



Underpowered studies resulting from insufficient recruitment is one of the most common causes of clinical trial and research failure. Digital clinical trial and research (DCTR) platforms alleviate the challenges of traditional recruitment and consent procedures:

- **Target recruitment more precisely** Flexible participant-facing electronic eligibility assessments make it easier to screen large populations for participants who meet complex criteria with less effort by each potential participant.
- Increase access Digital recruitment methods can reach patients anywhere, thus
  expanding the potential pool of participants, including historically underrepresented
  populations.
- Increase participant comprehension DCTR platforms enable use of multimedia (e.g., videos, voiceovers, images) to deliver informed consent content, which can improve participant comprehension of the study and subsequently increase retention. Comprehension quizzes can also be utilized to ensure all individuals are properly educated on the consent.
- Improve participant experience Participants are able to complete eConsent on their own time, in the comfort of their home, and at their own pace.
- Increase compliance DCTR platforms facilitate version control and "gatekeeping".
   This can ensure participants see the most current version of consent materials and complete study steps in the correct order, as subsequent steps are not made available until eConsent is completed.

### Who is CareEvolution?

With over 15 years of experience in healthcare interoperability, CareEvolution is a leading provider of health data and digital clinical trial and research platforms. The CareEvolution health data platform has enabled leading health plans, provider networks, and health information exchanges to unlock the value of their healthcare data assets. CareEvolution's MyDataHelps™ is your one-stop digital clinical trial and research platform for conducting clinical research, clinical trials, and mHealth projects.

Visit careevolution.com to learn more.





# **Use Case:** Independent Testing and Assessment Program (ITAP) Clinical Studies

The Digital Independent Testing and Assessment Program (Digital ITAP) clinical studies use the MyDataHelps™ DCTR platform to provide support for Food and Drug Administration (FDA) authorization of novel, over-the-counter (OTC) COVID-19 tests to increase their availability to the public. Digital ITAP studies utilize an adaptable recruitment and screening process with advanced branching and conditional logic to identify "preferred" participants that are then prompted to complete eConsent all within the MyDataHelps™ app.

View the full case study >

This research study is trying to understand the

accuracy of over-the-counter COVID-19 tests compared to other standard tests for COVID-19. If eligible, you will be asked to complete COVID-

19 tests at home for up to 2 days at no cost to

reimbursed \$25 for successful participation in the study and performing the tests. We will

explain more after we ask you a few questions to

confirm eligibility. Ready to see if you're

eligible?

MyDataHelps<sup>TM</sup> recruitment and eConsent experience

1.9M

Research and mHealth participants



FDA 21 CFR Part 11 compliant

### Why recruit and eConsent participants with MyDataHelps™?



#### **Multi-modal recruitment**

Participants can be recruited for a study via publicly shareable QR code, email or text invitation, and in-person visits. Email invitations are also highly customizable with a full HTML editor.

#### **Version control**

Screening surveys and eConsent are automatically versioned to ensure that only the most up-to-date materials are presented to potential participants. Version history is also easily accessible to help streamline regulatory submission processes.





#### Robust screening tool

Screening tool with advanced branching and conditional logic to determine participants' eligibility. eConsent delivery can be automated based on a participant's response to screening questions.



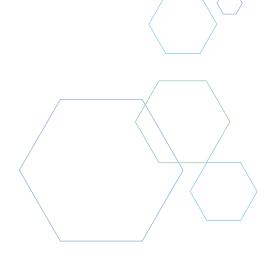
#### **Multi-platform accessible**

MyDataHelps™ is available through any internet-accessible device, including Apple, Android, and Web.



#### Potential participant outreach and tracking

Starting with an initial list of potential participants, MyDataHelps™ can email or SMS individuals with invitations to join a study. These invitations can also be sent as part of a nurture campaign—where different content is sent to potential participants at a set cadence—to encourage enrollment over time. In addition, MyDataHelps™ can track engagement with the invitations and screening tools, through to final consent, to help manage and improve enrollment rates.





## Unlock the full potential of recruitment and eConsent as part of a flexible suite of MyDataHelps™ digital clinical trial tools.

MyDataHelps™ is a digital clinical trial and research platform, powered by CareEvolution. Select the data and modules you need to quickly launch your next clinical trial or research project, hybrid or decentralized, with no coding required.



Multi-modal, multi-platform enrollment



Kitting & fulfillment



Eligibility screening tool



Wearable data integration



eConsent



Adherence notifications



Electronic clinical outcome assessments (eCOA)



Participant dashboards & rewards



EHR & claims data integration



Remote patient monitoring

Learn more at careevolution.com/mydatahelps.