

# Applied Pharmacoeconomics and Outcomes Research Forum:

## AMCP Dossiers: Useful for Decision Making?

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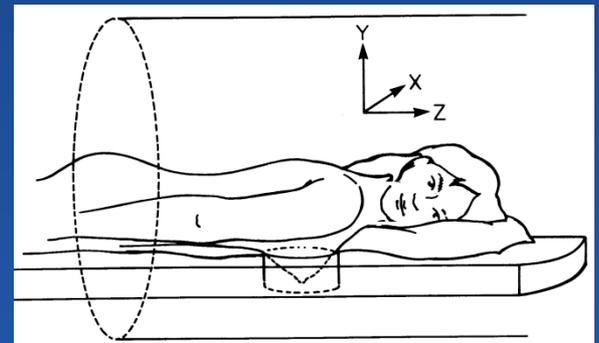
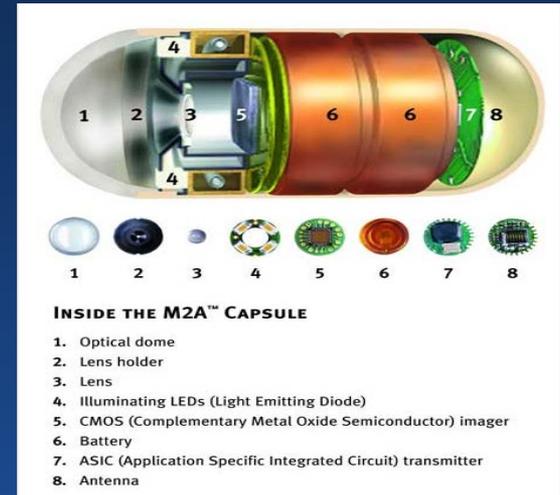
# A Debate

- ◆ Are Complete Evidence Packages for Health Technologies Useful for Decision-Making?
  - We will probably agree more than disagree this afternoon.
  - Evidence packages are not sufficient, by themselves, to improve resource allocation decisions.
  - The AMCP Format does, however, increase the likelihood that payers will acquire additional information –
    - Non-labeled, non-promotable and not published or presented data.
    - Whether these data are relevant to the P/T question or biased is up to the reviewer to judge.

