Compliance and Design Features of Electronic Participant-Reported Dosing Diaries

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Disclosure Statement: The authors are employees of Clario.

Background & Objectives

The extent to which participants adhere to prescribed dosing regimens is a critical factor in clinical trials and a regulatory priority[1].

- Adherence to study drug regime can increase the power of a study by decreasing variability unrelated to the study drug.

Participant-reported dosing using electronic diaries (eDiaries) is valuable in evaluating drug adherence by providing near-real time data for site monitoring and intervention.

The Present Study examined electronic dosing diary completion across studies and described design features that can impact data integrity.

Methods

Data from 16 studies across phases and multiple therapeutic areas were analyzed for content and compliance with at-home dosing eDiaries using Clario's app.

Results

eDiary Content Analysis

Sample & Study Characteristics

16 trials with dosing diaries were identified in the metadata based on the name of the diary.

Phases: 5 Phase III, 9 Phase II, and 2 Phase I trials
Therapeutic Areas: 5 dermatology trials, 3 central nervous system trials, 2 immunology trials, 2 respiratory trials, and 1 trial each of: oncology, hypoparathyroidism, myelofibrosis, and liver disease
Type of study drug: 12 oral meds, 3 topical applications and 1 self-injection
Participants: All studies included adult participants, 2 studies included ages 12 and up with functionality for caregivers to complete the eDiary on behalf of younger participants.

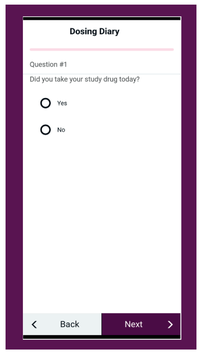

Figure 1: Example screen from a dosing diary.

Electronic Design Features

All diaries were programmed with reminder alarms, emails to sites when 1 or 2 consecutive diaries were missed, and an on-demand compliance report.

eDiary Content

Few studies included instructional screens. Dose timing was collected in most diaries (n=14); for the remaining 2 diaries, a morning and evening report design implied time of day for the study drug intake. A question to confirm if a dose was missed was included in about half of the diaries, and only two studies included a question about the reason for reporting a missed dose. See Table 1.

Table 1: Common questions types across dosing diaries in 16 clinical trials

Content across 16 clinical trials with Dosing Diaries	
Question	Number of Trials
Instructions about the diary	1 (6%)
Instructions about dosing	4 (25%)
Did you take your study drug?	15 (94%)
Confirmation screen for missed dose entry (e.g. You indicated you did not take the study drug, if this is correct select "Next". If this is NOT correct, please select "Back".)	7 (44%)
Reason for reporting a missed dose	2 (13%)
What time did you take/apply the study drug?	14 (88%)

Results

eDiary Compliance Analysis

Sample & Study Characteristics

9 trials, Included: dosing diaries designed to be entered either once per day or twice per day. Excluded: trials with fewer than 10 participants.

Phases: 2 Phase III, 6 Phase II, and 1 Phase I trials
Therapeutic Areas: See Figure 2
Type of study drug: 6 oral meds, 2 topical applications and 1 self-injection
Participants: See content analysis

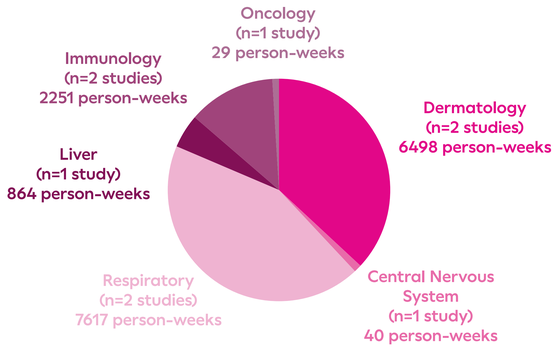

Figure 2: Amount of data (number of weeks on an individial person-level) that contributed to the compliance analysis

Diary Compliance by Diary Frequency

Compliance was similar for eDiary designs that required one entry per day (88%, n=5 studies) and designs that required two entries per day (89%, n=4 studies).

- **One entry per day**: In 4/5 trials, eDiaries were available all day for a study drug taken 1x/day. In 1/5 trials, diary availability was limited to evening hours for a study drug taken 2x/day (morning and evening) reported via two separate questions.
- **Two entries per day** : Morning diaries: In 1/4 trials, morning diaries were available all day. In 3/4 trials, the morning diary had limited availability that prevented entries after a certain time. Evening diaries: 4/4 trials had limited availability that prevented entries earlier than a certain time.

Compliance remained high over time, with 88% of diaries completed at 12 weeks across the sample, see Figure 3.

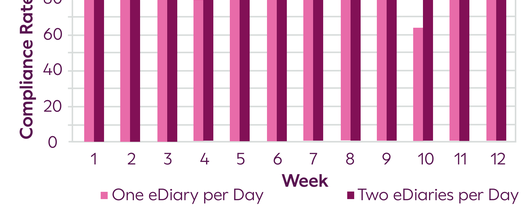

Figure 3: Average compliance over 12 weeks for dosing diaries that were to be completed once per day or twice per day

Conclusions

- The varied content of these dosing diaries suggests there is a need for more consistency and standardization of requirements to support data quality.
- The high compliance across studies and over time suggests that eDiaries are a feasible approach for assessing drug adherence in clinical trials.
- More work is needed to determine whether compliance with an eDiary is a useful proxy for, and the features that contribute to, dosing adherence.
- As we continue to advance in the development of therapies, optimizing participant-reported dosing using eDiaries will remain a critical component in testing drug efficacy and safety.

Reference

[1] US Food and Drug Administration. Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products: Guidance for Industry. Final. FDA; March 2019.

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