

DIGITAL CLINICAL TRIAL SOLUTIONS

Faster, cheaper, more innovative



a&r offers a new innovative clinical trial approach with fully virtual and hybrid options. With the aid of telemedicine, eDiaries, and connected devices like wearables, many of the study-related procedures that have traditionally taken place at a study site can be coordinated directly in the living room of any eligible person who wants to take part in a trial.

This makes it **much more convenient** for subjects to participate in a clinical trial and, even more importantly, subjects can be recruited from a much broader pool (e.g. the whole of Germany) because there are no more local limitations.

Decentralized clinical trials can **recruit faster** and a **higher diversity of subjects**, increase compliance and engagement, collect continuous data in real world settings leading to a shorter study time and **significant lower costs**.

KEY FEATURES

Faster recruitment

- Subjects can be recruited from a much broader pool (e.g. the whole of Germany) because there are no more local limitations.
- Subjects can participate using their own smart devices, from their own homes, reducing the need for unnecessary clinic visits and easing the burden of participation.

Better compliance & less drop-outs

- Mobile notifications, alerts, and reminders drive patient engagement, leading to increased protocol, dosing, and patient-reported outcome compliance.
- Medication through investigational product.
- Less schedule conflicts due to flexible time saving tele-visits reduce drop-outs.

More transparency

- Live view on subject activity and progress to quickly identify and re-engage subjects who have missed appointments or treatments.
- Site and enrollment dashboards provide real-time status updates on enrollment data, subject engagement, subjects events, and medication adherence.
- Alerts allow study teams to identify potential risks and intervene as needed.

Real-world data

- Collect more continuous data in real world settings.
- Gain more insights of individual life situation of target population.



CASE STUDY "HYBRID STUDY APPROACH"

Objective

- Clinical study to explore tolerability and benefit of a dietary supplement for subjects with sleep complaints.

Methodology

- In this case study, the study started with a screening visit at the investigational site to check eligibility. Thereafter, subjects consumed the dietary supplement and recorded daily study relevant data in an electronic subject reported outcome (eSRO) tool via their own smartphone, tablet or PC.
- The electronic questionnaire was sent to the participants on a daily basis via email or sms containing questions regarding study-specific benefit and tolerability outcomes.
- In the meantime, the study team had a "live view" on enrollment data and subject progress by use of a connected dashboard and could quickly identify and re-engage subjects who have missed data entries or whether any help was needed.

Results

- This hybrid approach made it much more convenient for subjects to participate leading to a very fast recruitment of several hundreds of subjects in only a few months with a retention rate and compliance of >95%.
- Less on-site visits and faster recruitment greatly reduced overall costs compared to a traditional study approach.

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