Tufts CSDD - Teckro 2020 Study

Investigative Site Protocol Administration Referencing Practices

Study Highlights

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Executive Summary

- **89% of sites are very confident that they are referring to the most up-to-date version of the protocol at any given time.**

- **Two-thirds of protocol sections are accessed frequently by investigative site personnel and the majority of sections are found to be very helpful.**

- **A hard copy of the protocol is the most common reference format followed by communication directly with study monitors and study teams.**

- **Although most sites have used tablets and smartphones during trials, these devices are rarely used to reference the protocol for answers and are considered the least helpful of the resources offered.**

Methodology

- **AIMS: to assess investigative site practices and experience referring to protocol administration instructions**

- **A global online survey was distributed to principal investigators, study coordinators and site administrators between April 28-June 5 (5.5 weeks)**

- **N= 228 valid responses**
  - Respondents were directly involved in the conduct of clinical trials at their site
  - Respondents conducted at least one clinical trial annually
  - The majority of respondents (61%) were study coordinators

Demographics

- **Investigative Site Setting:**
  - Academic and Community Health Centers - 46.4%
  - Individual Community-Based Sites - 41.2%
  - Investigative Site Networks - 6.2%

- **Top Therapeutic Areas of Focus:**
  - Cardiovascular- 39.6%
  - Endocrine and Metabolic- 31.9%
  - Medical Devices- 29.0%

- **Annual Trials Volume**
  - 62.4 trials on average, the majority (71%) in phases II and III

DETAILED STUDY FINDINGS

Protocol Sections- Frequency of Reference and Usefulness

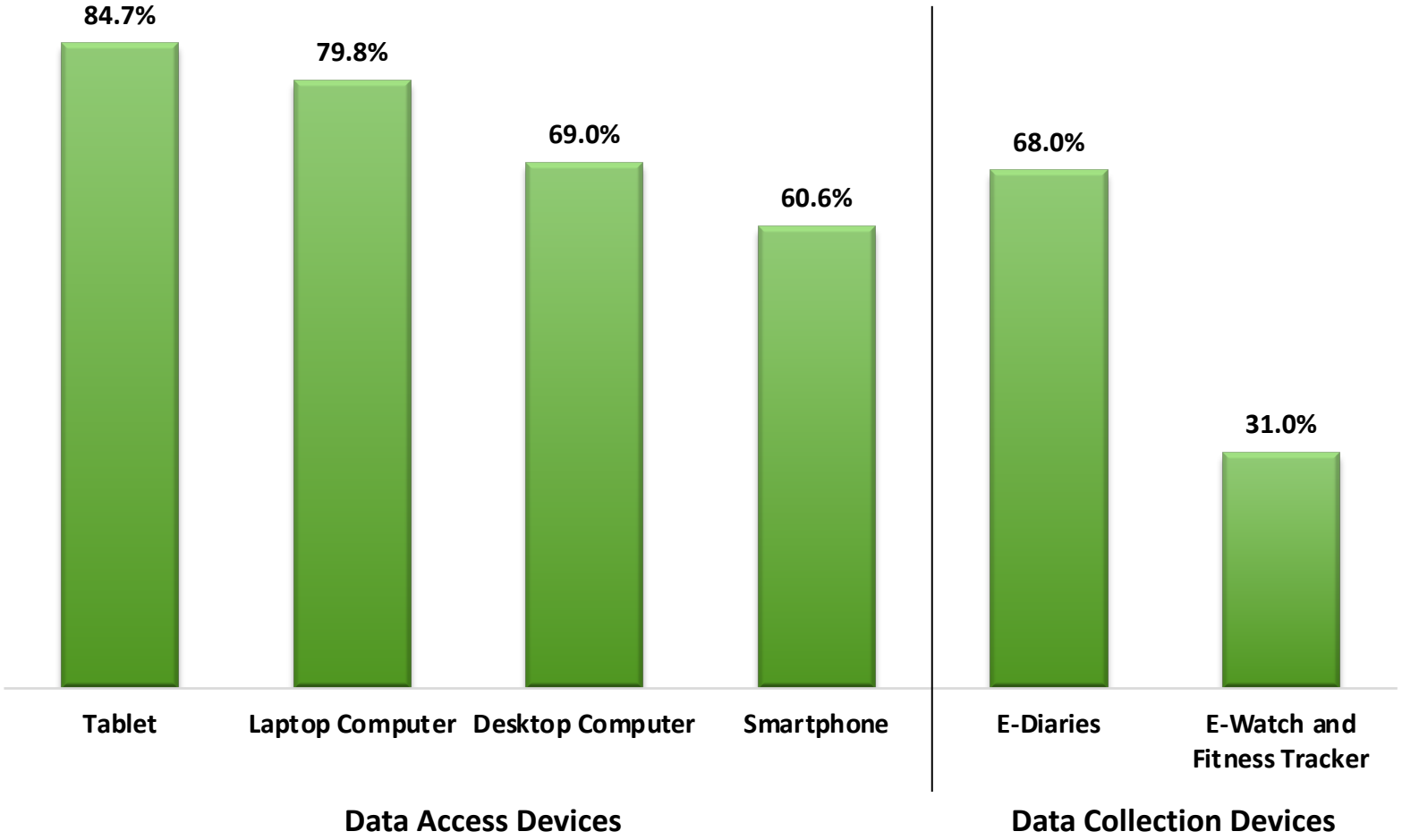
	Percent Accessed Somewhat or Very Often	Percent Rated Very Helpful
Schedule of Events/Assessments	99.0%	93.1%
Inclusion/Exclusion Criteria	97.4%	96.8%
Screening/Randomization Procedures	94.7%	81.2%
Prohibited/Concomitant Medications	93.1%	72.6%
Specific Procedures	91.7%	66.1%
Study Drug Administration	90.5%	75.4%
Reporting or Management of Adverse Events	75.0%	47.6%
Data Reporting Requirements	60.9%	41.1%
Management of Toxicity	58.2%	42.8%