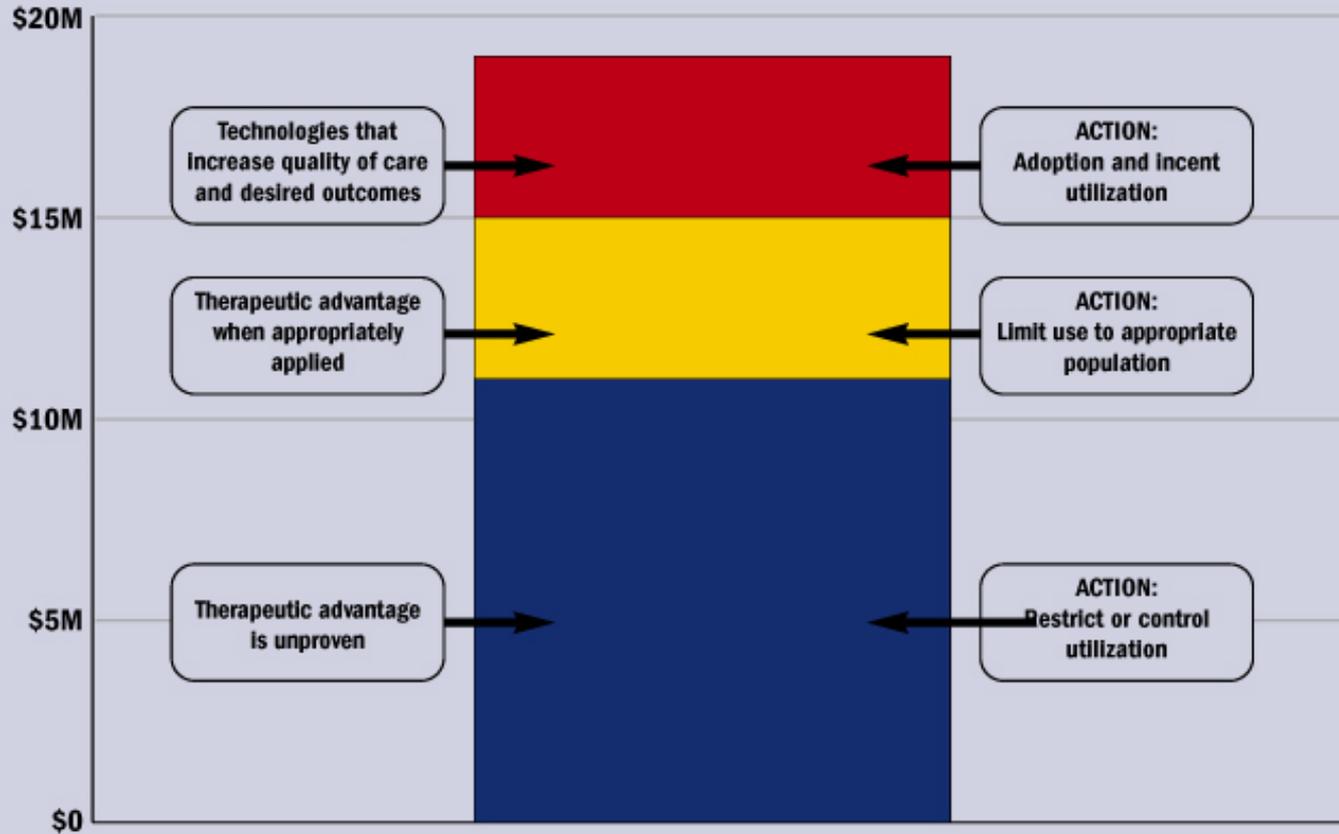


# The Horizon of New Technologies

- ◆Diagnostics: Virtual colonoscopy
- ◆Devices: Computerized knee
- ◆Procedures: Breast MRI
- ◆Drugs: Biologics



