

Protocol Rigidity vs Patient Reality: Operation Barriers and Opportunities for Flexibility in Lung Cancer Clinical Trials

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01 INTRODUCTION

- Lung cancer clinical trials (LCCT) **protocols** require **commitment** and **schedule stability** from the **patients**. However, their lives are **mobile**, **changeable** and can collide with rigid schedules.
- There is a mismatch between protocol expectations and patients' reality.
- Operational adaptations and multicenter coordination are essential to reconcile protocol integrity with patient reality.

02 METHODS

RETROSPECTIVE ANALYSIS

26 LCCT PROTOCOLS

4 year-period

1. PROTOCOL RIGIDITY

Duration
Visit frequency
Visit windows

2. COMPARISON WITH SoC

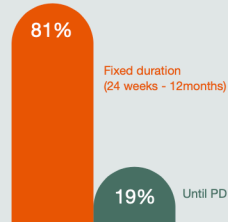
Specific activities
Time commitment

3.FLEXIBILITY PRECEDENTS

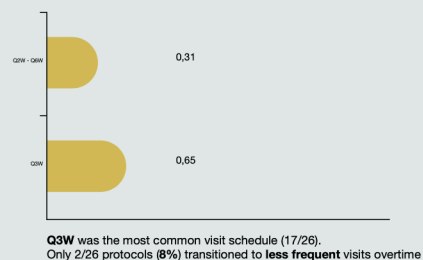
Decentralized clinical trials (DCT) elements
Emergency exceptions

03 RESULTS

TREATMENT DURATION



VISIT FREQUENCY



SoC vs. CLINICAL TRIAL ACTIVITIES

Trial-specific activities* entail a greater time commitment compared to SoC.
*PRO questionnaires, PK assessments, ECGs, post-dose observation, etc

FLEXIBILITY PRECEDENTS

65% of protocols permit emergency exceptions. Decentralized precedents include:

Home
healthcare

Virtual
consultations

Local
labs

Device support
specialists

Direct-to-patient
IP shipment
Only 1/26

TOTAL INDIVIDUAL PARTICIPATION

~30 weeks → 5 years
Participation varies widely from ~30 weeks to >5 years depending on follow-up

VISIT/ASSESSMENT WINDOWS

73%
+3 days

15%
+5-7 days

08%
+24 hours

04%
Transitions over time

Margins for visits/assessments range from flexible (5-7d) to more restrictive windows (24h)

Extra 114 min/visit on
trial-specific activities

Extra 40.50h/year on
trial-specific activities

04 DISCUSSION AND CONCLUSION

- Participation in LCCT is highly variable and long-term.
 - Narrow visit windows limit flexibility and may increase protocol deviations.
 - "Flexibility markers" can preserve data integrity while improving access and retention.
- KEY INSIGHT
- Existing emergency exceptions prove that **flexibility is possible**.
 - "Flexibility markers" should be integrated into standard protocol design.

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