Piloting ePRO capabilities in DFexplore

Abigail Isaacson, 26 September 2019
PRO 101

• “Patient reported outcome” data captures subjective, perceived responses
• Common for measuring:
  – primary outcome
  – data that cannot be directly quantified
  – out-of-window data
• Questionnaires must be well-designed and validated
• Collected data does not need querying or SDV
*patient-reported*
ePRO 101

• Electronic PRO:
  – greater data accuracy
  – avoids "parking lot" and recall bias
  – readily available endpoint data
  – lower long-term study costs
# (e)PRO Considerations

<table>
<thead>
<tr>
<th></th>
<th>Startup Resources</th>
<th>Setup Time</th>
<th>Cost</th>
<th>Data Accuracy</th>
<th>Subject Compliance</th>
<th>Data Accessibility</th>
<th>Subject Training</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Paper-based PRO</strong></td>
<td>Fewer startup resources</td>
<td>Less setup time</td>
<td>Less startup costs, potentially higher study costs overall</td>
<td>More prone to errors (legibility, data entry)</td>
<td>Data not definitively tied to time of entry</td>
<td>Lag in manual data entry time into database CRF</td>
<td>Minor questionnaire training (most people are familiar)</td>
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<tr>
<td><strong>ePRO</strong></td>
<td>More startup resources (unless organization is already using ePRO)</td>
<td>More setup time (unless reusing similar ePRO instruments)</td>
<td>Startup costs higher, overall study costs may be lower</td>
<td>Less prone to errors (data entry and legibility irrelevant)</td>
<td>Better monitored with time and date stamps</td>
<td>Faster access if electronically integrated with clinical database</td>
<td>May need greater training in data capture instrument (instructions can be electronic)</td>
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</tbody>
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Background

- "Hybrid" pain study, U.S. sites, 50 subjects ages 18-75
- Six validated scale paper PROs submitted via DFsend
  - Sleep, depression, pain, change and withdrawal assessments
- ePRO for primary outcome
  - daily pain assessment (1-10 scale) + study drug adherence via smartphone for ~100 days
  - how to get ePRO data into DFexplore?
(Complex) Process

1. Create study account with external text messaging company
2. Create daily survey in Google Forms
3. Train sites to sign screened subjects up for texts
4. Sites notify DF/Net when a new screened subject is ready for daily surveys
5. Create a copy of the Google survey, link it to the subject screening ID, schedules recurring daily text
6. Subjects receive text link each day
7. Submitted data is imported from Google Sheets into DFexplore
Visual Process

Welcome to the Omni-Pain 201

ePRO signup page

- Name (First, Last):
- ePRO ID:
- Mobile Number:

Pain Scale

On a scale of 0-10, with 10 being the worst pain and 0 being no pain, point to the number that best describes your pain?

No Pain | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Worst Pain

File | Edit | View | Insert | Format | Date | Tools | Form | Add-ons

Timestamp

1. Collection date: 26SEP2018
2. Collection Time: 19:17

Currently on Study Drug, please answer

Data of tablets taken

1. 6/28/2018 10:01:23
2. 6/28/2018 18:27:52
3. 6/28/2018 17:46:08
4. 7/10/2016 8:12:53
5. 7/10/2016 8:01:16
6. 7/10/2016 9:13:39
7. 7/10/2016 6:15:53

Subjects ID: 01102
ePRO ID: 00478
Visit Number: 0001

- Subject ID:
- ePRO ID:
- Visit Number:

Daily Survey

- Collection date:
- Collection Time:

Currently on Study Drug, please answer

1. Take any acetaminophen today?
   - Yes
   - No

2. Did you have any side-effect or illness in the last day?
   - Yes
   - No

3. Today, not including the study drug or acetaminophen, did you start or stop any medication(s) or treatments?
   - Yes
   - No

DFUG 2019
Achievements

• Integration of an external text messaging platform
• Complex company collaboration (extreme startup resourcing involving IT, DA, QA and DM)
  – Running smoothly and manageable on a small scale
• Google flexibility and question branching
• Affordable
• Tight training and communication from DF/Net> site coordinators
Challenges

• External platform inflexibility (not intended for clinical research)
• Subject confidentiality
• External data security
• Multiple moving pieces = more room for human error, not scalable
• Fragile process, highly dependent on Google
• Testing process (phone carrier blockages)
• Potential technical difficulties with some of the older study population
• Inability to troubleshoot directly with enrollees/subjects
• Difficult to measure site>subject training quality
• ePRO questions from sponsor, not validated instrument
Questions?
Simulate subject ePRO experience
'dfug' to 844-567-6664 (OMNI)
Have you collected ePRO data?
How would you begin?
What would be your concerns, as a sponsor, subject, site staff, or data manager?
What future innovations could simplify and scale this process?

DEMO AND DISCUSSION
Thank You

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