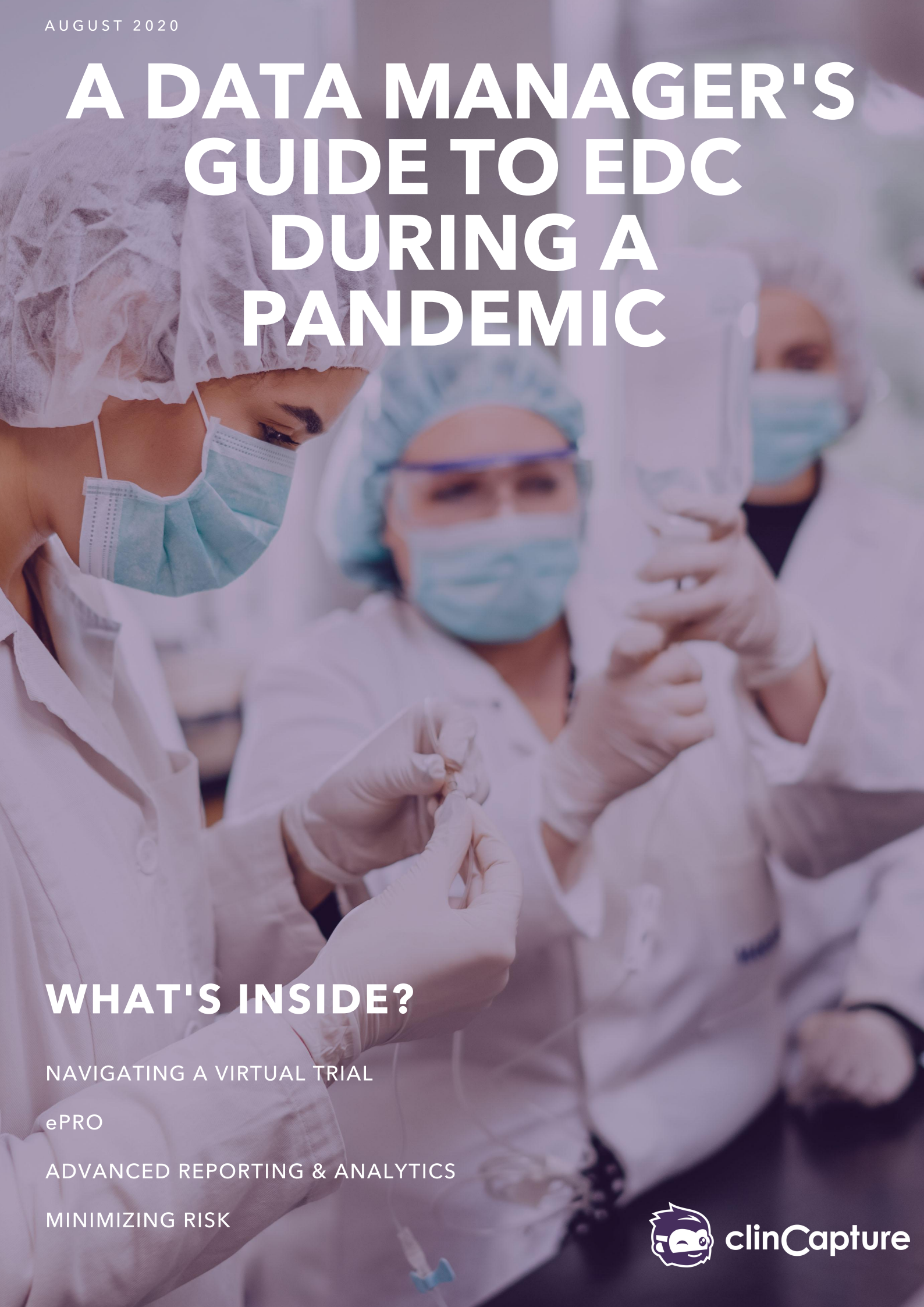
AUGUST 2020

A DATA MANAGER'S GUIDE TO EDC DURING A PANDEMIC



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clinCapture

WELCOME, DATA MANAGERS

WE'VE CREATED THIS TO HELP YOU NAVIGATE THROUGH YOUR STUDY IN 2020

Welcome to the 2020 edition of the Data Manager's Guide to Electronic Data Capture (EDC). In this guide, we will share the latest updates and features that will help you navigate your upcoming trials during the pandemic.

