Phase 1, First In Human, Safety, Dose Tolerance, Pharmacokinetics, and Pharmacodynamics Study of [IP] in Patients with Advanced Solid Tumors

Cmed
An Aixial Group Company

Trial

Design:

- 3+3 escalation to expansion
- Escalation: solid tumor
- Expansion: muscle invasive bladder cancer

Product: intravenous or subcutaneous administration, synthetic antifungal

Sites: 4 escalation, 7 expansion

Services: site management, project management monitoring, safety, medical monitoring, data and analytics, medical writing

Dates: 2017 to present

Successes

- Rapid site activation using proven study start up processes
- Enrollment ahead of schedule in escalation due to proactive cohort management, engaged investigators and minimal time between DLT close and Safety Review Committee meetings
- **Minimal time (> 3 days) to dose escalation review and decisions via use of encapsia exports and insights** allowing dose decisions to happen faster.
- **Information and data visibilty from encapsia** allowed Cmed management to seamlessly step into project work and each project transition burden on-site and sponsor teams.

Challenges with mitigations

- Slower than expected enrollment in expansion resolved by opening an additional site within the escalation site network.
- IP capping issue resolved by efficient collection and replacement of onsite IP material
- Team turnover addressed by Senior and Executive oversight.
- A younger client with limited budget mitigated by cross-functional client discussions looking at task and cost impact (positive and negative) of each protocol change being considered.

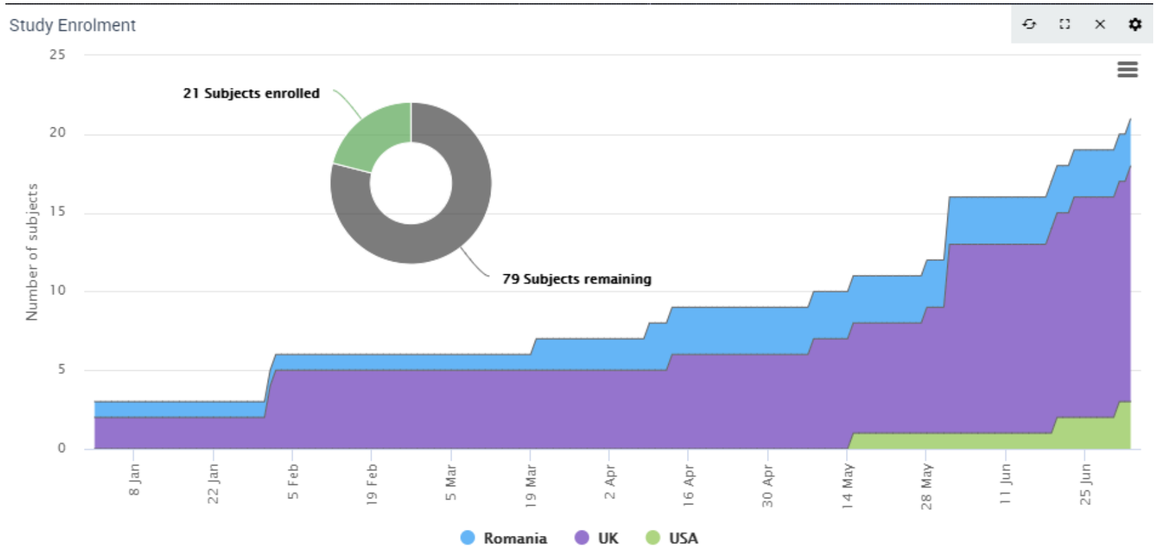

Fig 1. Study Enrollment. *A stacked area chart tracking the number of subjects enrolled during the study*

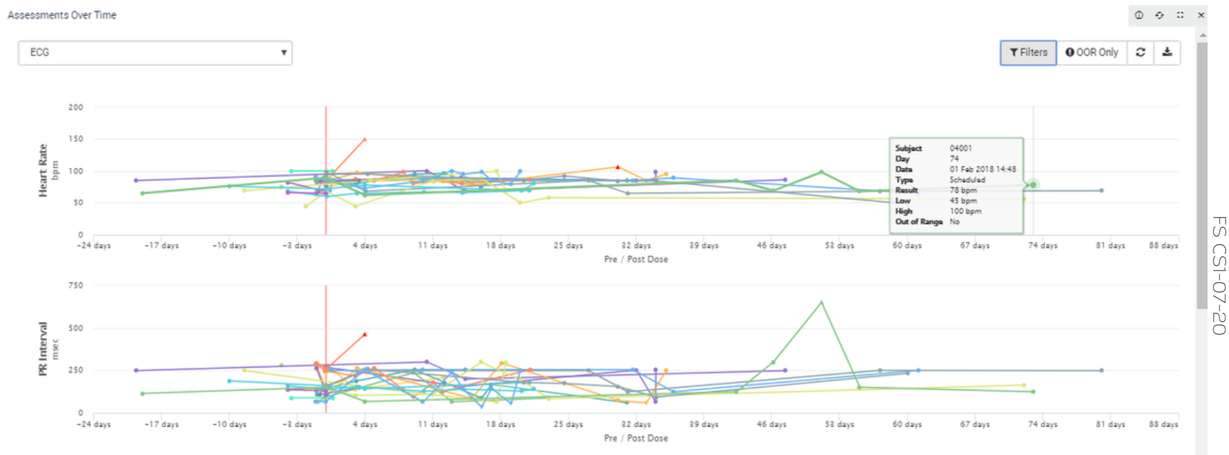

Fig 2. Assessments over time. *Displays line charts of assessment results overtime, highlighting out of range values*

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Results

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Trial Summary

Design:

- 3+3 escalation to expansion
- Escalation: solid tumor
- Expansion: single tumor type

Product:

- intravenous or subcutaneous administration
- synthetic antifungal

Sites: 4 escalation, 7 expansion

Services: Full Service

Dates: 2017 to present

Successes

- Rapid site activation using proven study start up processes
- Escalation enrollment ahead of schedule due to proactive cohort management, engaged investigators
- < 3 days to dose escalation review and decisions via use of encapsia exports and insights
- Information and data visibility from encapsia supported seamless project lead transition

Challenges with Mitigations

- Slower than expected enrollment in expansion resolved by opening an additional site within the escalation site network.
- IP capping issue resolved by efficient collection and replacement of onsite IP material
- Team turnover addressed by Senior and Executive oversight.
- Limited budget project mitigated by cross-functional client discussions looking at task and cost impact (positive and negative) of each protocol change being considered.

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