Early Health Technology Assessment and Prospective Clinical Research: Implementation

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On behalf of the THETA Team
Field Evaluations like any Clinical Trial

- Clinical Trial Protocol
- Regulatory approval of study protocol
- Clinical Research Agreements
  - Outlining Terms of Finances & Publications etc.
- Research Ethics Board (REB) approval
- Good Clinical Practice (GCP)
But Field Evaluations are Broader than Just a Clinical Trial

- Other integrated components (economics)
  - Cannot run sub-studies in isolation
  - Need research/data sharing and authorship agreements
- Link to MAS/OHTAC
  - Need additional procedures for engagement at beginning, throughout and at end of field evaluation
- Research questions linked back to policy needs, not interests of clinical investigators
- Tie to dissemination (KT) and policy
Clinical Trial Design

• Efficacy and effectiveness and ‘pragmatic’ controlled trials
  • Is there a need to see how the technology works in a ‘real world’ setting?
• Usual criteria for study quality and levels of evidence
  • Randomized controlled trial
    • Cluster randomized controlled design
  • Non-randomized trial with controls (contemporaneous, historical)
  • Dose-ranging studies
  • Surveillance (registries)
• Case series
HTA Collaboration/Stakeholders

- Community Care Services
- Healthcare Organizations and Associations
- Government Advisory Groups
- Federal / Provincial Government
- Individual (Patient)
- Clinicians (Physicians, Nurses)
- Community and Academic Teaching Hospitals
- Academic Institutions and Research groups
- Health Technology Industry
- Other Governments

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Stakeholder Involvement/Engagement

- Creating multi-disciplinary and multi-stakeholder study working groups (SWG) is critical so that the stakeholders have “ownership” of the study and its findings
- Input into study design and reflection of Ontario healthcare setting (generalizability)
- Acceptance “buy-in” of study results by peers is enhanced
- Implementation is enhanced
Study Working Group

- Identify and assemble key stakeholders and leaders in the field
  - Opinion leaders
  - Clinical practice
  - Researchers/academics
  - Administrators
  - Stakeholders (lobby groups, industry - arms length)

- “Art” of identifying working group members
  - MAS review, publications, professional associations, presentations, word-of-mouth, collaborative, team player

- Not just a clinical trial of peer investigators
Site Selection

- Site selection based on:
  - Access to patient population (geographic distribution)
  - Past performance of investigator/site
  - Projected number of subjects/anticipated enrollment rate
  - Competing studies
  - Ability to attend orientation meeting
  - Availability of required specialized staff/equipment

- Activation of a single site takes on average 100 days
- ~20-50% of studies bring new sites late in the game to enhance enrollment (rescue missions)
Study Management

- Steering committees, adjudication committees, data safety and monitoring board (DSMB)
- Trial registration (clinicaltrials.gov)
- Site and investigator training and initiation meeting
- On-going site, investigator, study personnel monitoring and training
- Screening and recruitment procedures
- Support and communication
  - Newsletters, e-mails, telephone, regular and ad-hoc meetings, problem resolution
Data Management

- Method of capture (paper, fax, web, combination)
- Develop, pretest and revise CRFs
- Database design and management at methods centre
- Process for identifying missing information and inconsistent data capture (error checks, logic checks, double data entry)
- Process for queries to participating sites
- Updating and resolution procedures
Ongoing Administrative Maintenance

- Study reporting (e.g., accrual, data quality reports)
- Committee communication
- Determining and resolving study issues (e.g., slow recruitment)
- Study communication
  - Meetings/Teleconferences
  - Newsletters
  - Question/Answers
- REB yearly renewal tracking
- Protocol amendments
- CRF, database and clinical centres personnel changes

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Lessons and Challenges from the Post-market Studies (1/2)

- Patient population selection
  - Targeted to the patient group most frequently using technology balanced with where informational uncertainty is the greatest
- Feasibility assessment at the beginning
- Timing, recruitment, participation by centres
- Funding of technology
  - Harder to tie data collection to utilization of widely available technology
Lessons and Challenges from the Post-market Studies (2/2)

• Medical technology evolution
• Community-based research infrastructure
  ➢ Need to invest - so research activities are not a burden and an add-on to regular clinical activities
• Delivering evidence in a timely manner
  ➢ Research may take longer than policy makers are willing to wait
  ➢ Interim evaluations of data
Summary

- Field evaluations are broader with many integrated components
- Many stakeholders involved and creating multi-disciplinary and multi-stakeholder study working groups (SWG) is critical
- Many lessons and challenges from the post-market studies are applicable to pre-market studies
Early HTA and Prospective Clinical Research: Implementation

Acknowledgments - THETA

Thank you