Mean (CoV)	Median	Interpretation
Protocol Approval to Approval by Oversight Body	20	10.7 (2.40)	0	Planned < **Actual**
Protocol Approval to FPFV	54	-11.4 (11.58)	0	**Planned** > Actual
Approval by Oversight Body to FPFV	22	0.4 (116.63)	0	Planned < **Actual**
FPFV to LPFV	29	-22.3 (8.94)	0	**Planned** > Actual
LPFV to LPLV	8	-171.1 (1.95)	-5.5	**Planned** > Actual
LPLV to DBL	7	4.7 (9.06)	0	Planned < **Actual**
DBL to CSR	6	-7.2 (3.60)	-4	**Planned** > Actual
Protocol Approval to DBL	7	-102.7 (3.22)	0	**Planned** > Actual
First Site Activated to Last Site Activated	12	-2.3 (127.59)	-5.0	**Planned** > Actual
First Site Activated to FPFV	38	2.3 (16.84)	0	Planned > **Actual**

Source: Tufts CSDD | PACT Consortium 2024; *n* = 69

DCT Solution Trials have a Lower Proportion of White Participants & Higher Proportion of Asian Participants Compared to the Benchmark

	PACT Sample			Benchmark*		
Demographic	**n**	**Mean Percent (CoV)**	**Median**	**n**	**Mean Percent (CoV)**	**Median**
Gender						
Male	44	44.3% (0.57)	41.5%	32	51.0% (0.41)	51.2%
Female	44	55.7% (0.45)	58.5%	32	49.0% (0.43)	48.8%
Race						
American Indian or Alaska Native	27	1.9% (1.74)	0.5%	19	0.5% (2.37)	0.0%
Asian	39	20.9% (1.01)	12.9%	31	14.2% (1.72)	5.6%
Native Hawaiian or Pacific Islander	18	0.3% (1.21)	0.2%	20	0.1% (2.16)	0.0%
Black or African American	37	7.3% (2.19)	3.1%	27	7.0% (1.13)	2.9%
White	39	72.6% (0.27)	78.6%	31	81.3% (0.23)	83.6%
More than one race	19	1.5% (1.97)	0.2%	17	0.7% (1.76)	0.0%
Ethnicity						
Hispanic/Latino	31	14.9% (0.96)	10.0%	26	12.6% (1.02)	9.9%

**Benchmark drawn from 2023 Tufts CSDD Study, includes only trials that indicated no DCT use*

Source: Tufts CSDD | PACT Consortium 2024; *n* = 69

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Thank you

To renew your PACT Consortium membership or for inquiries about joining, please contact Joan Chambers at joan.chambers@tufts.edu. New organizations are welcome to join.