Canadian Medical Devices Sentinel Network

Presentation to the Product Vigilance Workshop
May 29th, 2009

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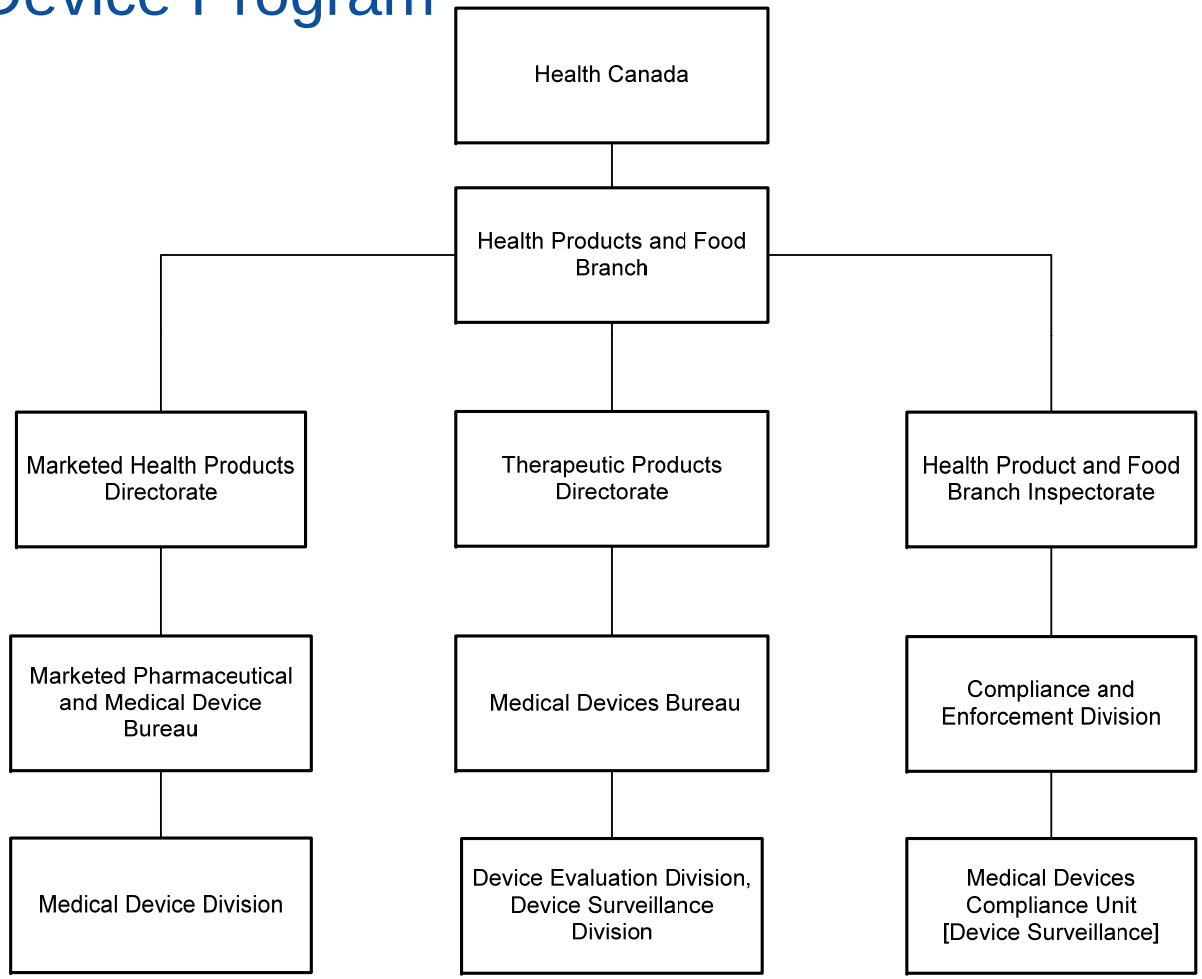
Objective of the Presentation

To provide information about a new medical device event reporting program being initiated within select health care facilities

