BACKGROUND

- Multinational academic clinical trials can encounter complex organisational issues.
- We describe our experience running the phase III ASCOLT trial (NCT00956708), investigating the impact of aspirin following surgery and standard adjuvant therapy in high risk colorectal cancer.
- This is the first large academic adjuvant trial fully conducted and overseen in the Asia Pacific (APAC) region.

Figure 1. ASCOLT Trial Design

Methods

- ASCOLT is coordinated by the National Cancer Centre Singapore and funded largely by academic grants.
- Following two years of preparation, the trial opened in Dec 2008.
- ASCOLT is nearing full accrual (1536 of 1587) at 58 sites in 12 countries/regions, including 5 middle income countries.
- Trial conduct was reviewed to document metrics relating to trial logistics and analyse barriers and enablers.

Figure 2. Countries and regions involved in the ASCOLT trial

RESULTS

- Diverse regulatory requirements necessitated:
  - >100 contracts
  - 49 ethics board reviews
  - start-up times of ~6 months per site
  - Consent Forms were translated into 13 languages
- The enrolment target and period were revised in 2017, and site numbers expanded in response to lower than projected accrual and event rates.
- Main challenges are listed in Table 1

Table 1. Challenges encountered during the trial

<table>
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<th>Challenges</th>
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<td>- Diverse regulatory requirements</td>
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<td>- Changes in local laws leading to recruitment holds</td>
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<td>- Limited funding for patient visits, particularly affecting countries where healthcare is not publicly funded</td>
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<td>- Communication and logistical barriers</td>
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<td>- Disparate experience and resources across sites</td>
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<td>- Lower than expected accrual and event rates, patient attrition</td>
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<td>- COVID-19 pandemic</td>
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- Strategies to overcome these included:
  - engaging local cooperative groups (e.g. the Australasian Gastro-Intestinal Trials Group in Australia and New Zealand)
  - using 6 contract research organisations to manage sites, to develop processes sensitive to local needs
  - transition to electronic data management relieving paper-based system inefficiencies
  - implementation of a centralised drug dispensing and transport system

CONCLUSIONS

- While ASCOLT highlights the feasibility and value of APAC academic collaborative trials, our challenges reflect the real-life complexities encountered in conducting a trial at a regional level, with cultural, linguistic, economic and regulatory diversity.
- An APAC academic GI trials consortium is suggested.

REFERENCES

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