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Toronto Health Economics and
Technology Assessment Collaborative

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)

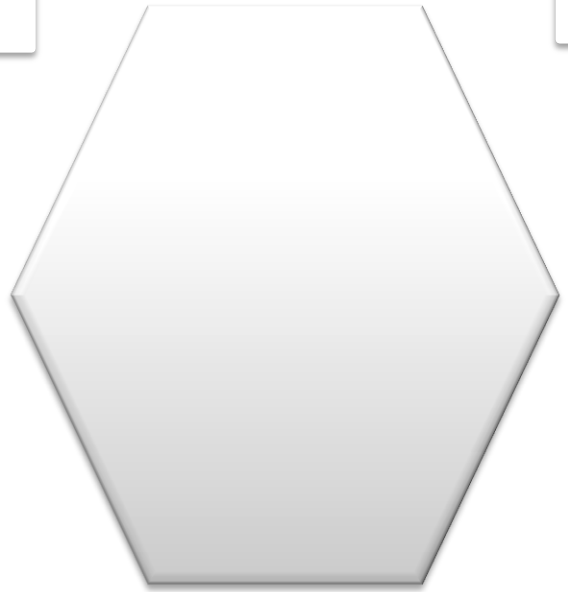
But Field Evaluations are Broader than Just a Clinical Trial

- 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



Individual (Patient)

Community Care Services

Community and Academic Teaching Hospitals

Healthcare Organizations and Associations

Academic Institutions and Research groups

Government Advisory Groups

Health Technology Industry

Federal /Provincial Government

Other Governments

Clinicians (Physicians, Nurses)

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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

Project Development

Scientific

- Acquisition of Clinical, Health System and Marketplace Knowledge
- Working Group, Study Planning and Writing Meetings
- Protocol Synopsis
- Study Feasibility and Logistics
- Protocol Development
- Case Report Forms

Financial and Administrative

- Initial and Detailed Study budget
- Financial Approval
- MOHLTC Peer Review
- Clinical Research Agreements Development and Approval
- REB and Institutional Approval

months

1.5 3 4.5 6

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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

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

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Acknowledgments – THETA

Thank you

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