Overview

- Describe medical devices event reporting with Health Canada?
- Is there a need for new approach?
- What is a sentinel surveillance system?
- Describe the steps taken to initiate a sentinel program here in Canada.
- Describe the Canadian Medical Devices Sentinel Network pilot. (see Appendix 2)

Medical Device Program



Medical Devices Reporting Requirements

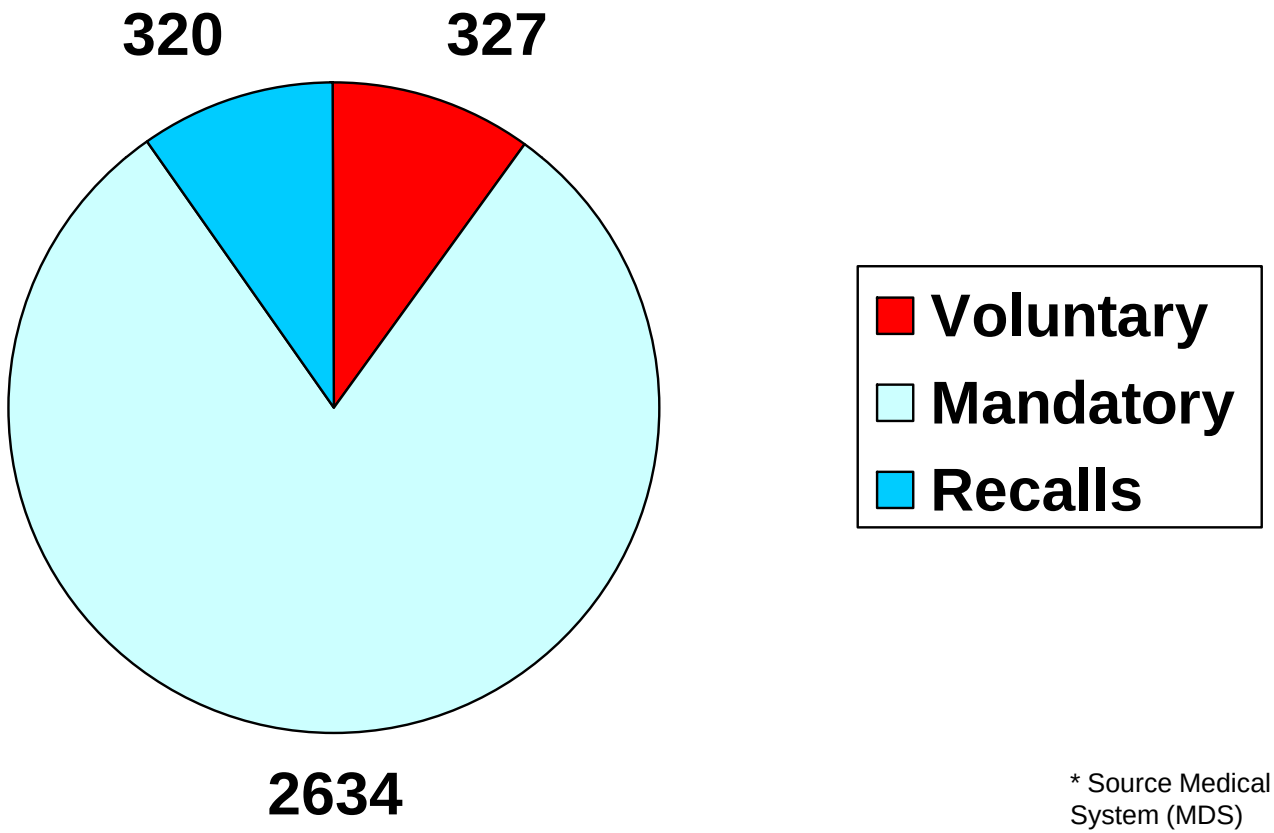
Manufacturers and importers are required to report incidents related to a medical device:

- Within 10 days: if an incident leads to death or a serious deterioration of health.

- Within 30 days: if an incident were to recur, could end in death or serious deterioration of health.

All other types of reports and reporters are voluntary.

