

# NEW PROCESSES TO STREAMLINE eCOA USABILITY AND VALIDATION

iUsability – Integrated Usability and Validation Service

## USABILITY TESTS AND INTERVIEWS

**iUsability** optimizes testing of the usability of patient-facing eClinical solutions. It is delivered by a tightly integrated team of eCOA design experts and outcomes researchers. Instead of testing a solution at the end of its design lifecycle, iUsability engages with patients and other stakeholders *early* in the process, using mock-ups and design alternatives, and gathering user input to optimize the performance of the final eCOA solution (e.g. patient-reported outcomes [PROs], clinician-reported outcomes). iUsability is ideal for preparing bring your own device (BYOD) solutions, in which patients use their own smart phone, tablet, or laptop.



## The iUsability process involves four key steps:

- 1 **Initial design** work to create the electronic solution and document the changes to the original paper version, including layout, navigation, reminders, time windows, and edit checks
- 2 **Development of the protocol and interview guide** based on key questions and including assessment of the changes made to the original version in step 1
- 3 **Patient test period** and interviews to collect patient insights and observe users using the solution on various devices, followed by revisions to the design as necessary
- 4 **Development of the eCOA design guideline** defining the optimal, standardized solution, which is independent of vendor and device.
- 5 **(Optional) Cognitive debriefing** to satisfy the recommendations for instruments used for labeling claims.

The most common use for iUsability is the migration of paper-based clinical outcome assessments (COAs) into an electronic modality, requiring adaptation of the original instrument. This often involves, for example, the addition of navigation menus, time windows, and electronic reminders, and changes to the layout. iUsability helps improve the overall usability of the solution and provides scientific evidence of equivalence with the original paper version.

iUsability is also a great solution for optimizing usability and evaluating user acceptance of other novel patient-facing eClinical solutions, such as eConsent and digital patient engagement solutions.

## eValidatePRO

**eValidatePRO** is service perfectly suited to the validation of psychometric testing of new or modified COA instruments that have already been through qualitative development. The eValidatePRO service uses the novel Clinpal™ remote trial model to recruit, consent, and capture data from patients in order to establish the psychometric properties of the new or modified instrument. The remote trial model is a streamlined direct-to-patient method that allows this

process to be completed more quickly than traditional models and at a lower cost.

## iUsability

- › Optimizes and confirms usability of any patient-facing eClinical solution
- › Supports BYOD platform approach
- › A fast and affordable process for testing novel solutions before deployment into clinical trials

## eValidatePRO

- › Psychometric testing of new COAs
- › Uses remote research methods to conduct validation studies more quickly than the traditional process and at a lower cost

## The Expert Team

These services are provided by leading eCOA design experts and outcomes researchers who work together seamlessly from start to finish. This ensures that all eCOAs are designed with the scientific objectives in mind, and that the outcomes researchers are fully aware of the technical and design considerations. This teamwork ensures that both the usability and research properties of eCOAs are optimal.



**Kai Langel**

Co-Founder & Director,  
Patient and Technology  
Solutions, eClinicalHealth



**Annabel Nixon**

Director,  
Clinical Outcome Assessment,  
Chilli Consulting



**Diane Wild**

Consultant,  
Clinical Outcome Assessment,  
Chilli Consulting

For more information, please contact us

[www.clinpal.com/usability-validation](http://www.clinpal.com/usability-validation)

[info@eclinicalhealth.com](mailto:info@eclinicalhealth.com)