# Understanding and managing the problem

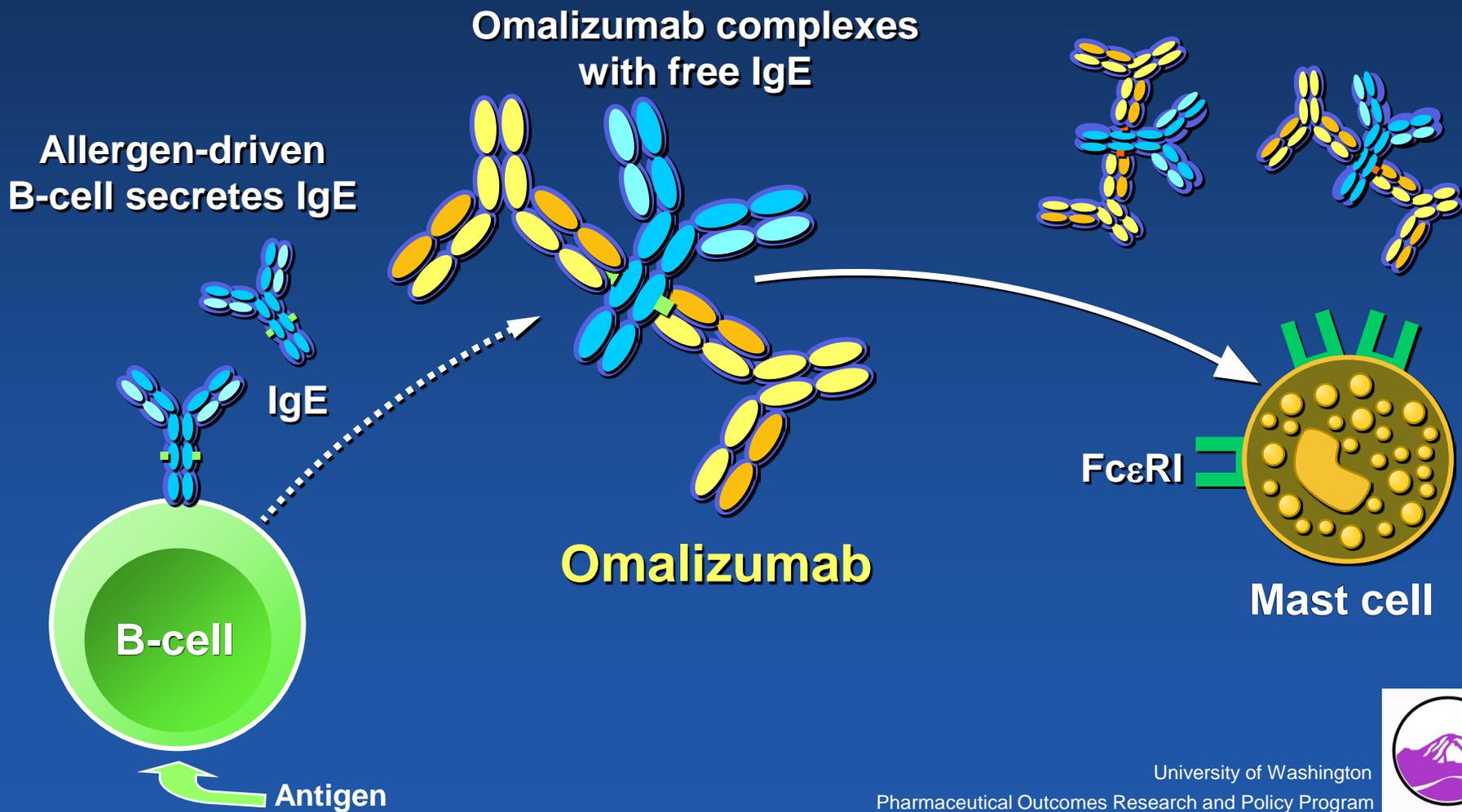


**Proactively addressing the impact of new medical technologies could save a 25,000-employee organization \$10 million over the next two to three years.**

Source: Ingenix Health Technology Pipeline



# Biologics for Chronic Disease



# New Technology



# AMCP Format

- ◆ A standardized format that serves as an unsolicited request by health plans and other payers to manufacturers for ALL information that exists about a pharmaceutical.
- ◆ The manufacturer can rely on a single format within which to submit a response that is compliant with FDA law on the promotion of drug information.



How does the Evidence Package (Dossier) Fit  
Within EBM Decision Processes?

# P & T Principles

- ◆ Members should have access to treatments that make them better
- ◆ Members should be protected from treatments that are harmful
  - Harm includes unnecessary inconvenience, discomfort and anxiety
- ◆ We should not waste our members' money
- ◆ We should spend our members' money as efficiently as possible to improve their health



# P & T Principles

- ◆ To achieve these principles, we
  - Use evidence-based decision making
    - High quality evidence in peer-reviewed, published literature trumps opinion
    - Full evidence packages include data beyond what is reported in the product label or promotional materials
    - Limit use of professional opinion and anecdote.
    - Discount unsubstantiated claims of benefit, harm or value.
  - The **burden of proof** for evidence related to the outcomes, harms and efficiency of medical technology lies with the manufacturer

