

Challenges to obtain real-life data in observational studies: What are the solutions when the patient is the main data provider?

Sohéla EL KEBIR¹, Yann BOURHIS¹, Xavier FOURNIE¹
¹REGISTRAT-MAPI, Lyon, France

Background

- Collecting patients' data in observational longitudinal studies is often a concern in terms of data accuracy and patient follow-up
- Depending on the study design, the physicians' assessment might not be sufficient and/or feasible
- Direct to Patient Contact (DtPC) process is commonly used to maximize long-term follow-up and ensure continuity and quality in data collection

Objectives

To demonstrate the benefit of DtPC, through example of a multinational, observational, longitudinal, prospective, cohort study. Challenges were to implement feasible and robust methods to collect and confirm Events of Interest (Eoi) for the study in 'real-life' settings, fitting health care standards, regulatory and cultural requirements of countries involved

Methods

- Enrolling physicians were not primary patients' Health Care Providers (HCPs); consequently, patients had to be the main contact to capture the Eoi
- Patients had to complete and sign a Contact Order Form (COF) that allowed trained interviewers performing follow-up calls at regular time points during the 24 month follow-up period (early contact at Week 6, then quarterly contacts)
- The current results are based on interim analysis performed at Month 6
- Baseline clinical and demographic data were collected by enrolling physicians. Then, the medical confirmation of Eoi detected through telephone interviews was ensured by the involvement of the concerned Eoi's treating physician on an individual basis

Results

- Overall 10,567 patients were enrolled and returned their COF
- Out of 28,946 contact attempts performed, 83.6% were successful (patient or relative reached), and questionnaires were actually assessed in 93.7% of the successful contacts. These successful contact rates increased over time (from 76.5% at week 6 to 89.2% at Month 6)
- At Month 6, 4.2% patients withdrew their consent, 2.1% passed away
- Among the 1,130 attempts to contact Event Treating Physicians (ETPs) for Eoi confirmation, 78.6% physicians were reached
- The process for medical confirmation of the Eoi was accepted by 94.5% of ETPs reached, despite strong variations depending on the country. Given that reminders and other escalating processes are performed to optimize the return of Eoi medical confirmation form, final rates for this actual return will be calculated at the end of the study (current interim rate for Eoi return is 63.7%)

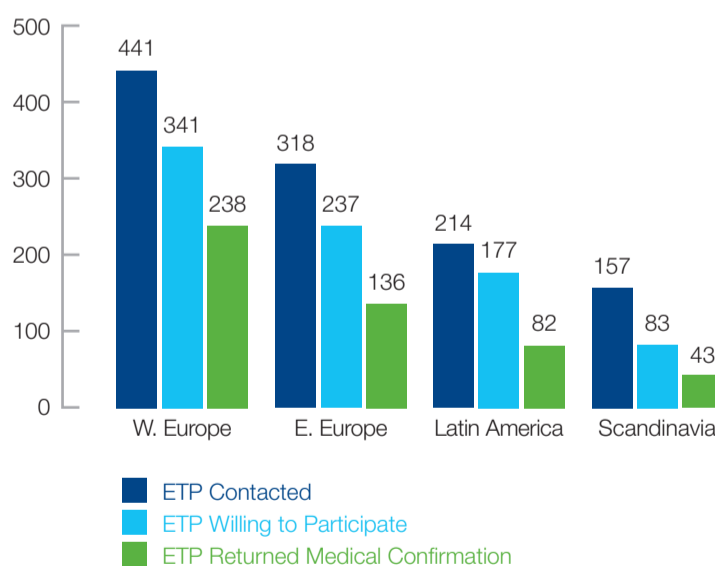
Table 1. Reason for missing assessments over time (excluding withdrawn consent and patients passed away)

	N	%
Reason for missing assessments over time:	5,757	100.0
All contact attempts unsuccessful for this contact (despite 6 attempts at different days and times)	2,617	45.5
COF incomplete, contact details not valid, COF received too late	1,630	28.3
Patient not willing to collaborate for this contact	1,025	17.8
Other reasons (e.g. do not speak the usual country language, technical issues with mobile phone/land line, deaf subjects, etc.)	485	8.4

Table 2. Reason for missing Eoi qualification

	N	%
Reason for missing Eoi qualification:	291	100.0
ETP contact details not available/ETP not identified	135	46.4
ETP unreachable (despite 6 attempts)	107	36.8
ETP not willing to qualify the Eoi	25	8.6
ETP not able to qualify the Eoi	24	8.2

Graph 1. Event Treating Physician participation



Conclusions

The results of this study are in accordance with our previous experience and confirms the benefits of using DtPC in international, observational and longitudinal studies. This process enabled a harmonized and centralized method to obtain real life data overview for all patients included, whatever their country, a high level of patient adherence and a low rate of patient withdrawal, despite the large number of countries involved.