Number of Medical Device Adverse Events Reported- 2008



* Source Medical Devices System (MDS)

Is There a Need for New Approach?

- Over 80, 000 devices currently licensed for sale in Canada; increase complexity care/technology
- Adverse medical device events have found to occur 83.7 times per 1,000 hospital admissions (Samore et al. 2004).
- Under reporting from clinical community (under 15% all reports); passive approach to collection
- Reports are device focused, not patient centred
- Technology required updating
  - Need modernized/more accessible report form
  - Not able to query database for patient outcomes

Auditor General report of Medical Device Program (2004) recommended a pro-active approach to post market medical device surveillance

What is a Sentinel Approach to Surveillance?

Sentinel system approach:

- It is a group of dedicated, trained health care facilities that report high quality data of adverse events associated with medical devices.

- It will provide a mechanism for enhanced 2-way communication with the clinical community.

Goal:

- The safety of Canadians will be impacted by better quality risk assessments and earlier regulatory interventions.

- It will provide citizens with timely information to make informed health choices will help them maintain and improve their health.

What Makes it Different?

Voluntary system

- Passive approach
- Universal system
- All types of reporters
  - no training
  - report for work/personal purposes
- All types of reports- more serious types valued?
- Basic information about adverse event
- Manual system to receive reports and enter them Medical Device System.
- Communication with Inspectorate only
- Delays ability to search for signals

Sentinel system

- Pro-active approach
- Subset of reporters
- Reporters are:
  - professionals with training
  - who report for the facility
- Any type of incident- near misses types more valued?
- Detailed reports on problem characteristics
- Web page report form, electronic system-database
- Feedback loop within network
- Provides early warning system for signals

Initiating the Sentinel System Project in Canada

- March 2004- Auditor General's recommendation
- May 2005- 2007- Review of other regulatory agencies, feasibility study
- Oct-Dec 2007- Project documents created
- Dec- Jan 2008- Stakeholder meetings
- July 2008- First sentinel health care facility recruited!! (St Joseph's in Hamilton)
- Sept 2008- Name chosen
  - **Canadian Medical Devices Sentinel Network /Réseau sentinelle canadien pour les matériels médicaux.**
    - Acronyms will be...**CMDSNet & ResSCMM** with the emphasis on networking!
- Dec 2008- Recruitment closed (12 centres)
- April, 2009- **Go live with pilot**

Others Using Sentinel Approaches?

Canada: IMPACT (Immunization Monitoring Program ACTive)

- Paediatric hospital-based national active surveillance network (12)
- Reports most serious adverse events following immunization, vaccine failures
- Designated nurse monitor and voluntary physician/centre
- IMPACT is administered by the Canadian Paediatric Society with funding from Public Health Agency of Canada.

United States: MedSun Approach

- Dedicated trained reporters- Voluntary
- Medical Devices specifically
- Providing feedback, sense of community
- Early warning of safety trends

Brazil: ANVISA

- Paid representatives in 100 hospitals
- All health products, disinfectants
- Network used to validate scope of problem
- Research/best practice focus

Feasibility Study of a Sentinel System

- Overview of Health Canada situation
- Interviews with 11 health care facilities- biomedical, risk management and nursing staff contacted
- Unaware of how to report to Health Canada
- Health Canada information used last; not timely
- No feedback from Health Canada
- Confidentiality and privacy not as big of a concern as in US
- Biggest concern: time required for reporting; <5-10 min
- Recommends Sentinel system; not a particular software tool

Business Requirements

- Electronic system, easily accessible
- Limited burden on reporter, <5-10 min
- Mix of mandatory fields & variety of data entry methods
- Compatible & linked with other Health Canada tables & databases
- Complies with Health Canada privacy and software requirements
- Auto generates acknowledgement and unique ID number to incident
- Able to archive, easy to query and generate reports
- Ready for pilot implementation in 2008-9

