

# THE TRUTH ABOUT TRIAL MODELS

Details, Differences, & Drawbacks

## Decentralized Trials

The FDA defines a decentralized trial (DCT) as, “A clinical trial where some or all of the trial-related activities occur at locations other than traditional clinical trial sites.”\*

Virtual/fully DCT and hybrid trials are DCTs.

## Confidently Navigate New Trial Models

### Partner With Elligo Health Research®

Elligo’s Research Partner Services has the solutions you need to successfully run trials in any model.

Get Started



|             | Traditional Trials  | Hybrid Trials  | Virtual or Fully DCT Trials   |
|-------------|---|--|---|
| DESCRIPTION | <ul style="list-style-type: none"><li>In-person visits at research sites</li></ul>  | <ul style="list-style-type: none"><li>Study activities are conducted at traditional sites and other locations</li></ul>  | <ul style="list-style-type: none"><li>Study activities conducted at locations other than traditional sites<ul style="list-style-type: none"><li>Virtually (in patients’ homes)</li><li>Local healthcare facilities, e.g., a primary care physician’s office</li></ul></li><li>Can include telehealth and in-person visits</li></ul> |
| ADVANTAGES  | <ul style="list-style-type: none"><li>Oversight of study activities</li><li>Increased patient comfort and trust</li></ul>   | <ul style="list-style-type: none"><li>Reduced patient burden<ul style="list-style-type: none"><li>Increased enrollment</li><li>More diverse participation</li></ul></li><li>Real-time monitoring</li><li>Increased patient comfort and trust</li></ul> | <ul style="list-style-type: none"><li>Reduced patient burden<ul style="list-style-type: none"><li>Increased enrollment</li><li>More diverse participation</li></ul></li><li>Real-time monitoring</li></ul>  |
| LIMITATIONS | <ul style="list-style-type: none"><li>Patient burden (traveling for study visits)</li><li>No real-time monitoring</li></ul> | <ul style="list-style-type: none"><li>Limited real-time monitoring</li><li>Limited oversight</li></ul>   | <ul style="list-style-type: none"><li>May not be suitable for interventional trials (IP administration via injection)</li><li>May not be suitable for severe diseases with higher levels of care</li><li>Reduced oversight</li><li>Reduced patient comfort and trust</li></ul>  |

\*Decentralized Clinical Trials for Drugs, Biological Products, and Devices Guidance for Industry, Investigators, and Other Stakeholders. U.S. Department of Health and Human Services Food and Drug Administration. Accessed 2023 May 19.