Protocol Sections- Frequency of Reference and Usefulness

- Of the nine distinct protocol sections rated, six were accessed 'somewhat often' or 'very often' by more than 90% of respondents. Five of these six areas were rated as very helpful by at least two-thirds of sites.

- Sections detailing reporting requirements for adverse events, data reporting requirements, and management of toxicity are the least accessed areas and are also rated the least useful.

Site Use of Electronic Devices During Clinical Trials



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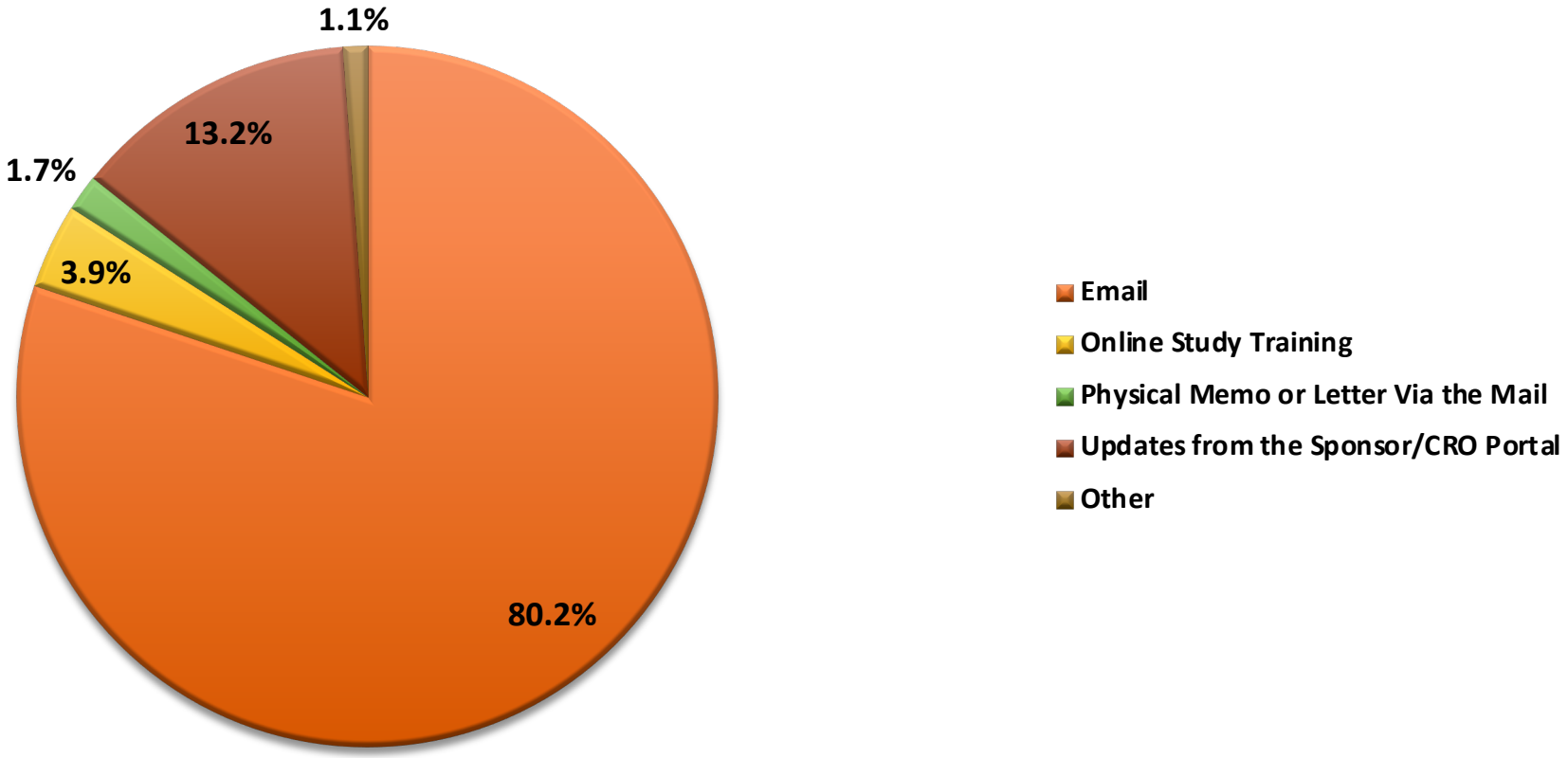
Site Use of Electronic Devices During Clinical Trials