Stakeholder Discussions

- **Internal- Medical Device Bureau, Inspectorate, Canada Vigilance Program, MedEffect Web Department, Information Technology**
  - Need to coordinate & compliment efforts
- **Associations- MEDEC, Canadian Heart Rhythm Society, Canadian Institute for Health Information, Canadian Patient Safety Institute, Institute for Safe Medication Practices Canada**
  - Need for feedback, standardized process
  - Concern for biases reporting and interpretation
- **Institutions- The Ottawa Hospital, Ottawa Heart Institute, London Health Science**
  - Variety of reporting structures, needs coordination
  - Concern about who reports & lack of time to do so

Challenges in Health Canada Environment

- No mandatory requirement for health care facilities to report
- No consistent structure within institutions for reporting
- No universal adverse event coding for medical devices
- Facilities funded by province; this is federal initiative
- Other reporting projects being undertaken by hospitals
- Information management strategy to have one approach and electronic portal for all health products
- Need to be able to merge data into other Health Canada databases
- Resources within Health Canada and in hospitals
- Health Canada software requirements

Challenges= Need to Start with a Small Pilot

First…pilot:

Use web page for on-line reporting and tracking mechanism

- Similar approach with drugs - report form on MedEffect webpage.
- Resource and time issue
- Less risk and able to gather more information about challenges of reporting with small implementation

Then…comprehensive implementation:

Need to explore other systems currently used for other Health Canada products (Canada Vigilance?)

- Will have buy-in from institutions
- Health Canada environment changed? I.e.: reporting structures and requirements
- Reporting activity by health care reporters for other products?

What will be the “Sentinel Process”

- Report sent in by select reporters> acknowledged
- Triaged & entered into tracking mechanism
- Report transferred to manufacturer
- Signal verification- network/other
- Feedback to reporting health care facility
- Codes event for future queries
- Reporting- internally & externally

Reports…to Data…to Risk Assessments

- **Focusing on…**
  - patient outcomes
  - safety concerns
  - characteristics of the problem
- **Create two way communication with clinical community to understand environment better**
- **Trying to identify factors that can be impacted by risk mitigation activities**
  - awareness of hazards/conditions of use
  - improved labeling
  - improvements to safety standards

Benefits of the Sentinel Program

- Fulfill Auditor General's recommendation for Medical Device Program program
- Increase in credibility of Health Canada as source for post market information
- Similar approach of other regulators- opportunity to share information
- Creates awareness of hospital staff to adverse event reporting
- Quality improvement transferable to other health care facilities
- May provide for safer product development and licensing in the future