Our goal at ClinCapture is to provide a high-quality EDC product to help you manage clinical trial data. We work closely with clinical data managers to continuously improve our product to fit the evolving needs of trials today.

You can learn more about our products by requesting a demo through our website: www.clincapture.com.

NAVIGATING A VIRTUAL TRIAL

This year, we have learned to change the way we work. As a clinical data manager, you've heard all the buzz about virtual trials, but how do you know if your EDC will help you during this time?

Your EDC should provide flexible options to conduct virtual and on-site trials. With COVID-19, many studies were forced to make mid-study changes or faced with delays that resulted in additional costs.

Let's take a look at what you need for a successful trial during this time:

ePRO

The ePRO from your EDC provider should have the ability to collect data in-person or remotely, it should sync with your EDC and be easy to set-up.

Previously, patient surveys were typically administered on paper. Using paper surveys poses many potential risks including loss of information, security and other logistical issues. Luckily, these problems have been eliminated with ePROs or electronic Patient Reported Outcomes.

> **"WITH PAPER FORMS, PENMANSHIP CAN BE DIFFICULT TO UNDERSTAND AND THE FORMS CAN BE EASILY LOST**
>
> NATALIA ORTEGA
> CLINCAPTURE CUSTOMER

There are many benefits to ePRO including solving security and logistical problems. Surveys can easily be distributed online to patients for completion. And well-designed surveys will allow high-quality data to be collected and easily imported into the EDC.

AMENDING DATA

One way to minimize delays with trials during the pandemic is the ability to easily amend data. Due to restrictions, data monitors are unable to physically visit sites, so this allows you to access the data you need for your trial.

By selecting an EDC that can easily adapt mid-study changes, your trial can move on without downtime. A system such as ClinCapture can easily amend or add Case Report Forms to begin remote monitoring.

MONITORING VISITS

An EDC with visit reporting tools can help you track data efficiently.

