

# Clinical Trials

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## Substantial data for faster clinical trial approval with compliance meds technologies' clever cap

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Pharmaceutical manufacturers have long struggled to create an efficient clinical trial process for faster next phase approval. The root cause of most failures is a lack of necessary efficacy data to support clinical trial claims. Subpar data can be directly tied back to an inability to track and report on patient adherence to drug protocol. Patient adherence is critical to the outcome of clinical trials in determining the drug's efficacy, establishing dosing guidelines, and receiving market approval. Compliance Meds Technologies (CMT) offers a novel approach to medication tracking during clinical trials with its patented CleverCap devices that track and record real-time dispensation of oral solid medications in the outpatient setting. CMT's robust cloud-based platform captures detailed dosing logs, enables timely screening and empowers enrichment interventions. CMT's platform presents data in ways that allow sponsors and CROs to benchmark sites and shed light to investigators regarding correlations between dispensation dosing patterns and efficacy. CMT's technology is applicable across different phases in research and development: Phase II-IIIb studies, where the participant is not taking the medicine in someone's presence; PK sampling studies not dosing in clinic, where the exact time that a subject took a dose prior to PK sampling is critical; protocols that call for complex dosing schedules; studies that require titration or adaptive studies; studies in high toxicity therapy classes and narrow PK profiles (e.g., Cancer, Hepatitis C, CNS – MS, ALS, Parkinson's), therapy classes with concerns of overdosing or when the study medicine is prone to diversion (e.g., Opioids).

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