



Winterlight Labs has developed an automated speech analysis platform to monitor neurodegenerative and psychiatric conditions. Our tools are objective, sensitive, and easy-to-use, and are used by 5 of the top 10 Life Sciences companies to monitor disease progression and response to treatment.

*“The measurement checklists provide a framework for best practices in developing and validating novel digital measures. These will help bring consistency and scientific rigour to the field!”*

## The Problem

Winterlight's technology is currently used as an exploratory endpoint in a number of clinical trials in neurodegenerative disorders. As we collect data in more indications and further develop our technology, we want to work toward being validated as a secondary or primary endpoint.

## The Impact

- ✓ Clear communication with internal team
- ✓ Clear communication with external partners
- ✓ Team education & cohesion
- ✓ Greater patient-centricity

## The Resource

The [Measurement Checklists](#) on *The Playbook* website provide useful summaries of the types of evidence and clinical data required for different contexts of use. These checklists have helped inform our validation strategy and guide our research program into how speech is affected in various disease and disorders. We can use these frameworks to organize our existing data, know what to communicate to our partners, and define our next steps for research and validation.

*The Playbook* | a DiME Tour of Duty


### Digital Clinical Measures Checklist | Primary Endpoint in Pivot Clinical Trial

**Purpose:** The purpose of this checklist is to document the minimum evidence necessary to support the use of a digital clinical measure used as a **primary endpoint** within a **pivot clinical trial**. The checklist can be modified as necessary, including through the addition of requirements relating to security, data rights, usability and utility, economics, and operations, which are not covered here.

**Instructions:** Any Study Team Member may use the Checklist to support the evaluation of whether a digital clinical measure is fit for purpose in this context of use. Relevant information for this checklist may come from third-party vendors (e.g. device manufacturer, CRO partner, etc.), a dedicated validation and verification (V&V) study, regulatory documents (e.g. FDA 510(k) filing), or reputable publication (e.g. peer-reviewed article or reputable white paper).

#### Best Practices:

- For each item in the checklist, record the origin as well as the location (physical or virtual) of all documentation constituting the evidence required in the appropriate column on the template.
- Once completed, this checklist is expected to be filed (*organization to insert own best practice*).

| Digital clinical measure:            |  |
|--------------------------------------|--|
| Context of use:                      |  |
| Sensor product:                      | Include sensor type, make, model, and software version of sensor product<br> Resource: <a href="#">BEST (Biomarkers, Endpoints, and other Tools) Glossary</a> |
| Form factor and wear location/usage: |  |
| Endpoint definition:                 | Define clinical data comprising the endpoint and its calculation   |
| Checklist completed by:              | Insert time range  |
| Checklist initiated on:              | Insert date initiated  |
| Checklist completed on:              | Insert date completed  |