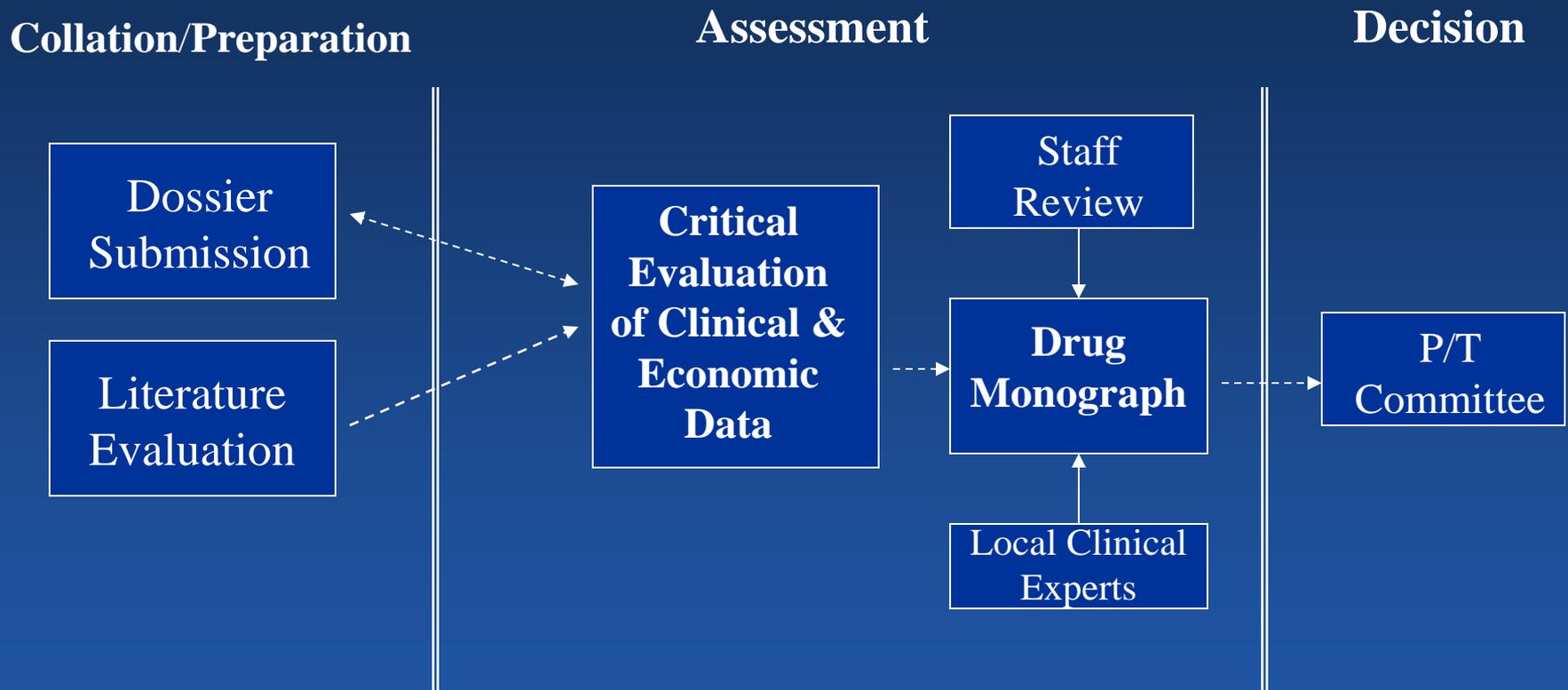


# The Cost of a Bad Decision

- ◆ **If we do not use EBM methods for decision-making:**
  - **Uncritical adoption, coverage or reimbursement of medical technology, which may**
    - **Provide little or no benefit to patients and their families**
    - **Result in unnecessary risks and adverse outcomes for patients**
    - **Cause higher costs for patients, the payer and employers, and**
    - **Reduce the payers ability to make expenditures on future technology with proven clinical and economic value.**



