Phase I ADC Breast Cancer Case Study

A First In Human, Phase I/II Study of an Anitbody-Drug Conjugate in Patients with Advanced Solid Tumors

Trial Summary

Design:

- Accelerated-titration design followed by the standard "3+3" design
- Escalation: solid tumor
- Expansion: two pre-specified cohorts (TNBC and not TNBC)

Product: intravenous administration

Sites: 3 escalation (USA), (7 expansion USA & Europe)

Dates: 2019 to present

Services: Full Service

Successes

- Rapid site activation, ahead of schedule
- Enrollment ahead of schedule in escalation
- Cooperative engagement with sites during single enrollment slot availability
- Prompt dose escalation review and decisions by smart data entry support and easy data visibility using encapsia insights/patient profiles
- No DTLs and single SAE (to date) quickly handled with electronic reporting processes and advanced data visibility via encapsia

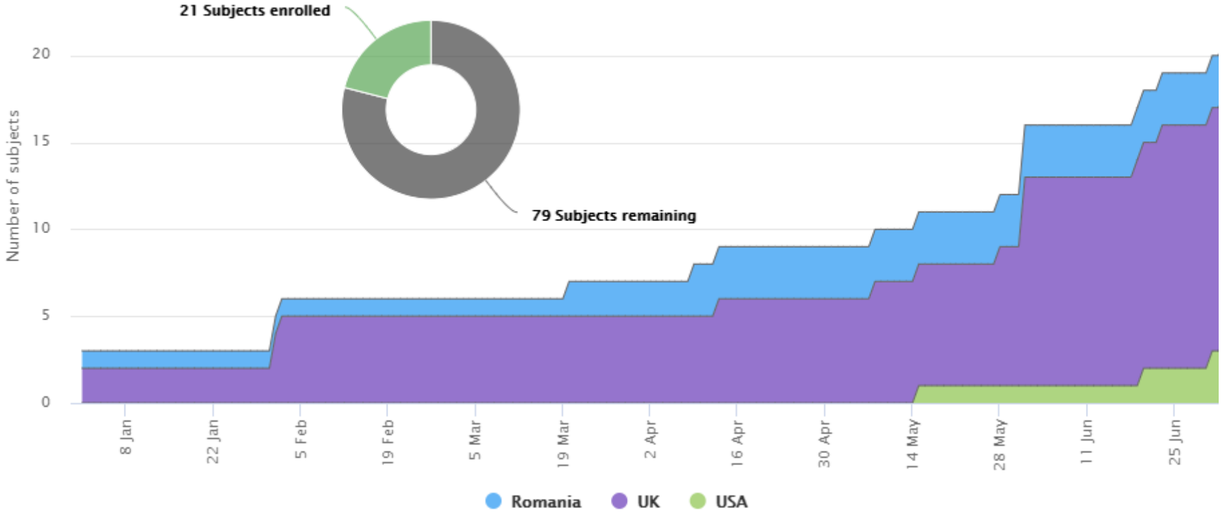

Fig 1. Real-time enrollment insight(s) support cohort management

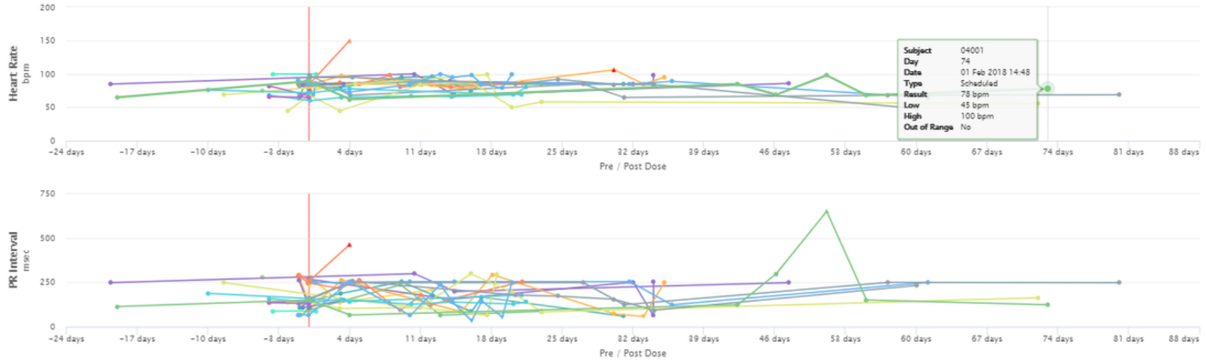

Fig 2 Real time, customizable results over time insights facilitate ongoing safety oversight

Challenges with Mitigations

- Multiple physicians supporting this trial have led to differences i opinion. Cmed established clear communication pathways to address and resolve differences quickly, to not impede enrollment, medical oversight, safety management, etc.
- Internal sponsor team turnover resulted in rework, but the Cmed team was able to support and resolve this quickly
- Cmed project manager turnover (n=1) addressed with senior oversight by stepping in to the project to apply their historical knowledge of the project to ease the transition burden on site and sponsor teams

Cmed
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