- **A high percentage of sites report using tablets, laptops, desktops and smartphones during clinical trials in the past two years.**

- **E-Diaries are more commonly used to collect patient data than are e-watches and fitness trackers.**

Communicating Protocol Amendments



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Communicating Protocol Amendments

- **Respondents report that email is by far the most popular method for sponsors and CROs use to communicate protocol amendments to the site.**

- **Amendment communication via website or a study portal is far less common.**

Formats for Accessing Protocol Instructions

Resource Group	Resource	Percent Accessed Somewhat or Very Often
Paper-based formats	Hard Copy of the Protocol	87.4%
	Quick Reference Cards	64.6%
Online/Digital formats	Online Version of the Protocol (Desktop)	79.1%
	Online Version of the Protocol (Laptop)	63.3%
	Frequently Asked Questions on Portal	39.6%
	Online Version of the Protocol (Tablet)	12.7%
	Online Version of the Protocol (Smartphone)	8.4%
Verbal formats	The CRA/Study Monitor	79.5%
	The Study Team	75.3%
	The Medical Monitor	36.1%

Formats for Accessing Protocol Instructions

- **Sites report that paper-based formats are some of the most frequently used methods of referencing the study protocol.**

- **Desktops — and to a lessor extent laptops — are also a regularly used to answer protocol questions by investigative sites.**

- **Communication with study monitors and study teams are some of the more common approaches to obtain protocol information, but the medical monitor is referenced less often.**

- **Despite their frequent use to support clinical trial execution, mobile devices (e.g., tablets and smartphones) are used far less commonly to answer protocol questions.**

Reference Format Value and Time

Resource Group	Resource	Percent Rated Somewhat or Very Helpful	Percent Reporting Answers Located in <10 Minutes
Paper-based formats	Hard Copy of the Protocol	91.4%	82.4%
	Quick Reference Cards	74.3%	89.3%
Online/Digital formats	Online Version of the Protocol (Desktop)	90.8%	92.5%
	Online Version of the Protocol (Laptop)	73.5%	
	Frequently Asked Questions on Portal	59.7%	77.0%
	Online Version of the Protocol (Tablet)	41.8%	83.0%
	Online Version of the Protocol (Smartphone)	33.6%	
Verbal formats	The CRA/Study Monitor	87.3%	23.1%
	The Medical Monitor	68.0%	
	The Study Team	82.5%	32.1%