# Model Process of Evidence Appraisal and Formulary Consideration



# CLASSIFICATION OF EXISTING GUIDELINES

SOURCE	PURPOSE		
	Reimbursement or Listing	Methodology Standards	Ethics and Conduct
Government or Payers	Australia, NZ Ontario The Netherlands Norway Portugal Finland, Germany Sweden, Scotland United Kingdom Korea, Spain Taiwan, Italy	CCOHTA (Canada) PHS Panel (USA) ISPOR	ISPOR
Academic	Sullivan <i>et al</i> (USA) Alban <i>et al</i> (DK)	LDI Task Force (USA) Rovira <i>et al</i> (Spain) Hannover (Germany) BESPE (Belgium) BMJ Working Party (UK) Garattini <i>et al</i> (Italy) College of Economists (France)	LDI Task Force (USA)
Industry		PhRMA (USA)	

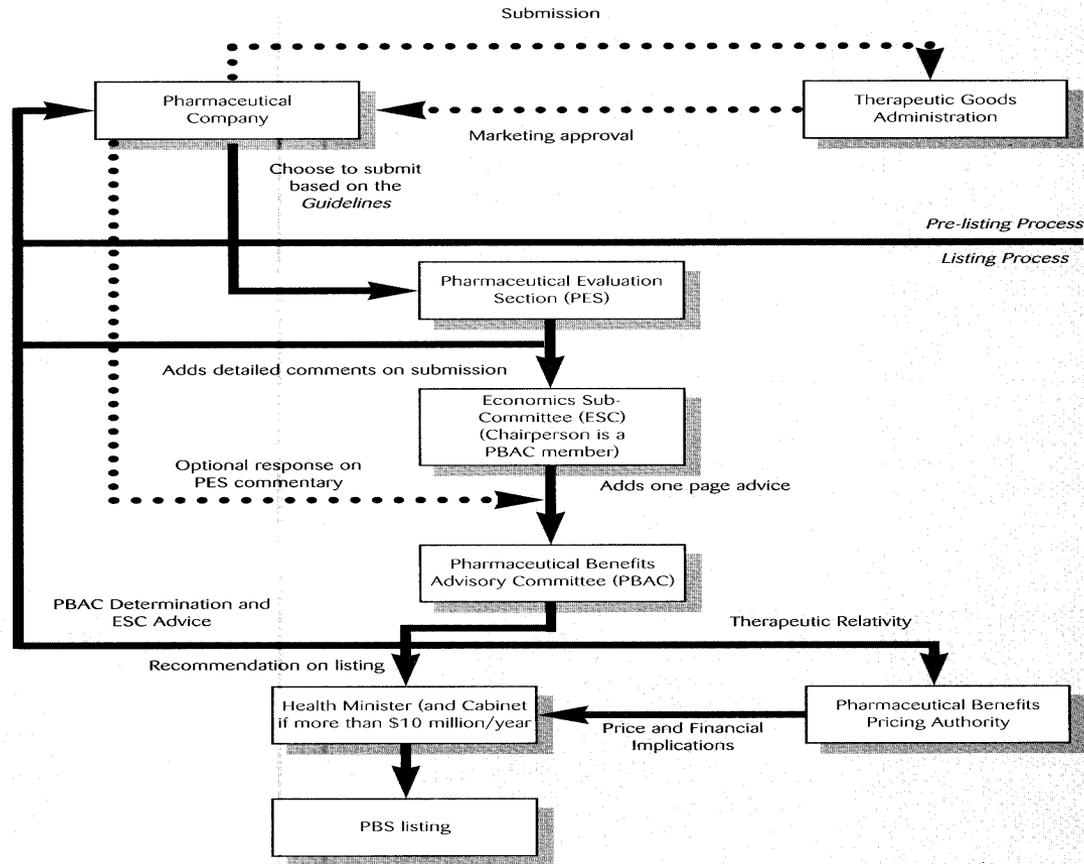


# IN GENERAL, WHAT IS COVERED BY GUIDELINES?

- ◆ Evidentiary requirements for coverage and reimbursement – clinical and economic data.
- ◆ Process and timeline.
- ◆ Format of submission dossier.
- ◆ Appeals process.



