

# Ontological Modeling of Clinical Study Forms

Jacques HILBEY<sup>a,b,1</sup>, Amel RABOUDI<sup>c</sup>, Marie-Odile KREBS<sup>d</sup> and Jean CHARLET<sup>e,b</sup>

<sup>a</sup>*Sorbonne Université, Paris, France*

<sup>b</sup>*Sorbonne Université, Sorbonne Paris Nord, INSERM, Laboratoire d'Informatique Médicale et d'Ingénierie des Connaissances en e-Santé - LIMICS, Paris, France*

<sup>c</sup>*Fealinx, 37 rue Adam Ledoux 92400 Courbevoie, France*

<sup>d</sup>*Institute of Psychiatry and Neuroscience of Paris, Université de Paris, GHU Paris Psychiatrie & Neurosciences, Paris, France.*

<sup>e</sup>*Assistance Publique-Hôpitaux de Paris, Paris, France*

ORCID ID: Jacques Hilbey <https://orcid.org/0000-0002-3351-9840>

**Abstract.** The use of eCRFs is now commonplace in clinical research studies. We propose here an ontological model of these forms allowing to describe them, to express their granularity and to link them to the relevant entities of the study in which they are used. It has been developed in a psychiatry project but its generality may allow a wider application.

**Keywords.** Biological Ontologies, Clinical Study, Form.

## 1. Introduction

Our proposal, retaining many elements of Bona's proposal [1] as well as proposals extending Bona's [2][3], aims at the best access to the data and its contextualization for future reuse. The proposed strategy includes maintaining the link to the original data files, ontological representation of their schema, enrichment with metadata.

## 2. Material and methods

The ontoPSYCARE modular ontology is being developed within the PsyCARE project<sup>2</sup> to allow data integration as well as semantic annotation. An event-centered foundational ontology (ontoPOF) and a data-centered core ontology (ontoDOME) provides the ontological commitment explaining the proposed representation of the assessment tools in the module dedicated to psychiatry data (ontoDOPSY).

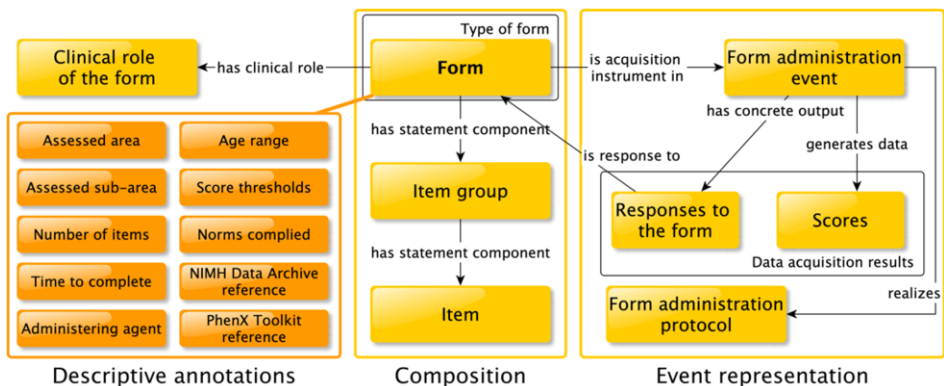
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<sup>1</sup> Corresponding Author: Jacques Hilbey; E-mail: [jacques.hilbey@sorbonne-universite.fr](mailto:jacques.hilbey@sorbonne-universite.fr).

<sup>2</sup> <https://psy-care.fr/>

### 3. Results

The result is a threefold model (Fig. 1) providing an overview of the assessment tool, that also allows the tool and the responses obtained from a patient to be enrolled in compositional relationships, and including the form in the entities representing its completion.



**Figure 1.** A threefold model (descriptive, compositional, event-related) of an assessment tool.

### 4. Discussion and conclusion

The model we propose here aims first at allowing the integration of data produced by a clinical research project on a data collection platform (while ensuring the traceability of data flows and treatments thanks to the BMS-LM ontology [5], which uses PROV-O), and an ontological representation centered on the form administration events is also provided ; it also allows the exploration of the assessment tools and the assessments.

### 5. Acknowledgments

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