Kayentis

Global provider of eCOA and patient-centric solutions

Infography: planning an oncology study with eCOA/ePRO

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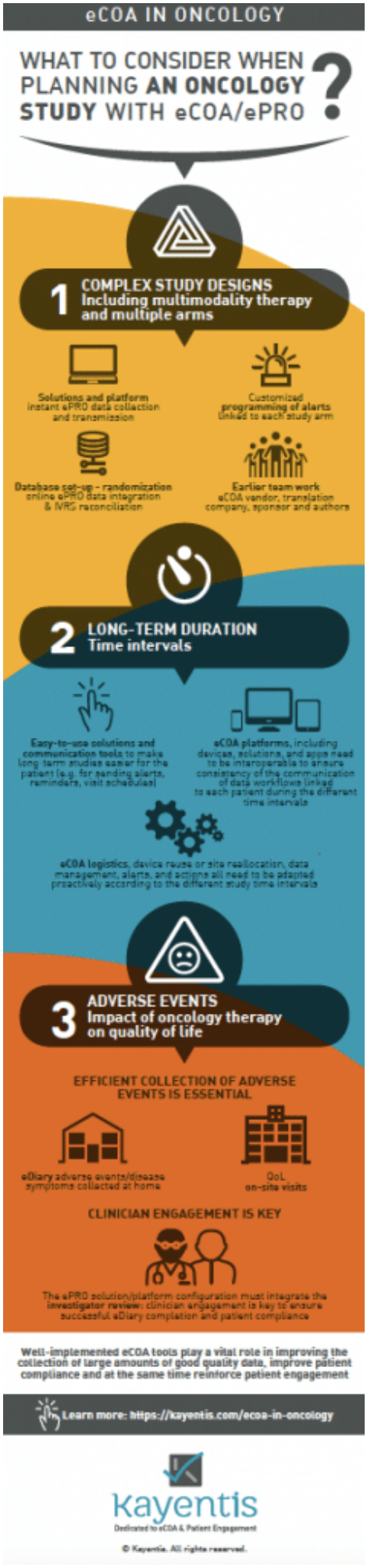
The FDA has provided guidance on methodology to be used for developing and using PRO in oncology drug development programmes, and has emphasized the increased importance on patient input in clinical trials. In addition to QoL, many PRO questionnaires are used to assess complementary areas in oncology study, including: disease related symptoms (pain or fatigue), physical/social/emotional aspects, symptomatic adverse events, and satisfaction with the care provided.

Using eCOA for oncology trials can be particularly challenging because of the range of therapeutic approaches. Key components should be taken into consideration in your oncology study to ensure the success of eCOA implementation.

To download the infography, click here:


eCOA IN ONCOLOGY
WHAT TO CONSIDER WHEN PLANNING AN ONCOLOGY STUDY WITH eCOA/ePRO ?
1 COMPLEX STUDY DESIGNS
Including multimodality therapy and multiple arms
Solutions and platform instant ePRO data collection and transmission
Customized programming of alarms linked to each study arm
Database set-up - randomization online ePRO data integration & IVRS reconciliation
Earlier team work eCOA vendor, translation company, sponsor and authors
2 LONG-TERM DURATION
Time intervals
Easy-to-use solutions and communication tools to make long-term studies easier for the patient (e.g. for sending alerts, reminders, visit schedules)
eCOA platforms, including devices, solutions, and apps need to be interoperable to ensure consistency of the communication of data workflows linked to each patient during the different time intervals
eCOA logistics, device reuse or site reallocation, data management, alerts, and actions all need to be adapted proactively according to the different study time intervals
3 ADVERSE EVENTS
Impact of oncology therapy on quality of life
EFFICIENT COLLECTION OF ADVERSE EVENTS IS ESSENTIAL
eDiary adverse events/disease symptoms collected at home
QoL on-site visits
CLINICIAN ENGAGEMENT IS KEY
The ePRO solution/platform configuration must integrate the investigator review: clinician engagement is key to ensure successful eDiary completion and patient compliance
Well-implemented eCOA tools play a vital role in improving the collection of large amounts of good quality data, improve patient compliance and at the same time reinforce patient engagement
Learn more: https://kayentis.com/ecoa-in-oncology
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Dedicated to eCOA & Patient Engagement
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