A literature review of methodology used in in-trial interview-studies in clinical development

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Alladin A[1], Barrio J[1], Dikariyanto V[1], Venerus M[1], Rolst M[2], Krol M[1]

[1]IQVIA, London, United Kingdom
[2]Novo Nordisk, Copenhagen, Denmark

BACKGROUND & OBJECTIVES

- Patient experience data on the clinical trial, their disease and the treatment can be collected through in-trial interviews (ITIs) at different timepoints during the trial. Information from ITIs helps provide context to quantitative data and clinical measures collected, and adds value to stakeholder communications
- This study aimed to:
  i. Analyze the research questions and methods in recent qualitative in-trial interviews (ITI) study publications, and
  ii. Identify the value that ITI studies provide during clinical development

METHODOLOGY

- ITI studies published in the last 10 years were identified via PubMed search. Further screening was conducted to select qualitative studies involving patient interviews associated with a clinical trial
- Extracted data included clinical trial intervention and phase, ITI's research questions, design, execution and reporting of ITIs, ITI timing and frequency, and sample size, methodology and blinding of the qualitative studies

RESULTS

- Fifteen publications were included covering a range of diseases (oncology, mental health, diabetes, gynecology, and Alzheimer's disease).
- The main objectives of the ITI studies were to understand patients' experiences with the disease, treatments, and the clinical trial, as well as patient preference.
- The ITI studies were conducted at different timepoints in the trial (baseline, mid-point, exit interviews), and most commonly in drug trials across all phases of clinical development. Different patient experiences were collected at different timepoints. Exit interviews were most frequently conducted (n=14 [All except 3]).
- Patients can be interviewed at multiple timepoints during the clinical trial if relevant to the research question. Three studies included interviews conducted at multiple timepoints (e.g., baseline and exit interviews [3,6,15]). Research objectives, data available, population groups or logistics are some of the variables that may affect the decision of conducting one or more qualitative interviews with patients.
- Nine ITI studies [3,4,6,7,8,9,10,12,13] were considered part of the trial and included in the clinical study protocol (CSP), rather that as stand-alone studies, but patients could be in the trial without consenting the interviews.
- On average, ~9% of trial participants were included in the ITI study, commonly via non-probability sampling.
- Eight studies [4,5,6,7,10,12,14,15] specified using semi-structured interview guides.
- Seven studies informed the mode of interviews (either via telephone (n=5 [5,6,8,11,13]) or face-to-face (n=2 [3,9])).
- One study explicitly referred to GDPR and GCP [3] compliance measures and two [3,7] studies mentioned safety reporting procedures

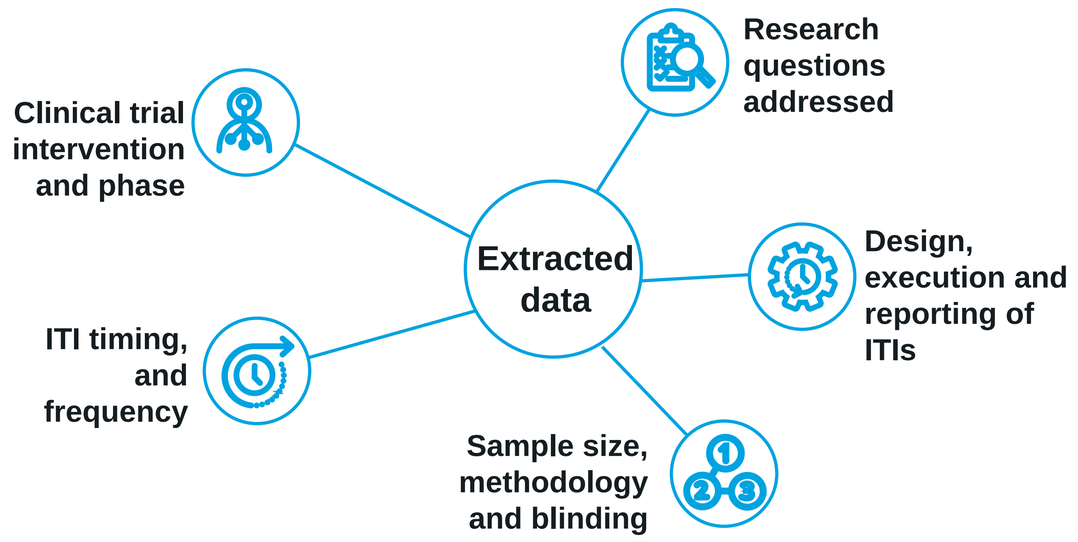
CONCLUSIONS

In-trial interviews are being used in clinical development to help understand patients' experiences and preferences