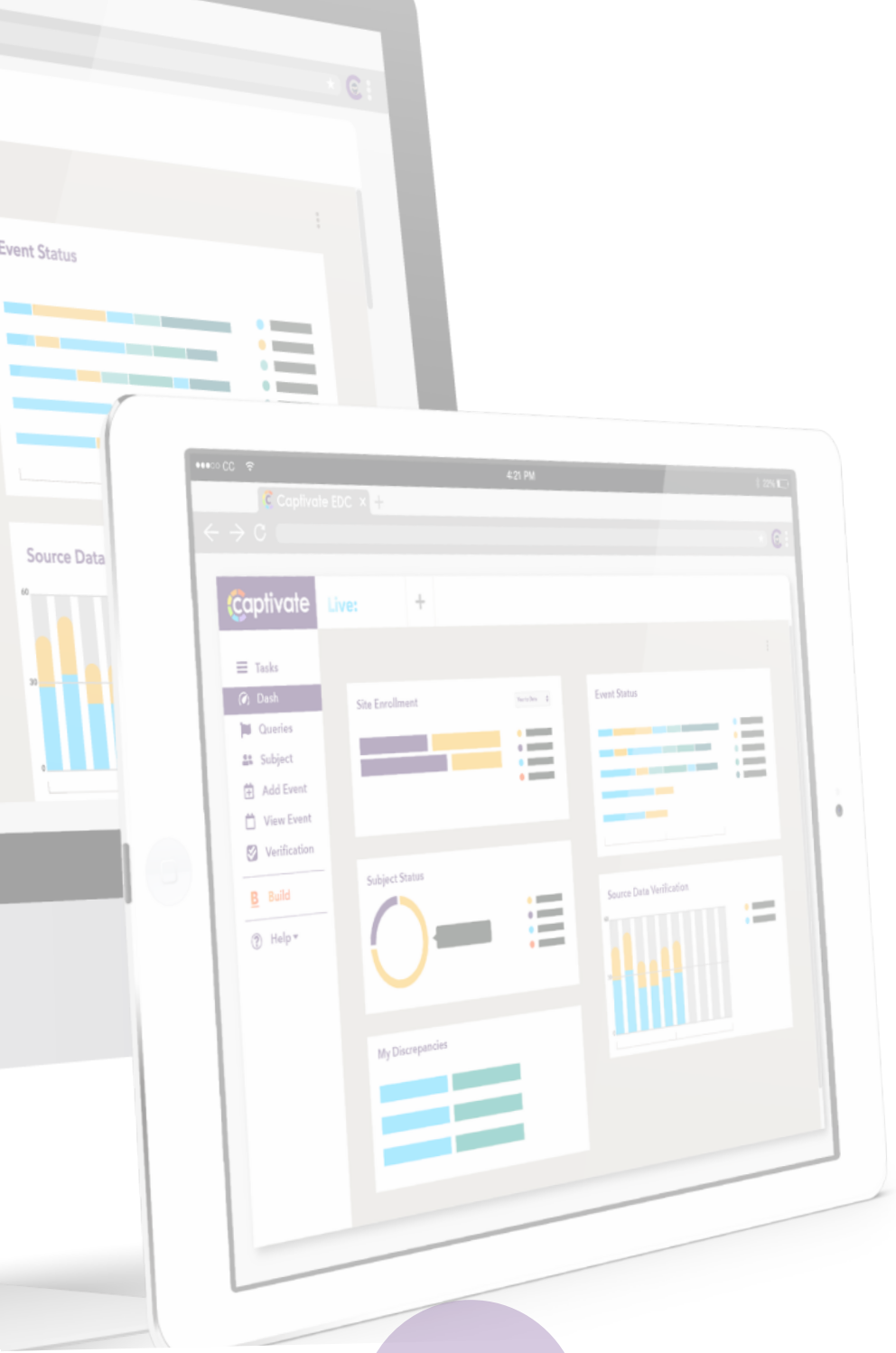
This type of tool will give users the ability to collect data accurately and on-time. The tool should allow users to track patient visits and schedule reminders.

Aside from tracking data, other benefits of having this include the ability for data managers to see real-time ad-hoc reports with patient information including visits.

ANALYTICS AND REPORTING

As a data manager, you know that seamless advanced reporting is crucial for your study. Your EDC should provide insight into your data with real-time reports and progress updates.

EDC systems today, have the ability to provide data in real-time, customize reports without assistance and analyze data across multiple studies and/or sites.



As you evaluate your EDC, ask yourself the following questions:

- Can you view your data in real-time?
- Are you able to create and customize reports without expert assistance?
- Does your reporting and analytics tool feature an intuitive interface?

> ADVANCED, REAL-TIME REPORTING IS CRUCIAL FOR CLINICAL TRIALS AND CLINCAPTURE OFFERS A ROBUST REPORTING TOOL TO GIVE IMMEDIATE INSIGHTS TO RESEARCHERS.

SCOTT WEIDLEY
CEO OF CLINCAPTURE

MINIMIZING RISK

COVID-19 has emphasized the need for virtual trials to run smoothly and with minimal risk.

In March 2020, the Food and Drug Administration (FDA) released guidance for continuing studies during the pandemic. The FDA said, ensuring patient safety is paramount and studies should be modified to reduce risk to include remote monitoring, collecting data from patients directly, collecting electronic signatures, and if possible, collect remote clinical outcome assessments.

Studies that are unable to adapt to changes due to COVID-19 face problems such as missed visits or site closures that result in costly mid-study changes.

Your EDC should be able to handle mid-study changes during the pandemic, remote monitoring, eConsent and remote clinical outcome assessments.

ABOUT CLINCAPTURE

ClinCapture accelerates clinical trials.

By lowering costs, streamlining data capture processes, and protecting patient privacy, ClinCapture's technologies help advance the evaluation and development of drugs, biologics, and devices that demonstrate promise for the diagnosis and/or treatment of a wide range of diseases or medical conditions.

ClinCapture offers Electronic Data Capture on a private cloud with ePRO, advanced reporting and analytics, eConsent, randomization, medical coding and more.

INTERESTED IN A DEMO?

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