

March 18, 2019

Design of Patient Centric Trials

Case Examples: **CoDESIGN** - Eli Lilly and Company

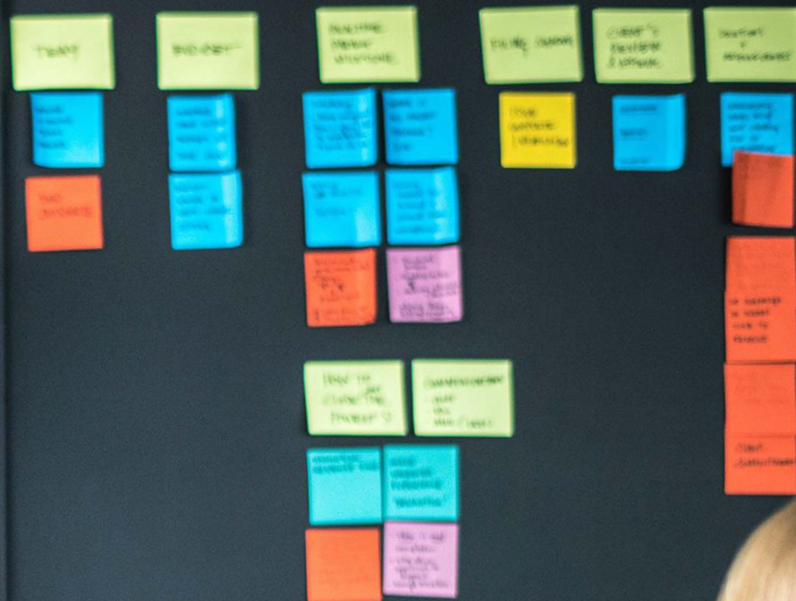
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Disclaimer

The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative (CTTI) or the U.S. Food & Drug Administration (FDA).

CODES



PURPOSE: Ensure Lilly's **Clinical Programs and Trials** are designed to **provide exceptional experiences** for patients & research professionals

MISSION: Utilize the CoDESIGN experience to **understand and appreciate the needs of individual Clinical Programs and Trials** by ensuring trial designs are...



Thoughtfully
supportive of the
patient



Implemented
effectively by
sites



Differentiated
against the market
by payers



Meet the safety and
efficacy thresholds
set by regulatory
bodies

Case Study 1 - Endpoints

- **Endpoints**

- **Problem:**

- While FDA approved end points might be focused on evidentiary disease progression/modification, measurement of symptomatic relief can be strongly desired.

- **Outcome:**

- Patients help us to include these as endpoints based on their feedback

Case Study 2 - Procedures

■ Timing/Volume of Procedures

■ Problem:

- Study team was unsure of number of procedures or the timing between them
- Were they out of sync with the practical realities of the health care system or patient lives?

■ Outcome:

- Through patient and site collaboration, Lilly is often able to uncover these scenarios and have redesigned the schedule of procedures as a result.

Case Study 3 - Invasiveness

■ Invasive Procedures

- Problem:
 - Invasive procedure proposed in an immunocompromised patient
- Outcome:
 - Patients informed us that this was a non-starter. Protocol changed procedure to “optional.”

Case Study 4 – Drug appearance

- **Drug Appearance**

- **Problem:**

- Multiple pills involved and they all share a similar look

- **Outcome:**

- Patients helped to create solutions to help make sense of the different pills and any associated activities

Case Study 5 – IRB perspectives

- IRB perspectives

- Problem:

- Digital health wearable desired as a solution to help patients participate successfully
 - Historically, not viewed favorably by IRBs

- Outcome:

- Lilly collected strong site and patient feedback on better ways to support patients with digital health wearable

Questions