When to conduct interviews depends on the research questions and operational considerations

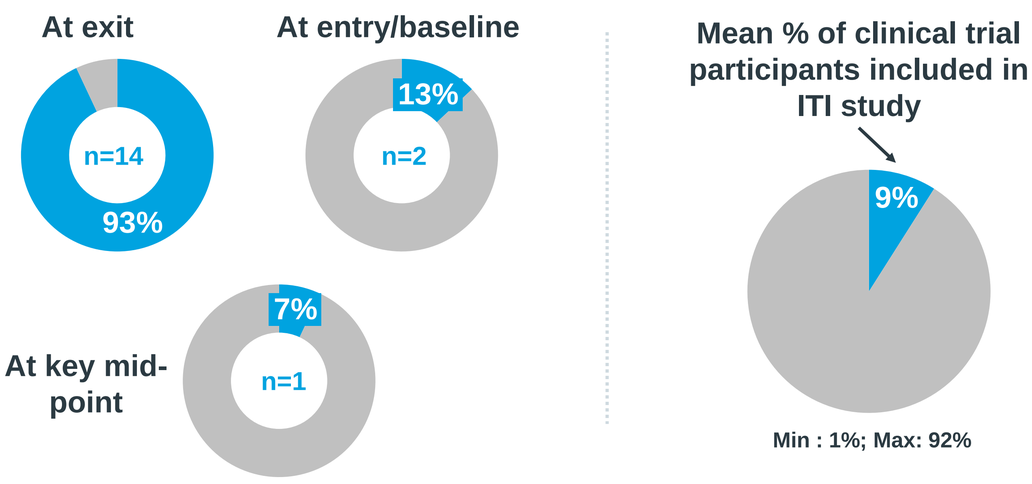
Potential use of In-Trial Interview outcomes

Data domains extracted from published ITI studies



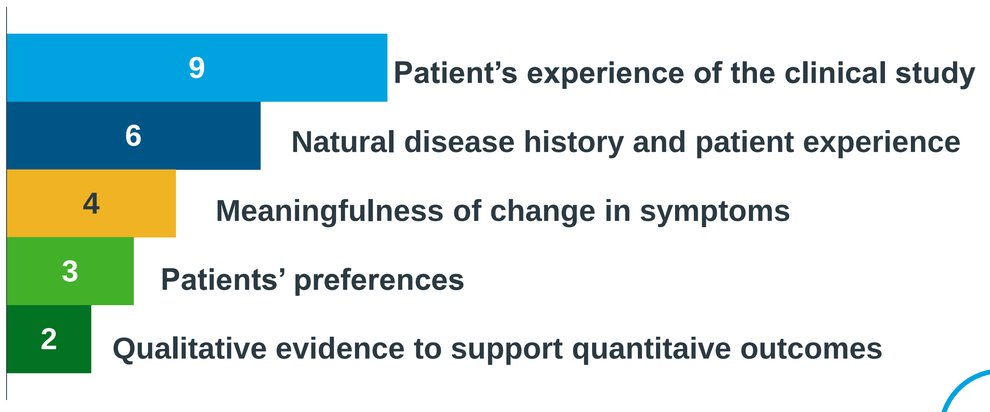
When and with whom are ITIs conducted?

(n=15 studies)



What are the common research questions addressed?

(n=15 studies)



Importance of in-trial interviews is steadily increasing, with the most notable impact observed on regulatory decision making. Qualitative data has been included in label claims/marketing authorizations by the US FDA and EMA

1. Simmons A *et al*., *Cambridge Core* (2021)
2. Sawyer C *et al., BMJ Open* (2021)
3. Wode K et al., *Trials* (2020)
4. Ahmadopour P et al., *Reprod. Health* (2020)
5. Lapuerta P *Clin Ther* (2019)
6. Warnock C *et al., Trials* (2019))
7. Lewis S *et al., The Patient* (2019)
8. Ta NH *et al., Rhinology* (2019)
9. Coppell K *et al., BMJ Open* (2019)
10. De Fonseka D *et al., Trials* (2018)
11. Pierce AL et al., *Alzheimer Dis Assoc Disord* (2018)
12. Di Benedetti D, *Clin Ther.* (2017)
13. Ervin CM *et al., Adv Ther.* (2017)
14. Vloemans AF *et al., Diabetic Medicine* (2017)
15. Jenkins N *et al., Diabetic Medicine* (2011)

Abbreviations: ITI: In-trial interview; COA: Clinical Outcomes Assessment; GDPR: General Data Protection Regulation; GCP: Good Clinical Practice; FDA: Food and Drug Administration; EMA: European Medicines Agency

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