WHICH ePRO MODALITY IS APPROPRIATE FOR YOUR STUDY?

Jennifer Ross (MS, M.Phil.Ed.), Eric Ross (BA), & Graham Nicholls (MSc)

OBJECTIVES

To provide guidance in the decision-making process of selecting the most suitable electronic patient-reported outcomes (ePRO) modality to collect data efficiently.

METHODOLOGY

Based on experience/expertise, three study scenarios are provided that illustrate the evaluation of ePRO modalities in selected situations. Study scenarios are based on individual study characteristics and appropriate ePRO modality choice. Each scenario is required to record the Patient Requested Outcome (PRO) data electronically.

Study characteristics (location, therapeutic area, target enrollment) and situations (relevant diary factors—description, setting, design, length, frequency, etc.) are defined for each scenario (see below).

RESULTS

The ePRO selection should be considered prior to or during Phase II, such that the optimal implementation approach is in place when the product enters Phase III.

Planning is key for the successful implementation of ePRO—which includes the appropriate training of sites and patients on the practicalities of data entry.

EVALUATION

Factors for Evaluation:

1) Choosing the appropriate ePRO modality should be based on a number of different factors, which have been summarized in the three categorizations below:
2) Diary factors: Length of study, frequency of diary, duration of diary, number of response options, number of questions, diary design, visual requirements, setting (location of where diary is conducted—home-based or other)
3) Logistical factors: Location of study, supply requirements, access (phone, internet, equipment), costs, timelines, study budget, etc. (See Table 1).

EVALUATION

Factors for Evaluation:

1) Choosing the appropriate ePRO modality should be based on a number of different factors, which have been summarized in the three categorizations below:
2) Diary factors: Length of study, frequency of diary, duration of diary, number of response options, number of questions, diary design, visual requirements, setting (location of where diary is conducted—home-based or other)
3) Logistical factors: Location of study, supply requirements, access (phone, internet, equipment), costs, timelines, study budget, etc. (See Table 1).

RESULTS

The ePRO selection should be considered prior to or during Phase II, such that the optimal implementation approach is in place when the product enters Phase III.

Planning is key for the successful implementation of ePRO—which includes the appropriate training of sites and patients on the practicalities of data entry.

EVALUATION

Factors for Evaluation:

1) Choosing the appropriate ePRO modality should be based on a number of different factors, which have been summarized in the three categorizations below:
2) Diary factors: Length of study, frequency of diary, duration of diary, number of response options, number of questions, diary design, visual requirements, setting (location of where diary is conducted—home-based or other)
3) Logistical factors: Location of study, supply requirements, access (phone, internet, equipment), costs, timelines, study budget, etc. (See Table 1).

RESULTS

The ePRO selection should be considered prior to or during Phase II, such that the optimal implementation approach is in place when the product enters Phase III.

Planning is key for the successful implementation of ePRO—which includes the appropriate training of sites and patients on the practicalities of data entry.

EVALUATION

Factors for Evaluation:

1) Choosing the appropriate ePRO modality should be based on a number of different factors, which have been summarized in the three categorizations below:
2) Diary factors: Length of study, frequency of diary, duration of diary, number of response options, number of questions, diary design, visual requirements, setting (location of where diary is conducted—home-based or other)
3) Logistical factors: Location of study, supply requirements, access (phone, internet, equipment), costs, timelines, study budget, etc. (See Table 1).

RESULTS

The ePRO selection should be considered prior to or during Phase II, such that the optimal implementation approach is in place when the product enters Phase III.

Planning is key for the successful implementation of ePRO—which includes the appropriate training of sites and patients on the practicalities of data entry.

EVALUATION

Factors for Evaluation:

1) Choosing the appropriate ePRO modality should be based on a number of different factors, which have been summarized in the three categorizations below:
2) Diary factors: Length of study, frequency of diary, duration of diary, number of response options, number of questions, diary design, visual requirements, setting (location of where diary is conducted—home-based or other)
3) Logistical factors: Location of study, supply requirements, access (phone, internet, equipment), costs, timelines, study budget, etc. (See Table 1).