Regulatory Acceptance of Patient-Reported Outcome (PRO) Data from Bring-Your-Own-Device (BYOD) Solutions to Support Medical Product Labeling Claims

June 16, 2022 11 am ET
But first, housekeeping

- Please note today’s session is being recorded
- To ask a question for discussion during Q&A, please:
  - Either ‘raise your hand’ in the participant window and moderator will unmute you to ask your question live, or
  - Type your question into the chat box
- Slides and recording will be available after today’s session
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Key Points

- Hesitation from trial sponsors due to:
  - concerns around data quality, integrity, and variability
  - regulatory acceptance uncertainties
  - lack of formal guidance around BYOD from regulators

- So, important considerations for BYOD concern the conservation of the measurement properties of validated instruments when used on screens of different sizes, and the technical and practical considerations related to use of the patient’s own mobile devices or computers
A regulatory approved labelling claim based on ePRO data collected using BYOD has occurred!!!!!!

The Pfizer and BioNTech mRNA Vaccine study for the treatment of COVID-19 collected PRO safety data from over 40,000 participants worldwide using an electronic diary, with 79% of participants using their own device (BYOD) and 29% using a provisioned device.

**BUT....... We need more evidence......**

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>TI</th>
<th>Product name</th>
<th>Study phase</th>
<th>Endpoint position and Type</th>
<th>PROM</th>
<th>PRO endpoint</th>
<th>% of BYOD</th>
<th>ClinicalTrials.gov identifier</th>
<th>Approval agencies</th>
<th>PI link</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioNTech SE, Pfizer</td>
<td>COVID-19</td>
<td>COMIRNATY</td>
<td>Phase 3</td>
<td>Primary safety</td>
<td>Solicited local and systemic reaction diary</td>
<td>% of participants reporting the following for 7 days after Dose1, 2, and 3: pain, redness, and swelling at injection site, fatigue, headache, muscle pain, chills, joint pain, fever, vomiting, diarrhea</td>
<td>79%</td>
<td>NCT04713553</td>
<td>FDA, EMA</td>
<td><a href="https://www.fda.gov/medial/151707/download">https://www.fda.gov/medial/151707/download</a></td>
</tr>
</tbody>
</table>

TI therapeutic indication, PROM patient reported outcome measure, BYOD bring your own device, PI package insert
A call to action:
Pledge your intention to contribute to a database of PRO endpoints captured via BYOD used in medical product labelling

https://lnkd.in/e-VZe7e2

Article link: https://link.springer.com/article/10.1007/s43441-022-00412-1
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June 16, 2022 11am ET
IMPACT
Virtual First Medical Practice Collaboration

Care Transitions
Supporting Effective Virtual First Care (V1C)

Public Launch Event
June 28, 2022 | 1:30 p.m. ET
Moving from “Should Do” to “How To”
A deep dive into the DATAcc Toolkits for Inclusivity with the creators

July 12, 2022 11am ET
Sensor data integrations to power better decisions, faster, across healthcare & research

Public launch event

July 18, 2021 | 10.30am - noon ET
THANK YOU