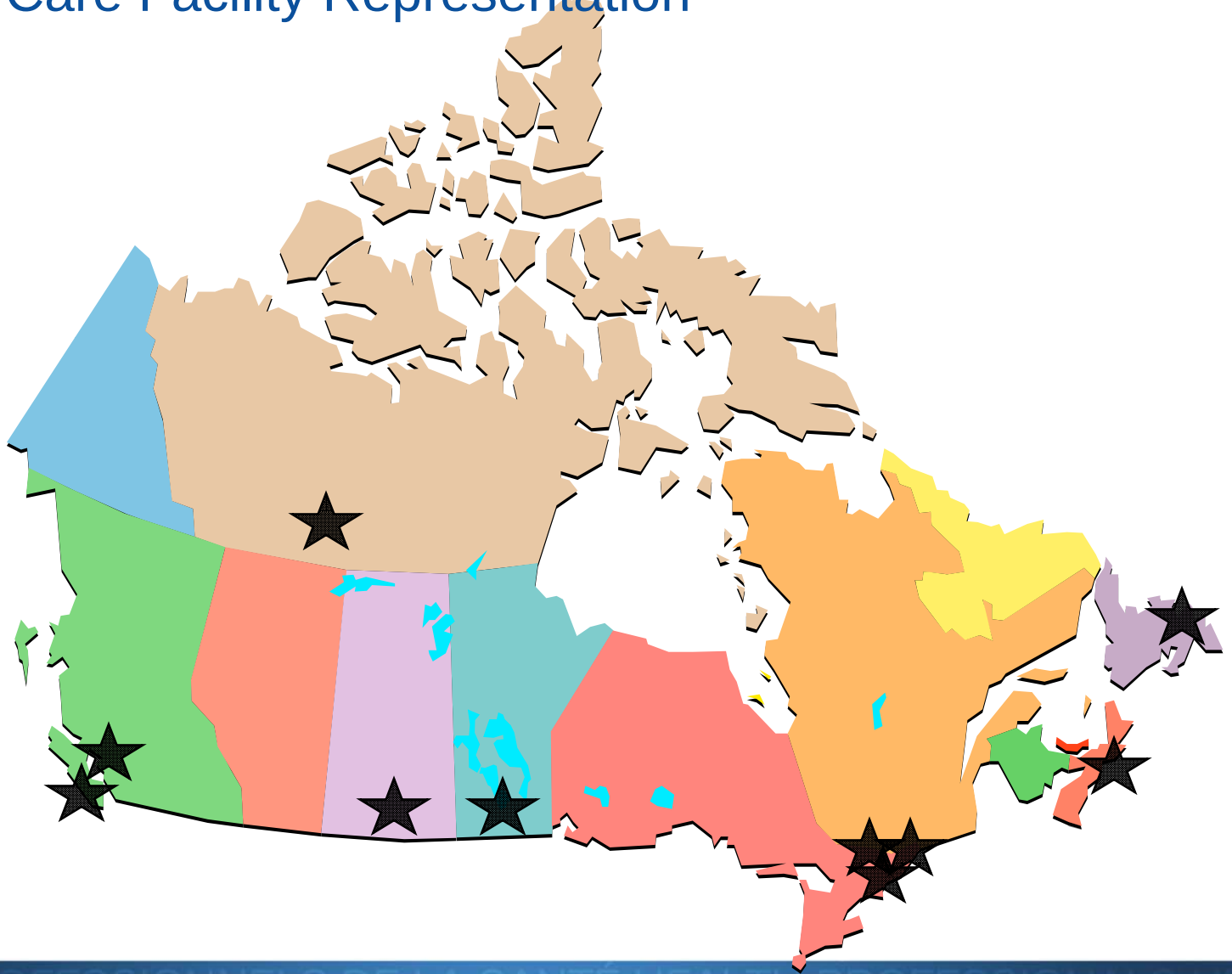
Canadian Medical Devices Sentinel Network Pilot

- **Representative samplings of different types of facilities & reporting structures**
- **Run pilot long enough to have enough incidents to see safety trends**
- **Objectives**
  - Increase number of voluntary reports received
  - Validate data fields, reporting tool and database requirements
  - Determine best reporting structures and processes to target for program
  - Identify any reporting gaps
  - Validate business unit re-development
  - Test communication tools

