RWD70

Electronic Implementation of Patient-Reported Outcomes: Challenges and Potential Solutions

Cassanelli F.[1], Ferri F.[1], Ori A.[1], Simoni L.[1]
[1]Medineos Observational Research, an IQVIA company, Modena, Italy

BACKGROUND

Recent advances in information technology and a wider availability of electronic personal portable devices

Constant growth in electronic Patient-Reported Outcomes (ePROs) use in clinical trials and routine clinical practice (Coons et al., 2015; Aiyegbusi et al., 2021)

Several advantages:

- Limited data entry errors
- Less missing or inconsistent data
- Ease of remote compilation
- Lower data collection costs compared to paper-based compilation and manual data-entry

New challenges:

- Reproducibility paper-based PROs onto electronic platforms
- Migration of already available ePRO from the original implementation platform to a different data collection system

OBJECTIVE

The aim of this work is to report our experience in the last year when implementing ePROs, with challenges and solutions

METHODS

Analysis of 11 different ePROs implemented during 2021-2022

Information collected:

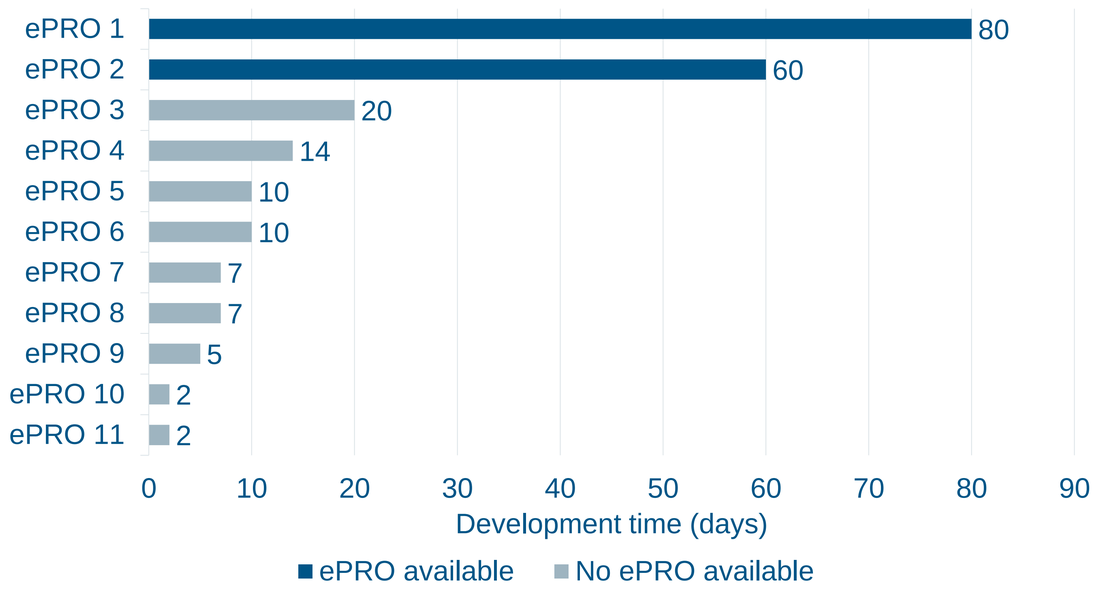
- Electronic version already available
- Implementation guidelines availability
- Languages implemented
- Time for development and revision by ePRO providers

ePROs DESCRIPTIVES

Out of 11 ePROs implemented:

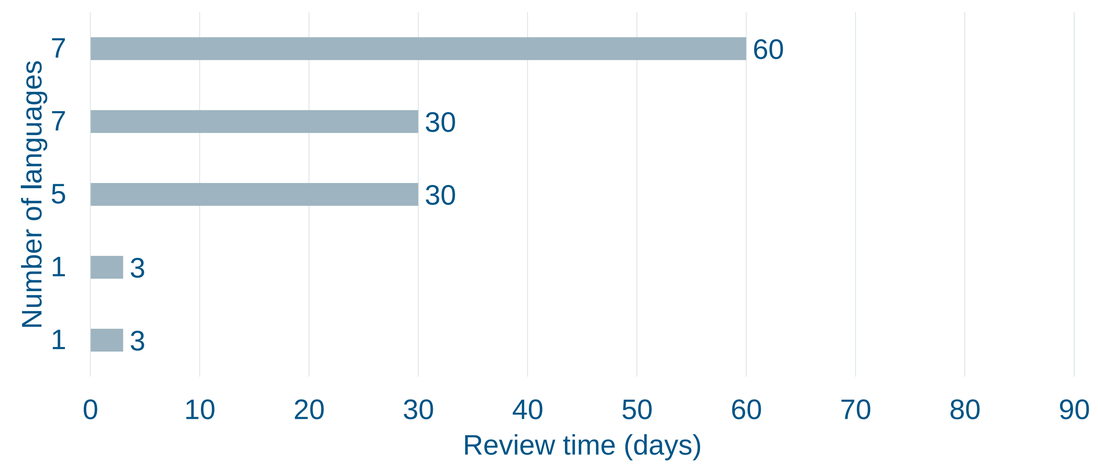
- **2 already** available in **electronic format** were migrated from the original implementation platform
- **4** had electronic **implementation guidelines**
- **8** (63.64%) were adopted in **multiple languages**

Figure 1: ePROs* development time



* Data reported in the figure refer to ePROs implemented in observational studies in agreement with signed copyright contracts

Figure 2: Relation between the nr of languages implemented and revision time



RESULTS

- Development time, including the time to discuss alternative implementations with ePRO provider, was on average 20 days, ranging from 2 to 80 days (Figure 1).
- Longer development period (60-80 days) was necessary for already available ePROs that had to be moved to a different electronic platform.
- Final revision by providers was required in 5 cases, taking 3 days for 2 ePROs and 30 to 60 days in 3 cases (Figure 2).
- On average, 5 days were necessary for each language review, increasing up to almost 9 days in case usability testing was required too.

CONCLUSIONS

Understanding copyright holder requirements and platform limitations is crucial. Planning in advance adequate time for discussion, development, revision, and final approval from the ePRO provider may solve the shortcomings. Our conclusion is that being aware of the potential implementation challenges is of paramount importance to tackle them and ensure data quality and availability of data collections tools in a timely manner.

REFERENCES:
- Coons, Stephen Joel, et al. "Capturing patient-reported outcome (PRO) data electronically: the past, present, and promise of ePRO measurement in clinical trials." *The Patient-Patient-Centered Outcomes Research* 8.4 (2015): 301-309.
- Aiyegbusi OL, Nair D, Peipert JD, Schick-Makaroff K, Mucsi I. A narrative review of current evidence supporting the implementation of electronic patient-reported outcome measures in the management of chronic diseases. *Therapeutic Advances in Chronic Disease*. 2021;12.