



## The Role of IoT in Clinical Trials

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## The need

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Regulatory: significant increase in Patient Reported Outcome (ePRO) Data before market authorization and Post Marketing trials

Reaching the measurement of patients' real life, breaking limits of actual study data collection focused on disease measurement, compliance, etc.

Reaching the patients easier to support Clinical study recruitment



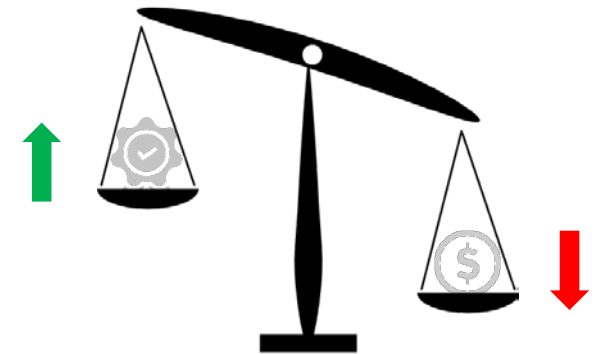
## The opportunity

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- The proliferation of consumer-oriented **Internet-connected devices** (e.g. smart phones, wearables, in-home medical devices) is gradually transforming the healthcare ecosystems.

- Opportunities are deriving for **value added health services that improve the quality and cost of processes** associated with the prognosis, diagnosis and treatment of diseases.



## The challenge

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- Integration of IoT technologies in clinical trials, is also realizing the **convergence of care processes with clinical research processes**, through common data collection and sharing processes.
- Blending of IoT technology in clinical trials processes **can lower the costs of clinical research** and facilitating the **invention and validation of new medical products** and services that will revolutionize healthcare in the years to come.

