



[ki:elements](#) (ki:e) was founded in 2017 as a spin-off of the German Research Center for Artificial Intelligence (DFKI).

It pioneers the speech-based assessment of neurological and psychiatric diseases. ki:e combines artificial intelligence with natural language analysis and interpretation technologies. It offers digital biomarkers for a variety of clinical, before and in-trial usage scenarios.

“We strive to be pioneers in speech biomarkers and The Playbook provided us with rich and helpful resources to structure our development work towards this goal.”

— **Jian Zhao**, Regulatory Compliance Manager, Regulatory and Compliance, ki:elements

The Problem

1. The regulatory requirements to use digital measurement tools in clinical trials are not standardised.

2. The terminologies used by FDA/EMA, such as content validity, concurrent validity, are not synchronised across different products and different disease areas.

3. The usage of digital measurement tools is just one link in a large clinical trial. Guidance on how to prepare its integration from a holistic point of view is rare.

The Resource

The entire *The Playbook*! It breaks down a digital measurement into individual components, so that it will be easier to map to different validation requirements with many examples and uses cases. Its stepwise guidance is effective and very logical.

[Section 2.0 Build a shared foundation](#) was especially helpful as was the [V3 framework](#).



The Impact

- ✓ Project success
- ✓ Greater patient centricity
- ✓ More buy-in
- ✓ Clear communication internally (team + execs) & externally
- ✓ Operational efficiencies/faster decision making
- ✓ Team education & cohesion
- ✓ Refined/improved strategy