Electronic devices have been systematically provided to participants to report Patient Reported Outcome (PRO) data in clinical trials and electronic Patient Reported Outcomes (ePRO) data collection methods have evolved over time. The current desire to reduce participant burden and drug development costs, combined with improved technology, has led to increasing interest in having study participants use their own devices (‘bring your own device’ or BYOD) to collect PRO data.

However, the uptake of BYOD technologies remains low despite significant interest from industry in their development. The lack of clear regulatory guidance on BYOD approaches has created a vicious circle: clinical teams are not encouraged to pioneer clinical trials submissions using BYOD-collected data, which limits publications on BYOD success stories, meaning that cautious clinical trial teams are not prompted to take the plunge and broadly adopt BYOD options.

What does the industry need to make a step forward and implement BYOD strategies? How can confidence grow so that study participants can benefit from the comfort of using their own device to collect PRO data? This white paper sets explicit expectations as to what BYOD strategies bring as well as the associated risk, and proposes structured help to support successful BYOD strategy decision-making processes and implementation.

CONTENT

Draw clear expectations: What are the true benefits of Implementing a BYOD strategy?

Compliance

Flexibility

Understanding the challenges of BYOD: What do we need to pay attention to?

Data storage constraints

- Data security challenges

Smartphone availability verifications

Choose a relevant BYOD strategy: When does it make sense?

Study design criteria

Patient population criteria

Geographical constraints

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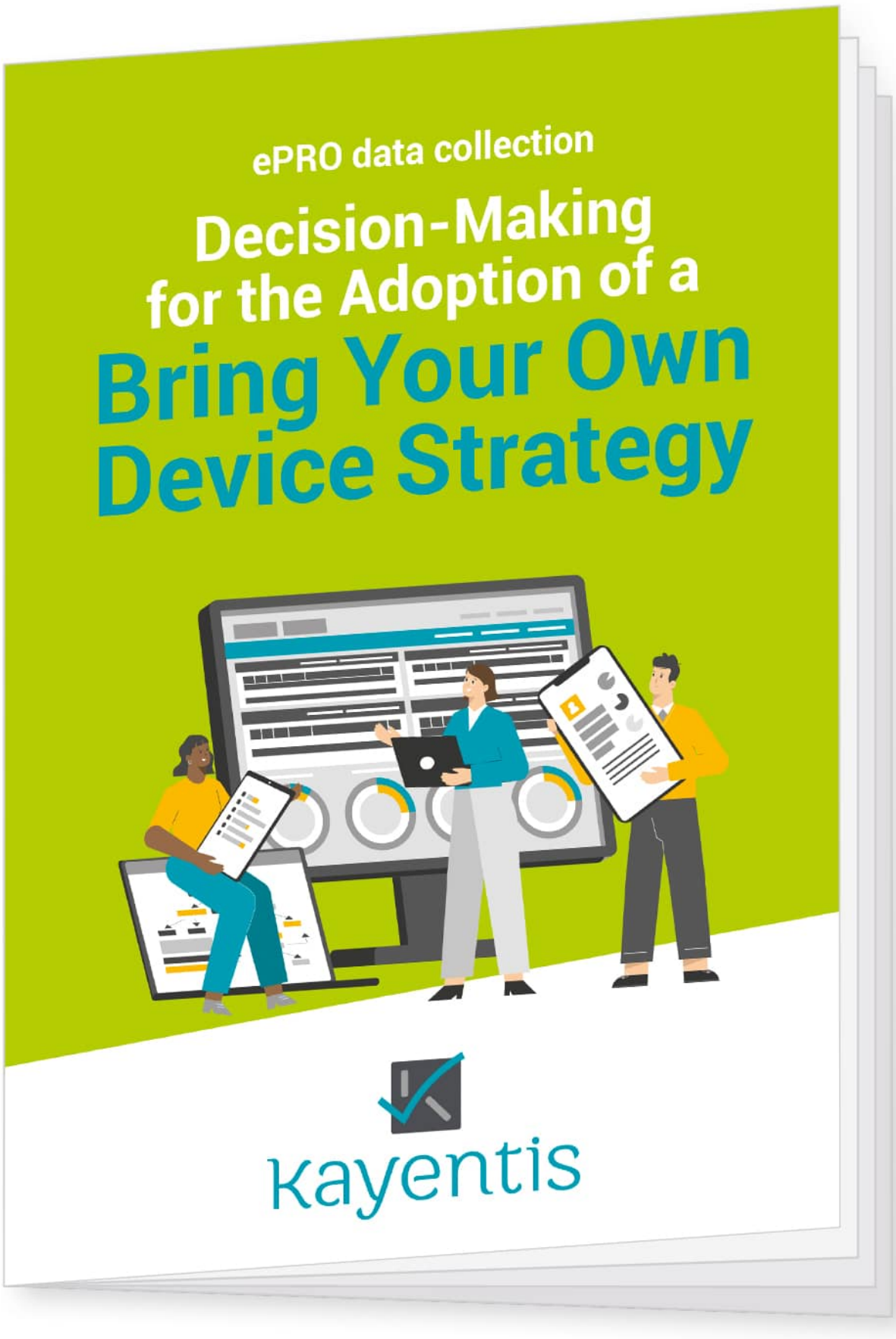

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Key Words:

- BYOD
- ePRO
- clinical trials
- data collection

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