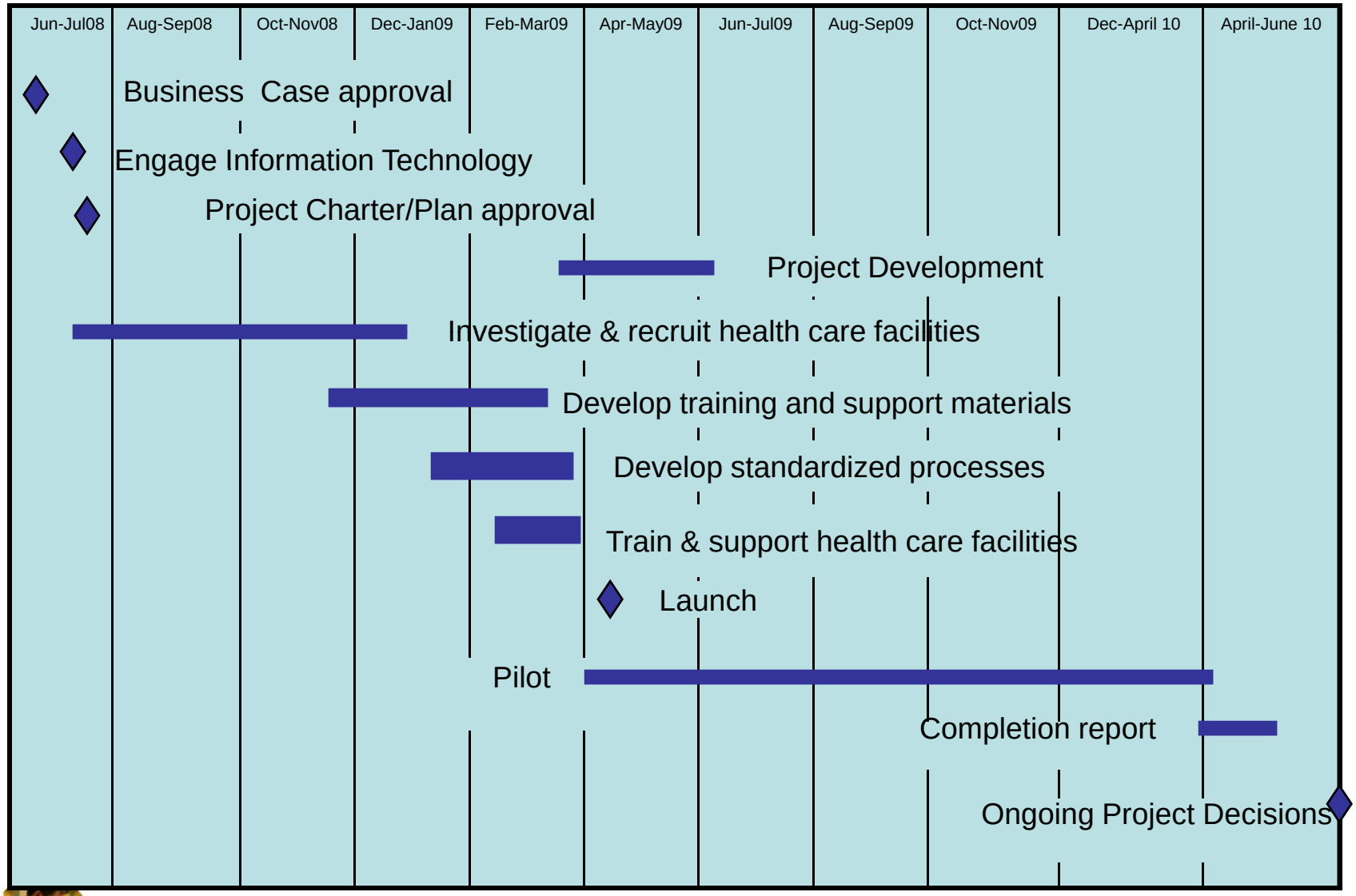
Pilot thus far…

- Recruitment completed
- PDF/print bilingual forms developed
- External/Internal materials developed
- Hiring of analysts started
- Sample reports received
- Scope: All devices
- Quarterly evaluations planned with health care facilities/manufacturers
- Pilot launched: April 15th, 2009
  - For one year duration

Health Care Facility Representation



Project Schedule



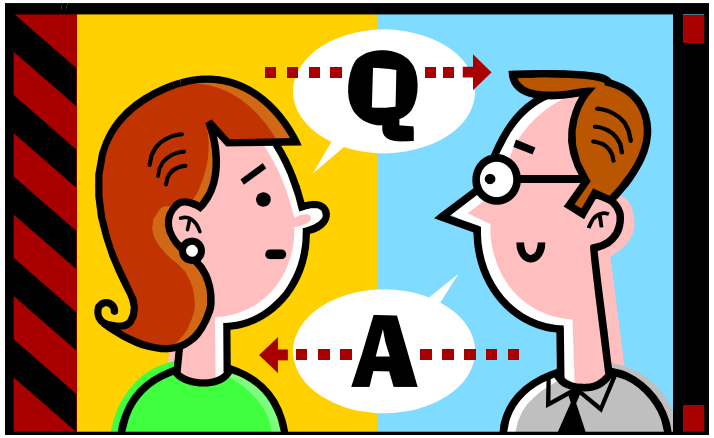
Next Steps

Pilot: Planned completion April 2010

- Will review outcomes of pilot and consider more fulsome implementation of project.

Questions?

Thank you!



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