Reference Format Value and Time

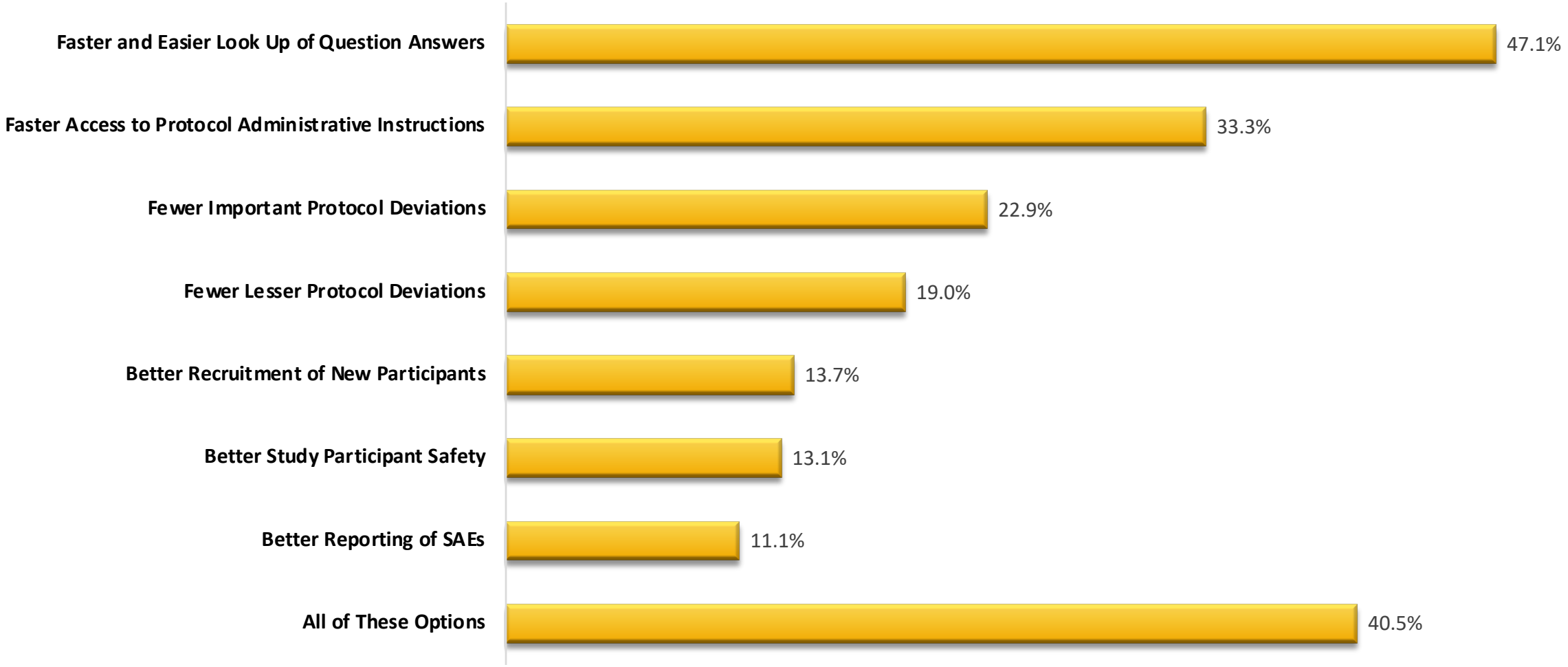
- **Paper-based formats are rated as very helpful, though sites report that they are more time consuming than some other formats.**

- **Despite being the most helpful, conversations with study monitors and study teams are by far the most time consuming method of finding answers.**

- **Sites report that online approaches using a desktop or laptop are helpful and require less time to access.**

- **A relatively low percentage of sites consider tablets and smartphones helpful although they are time efficient.**

Expected Improvements with Real Time Access with Portable Formats



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Expected Improvements with Real Time Access with Portable Formats

- Most sites expect portable formats to offer faster and easier access to protocol administration instructions

- More than half of sites expect portable formats to improve participant safety, SAE reporting, and recruitment effectiveness

About the Tufts CSDD

The Tufts Center for the Study of Drug Development (Tufts CSDD) is an independent, academic, non-profit research center at the Tufts University School of Medicine in Boston, Massachusetts

Our mission is to provide data-driven analysis and strategic insight to help drug developers, regulators, managers and policy makers improve the efficiency and productivity of pharmaceutical R&D