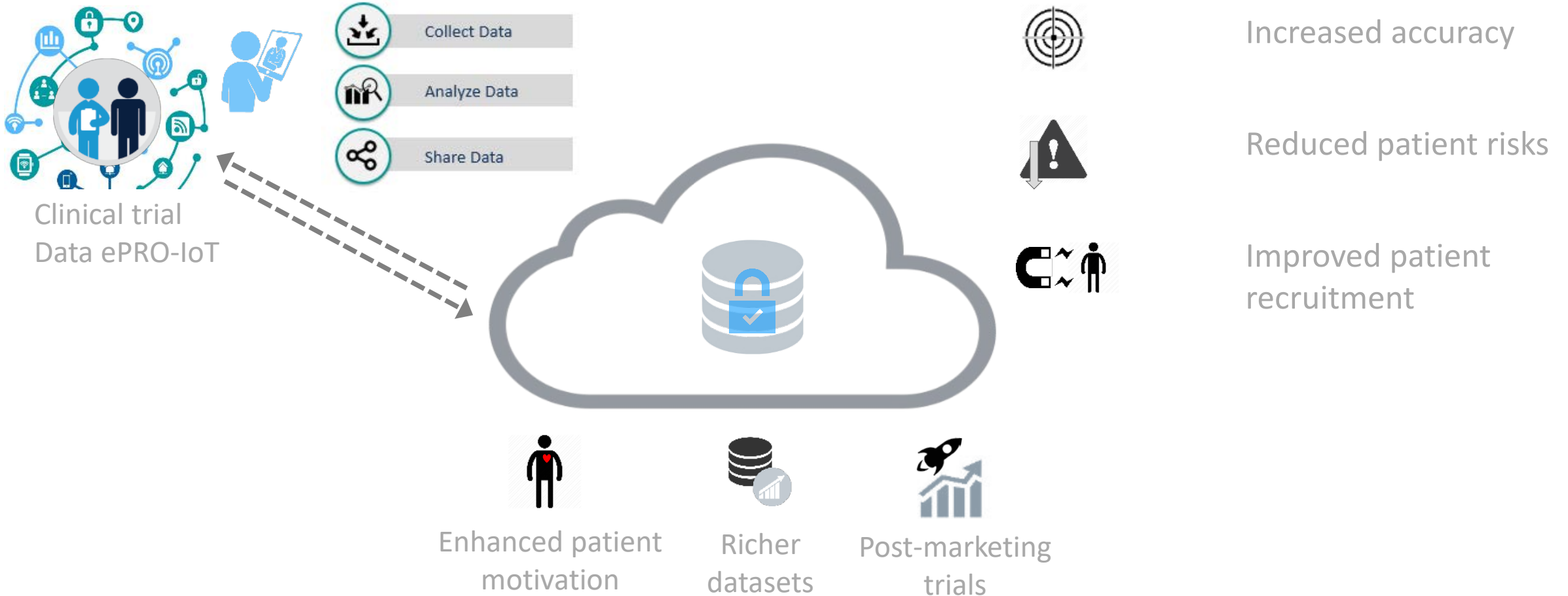


## IoT and Big Data in Clinical Trial

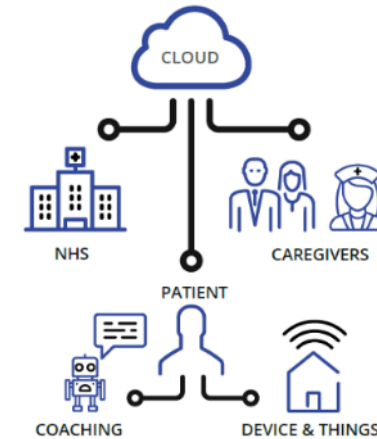
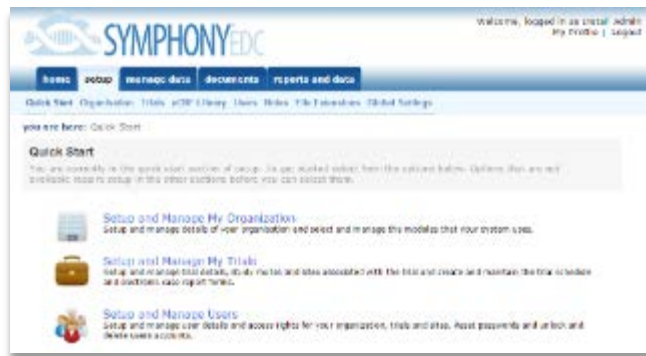
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- **IoT** and **Big Data** technologies hold the **promise to revolutionize clinical research processes** enabling the seamless and effective blending of real-world data into clinical trials.
- Rather than relying on static data obtained by clinical, IoT could enable the **dynamic acquisition and processing of data** from consumer and medical devices, as well as from related data processing and analytics services.

# IoT in Clinical Trials



# ePRO-IoT Elements



## Case Studies

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ARTICLES

**nature  
biotechnology**

### The Asthma Mobile Health Study, a large-scale clinical observational study using ResearchKit

Yu-Feng Yvonne Chan<sup>1,2</sup>, Pei Wang<sup>1</sup>, Linda Rogers<sup>3</sup>, Nicole Tignor<sup>1</sup>, Micol Zweig<sup>1</sup>, Steven G Hershman<sup>4</sup>, Nicholas Genes<sup>1,2</sup>, Erick R Scott<sup>1</sup>, Eric Krock<sup>4</sup>, Marcus Badgeley<sup>1</sup>, Ron Edgar<sup>4</sup>, Samantha Violante<sup>1</sup>, Rosalind Wright<sup>3,5,6</sup>, Charles A Powell<sup>3</sup>, Joel T Dudley<sup>1,7</sup> & Eric E Schadt<sup>1</sup>

The feasibility of using mobile health applications to conduct observational clinical studies requires rigorous validation. Here, we report initial findings from the Asthma Mobile Health Study, a research study, including recruitment, consent, and enrollment, conducted entirely remotely by smartphone. We achieved secure bidirectional data flow between investigators and 7,593 participants from across the United States, including many with severe asthma. Our platform enabled prospective collection of longitudinal, multidimensional data (e.g., surveys, devices, geolocation, and air quality) in a subset of users over the 6-month study period. Consistent trending and correlation of interrelated variables support the quality of data obtained via this method. We detected increased reporting of asthma symptoms in regions affected by heat, pollen, and wildfires. Potential challenges with this technology include selection bias, low retention rates, reporting bias, and data security. These issues require attention to realize the full potential of mobile platforms in research and patient care.



Thank you

