

ANJU SOFTWARE



FASTER ANSWERS THROUGH BETTER INSIGHTS

DCT Trials:

What do we have and where are we going?
Structuring your current options for success
and predicting the next 24 months

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EVP | OPERATIONS

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Leiden Netherlands, Europe
Southampton, United Kingdom

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Pune India, Asia



+300 EMPLOYEES

9 OFFICES

1 COMPANY

Office Locations

Anju Software global presence with headquarters in Ft. Lauderdale office, Florida USA.





eClinical Suite

Easy-to-use solutions for the conduct and management of clinical trials enabling informed decision making, risk-based monitoring, and an accelerated clinical trial lifecycle.

TrialMaster

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CTMS Master

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TA Scan

TA Scan^{CRM}

TA Scan^{Essential}

Previous Predictions June 2021



MIKE KEENS | EVP

“Industry interest will result in advancing DCT offerings in China”

- Status: Correct
 - Proof: Increase of home health and CRO providers now working in China to support DCT *
- *2022 expanded prediction



“France (and potentially UK) practices will stifle DCT adoption”

- Status: Likely, but too early to tell.
- Proof: Likely based on feedback from CROs and independent provider on impact on Agency/Health system and employment rules



“DCT will almost completely replace patient centricity as an industry focus”

- Status: Correct!
- Proof: Currently zero references to “patient centricity” in the DIA 2022 Program.
- Note: Digital (10) and Decentralized (6)



“Providers will need to offer comprehensive global services or risk marginalization”

- Status: Likely, but too early to tell
- Proof: Science 37 and China, Medable + CVS partnership, LabCorp expanded test ordering



Keens Predictions 2022-2023

Sponsors & Dollars



CRA monitoring budgets will be shifted to off-set the use & cost of technology and home health in DCT



Sponsor impatience with overpromise of ROI in technology (and expense) may slow down rate of tech deployment



HCW burnout will increase home nurse DCT resources, but increased provider wage expectations ("crisis pay") may temper continued accelerated rate of home health adoption

Keens Predictions 2022-2023

Regulatory



Acceleration of DCT adoption based on increased comfort post pandemic, FDA guidance's, and EMA Comment

("No going back" – Fergus Sweeney)



Telemedicine will be the slowest growing DCT component due to ongoing issues with state laws governing telemedicine (limiting physician comfort with overall adoption)



China providers increase but actual use will still be very limited given government technology laws, regulations, and cultural norms

Keens Predictions 2022-2023

Landscape



Pharmacy chain involvement in COVID vaccine efforts will increase competition with “traditional” sites

(Not until 2023 when coupled with wind-down in large scale COVID trials)



CROs will not acquire any well-known DCT providers, but well-known DCT providers will make acquisitions to shore up existing service gaps



Supply chain issues will favor larger integrated DCT providers (e.g., CROs w/labs) who will adjust more easily to logistics and equipment provisioning vs. smaller independent providers (“supply squeeze”)

Keens Predictions 2022-2023

Watchful Waiting



Inundation of multiple technology platforms will create site friction - adding to site “pain”



Expanding adoption of DCT into more infirmed/higher morbidity patients and therapeutic areas will result in a high-profile negative patient outcome/press event and may temporarily slow DCT adoption



The Sanofi RADIAL trial results will yield best results for the arms in this order:

(1) Hybrid → (2) Traditional → (3) Virtual

Questions & Perspectives



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