# SUBMISSION AND REVIEW PROCESS UNDER THE AUSTRALIAN GUIDELINES (Glasziou and Mitchell, 1996)

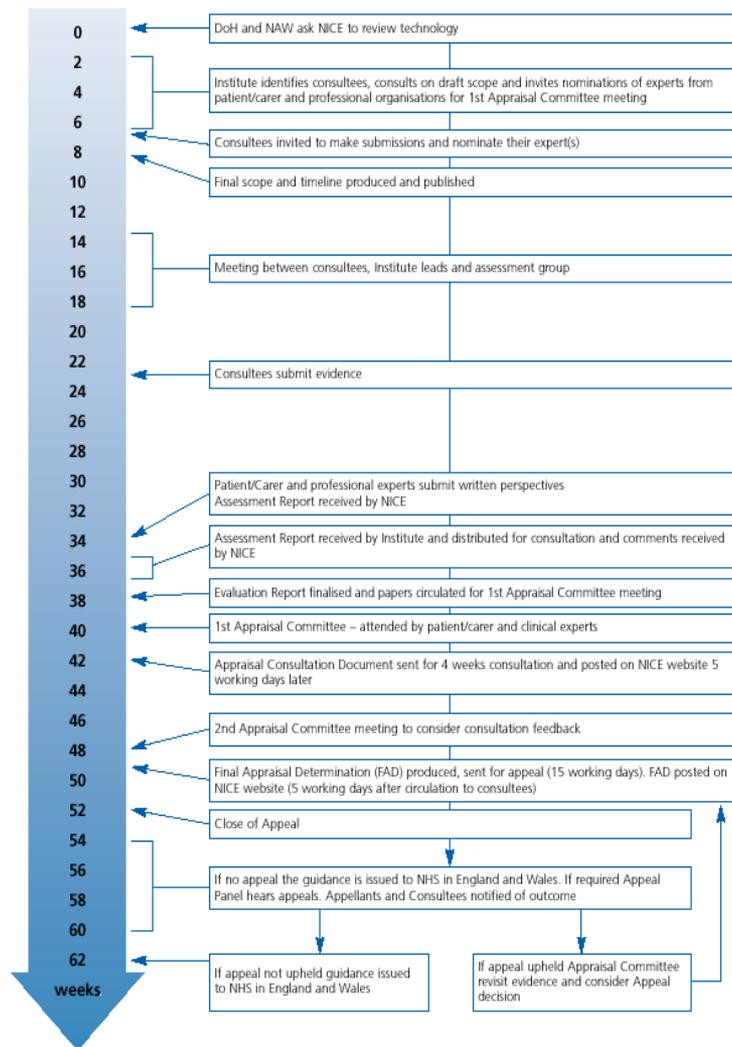


Source: Glasziou and Mitchell<sup>4</sup>.



# NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE (NICE) APPRAISAL PROCESS

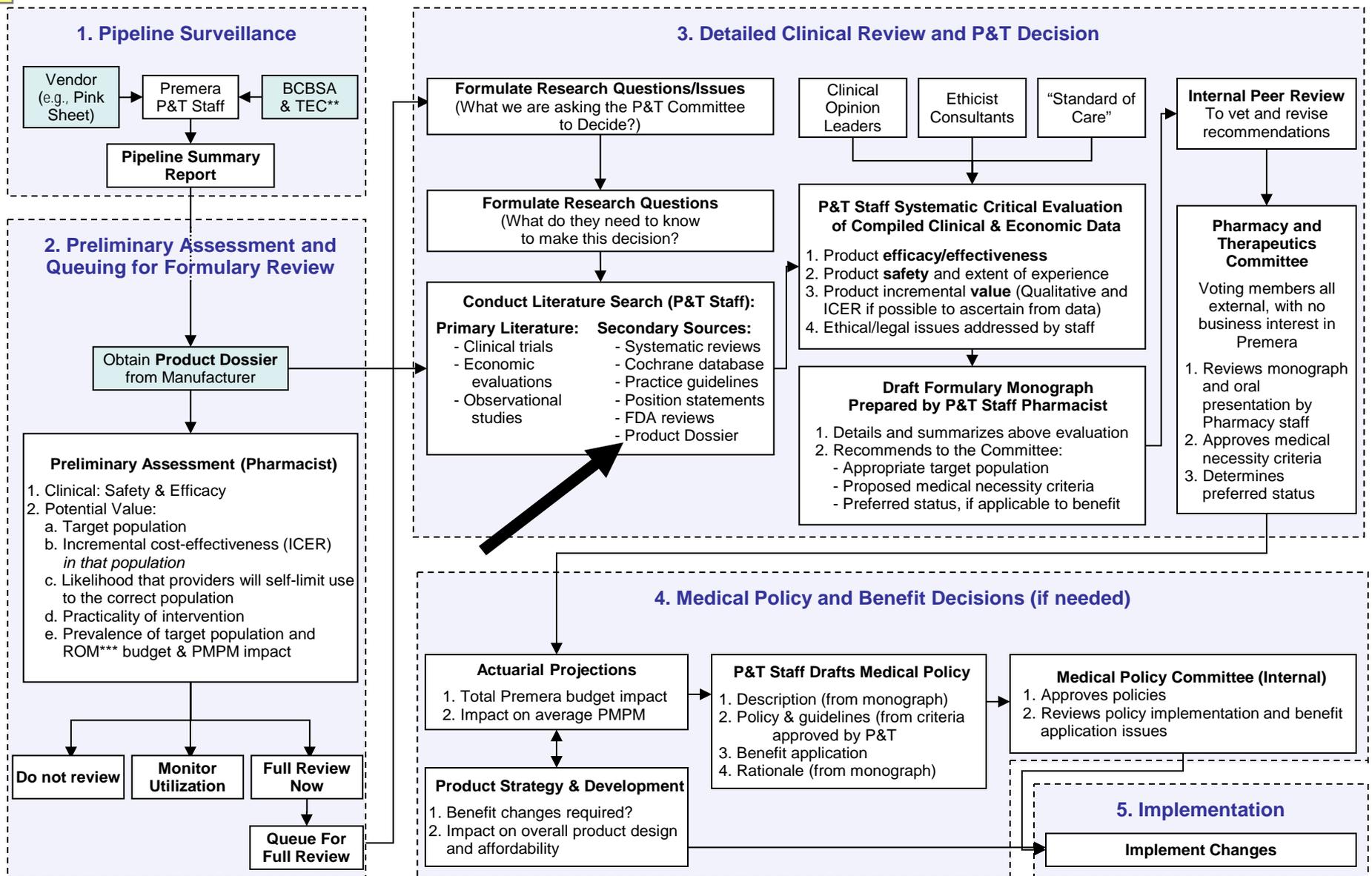
## Appraisal Process Diagrammatic Timeline



DH = Department of Health  
NAW = National Assembly of Wales  
NHS = National Health Service

Source National Institute for Clinical Excellence *Guide to the technology appraisal process. 1: Introduction and background to the appraisal process* London, NICE, 2001.





Vendors
  Outside Clinical Experts
  Premera Staff

\*\*TEC – Blue Cross Blue Shield Assn Technology Evaluation Center    \*\*\*ROM-Rough Order of Magnitude    \*\*\*\*CEA- Cost Effectiveness Analysis

**Exhibit A. Enhanced formulary review process for biotech drugs, utilizing AMCP Format submissions.**

# Summary

- ◆ AMCP is like any other trade organization. It can convene experts and suggest standards, but is not in the business of telling individual members (organizations) how to conduct their own affairs.
- ◆ The AMCP Format solves a heretofore unresolved legal problem by providing a mechanism for the flow of information between producer and user.
- ◆ However, payers make coverage and reimbursement decisions – not the AMCP Format. It remains the responsibility of the payer to decide the quantity and quality of information that it considers for these decisions.

