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Evidence Based Medicine Tools for Decision Making

Jasmine Knight, PharmD, MS, MS

Manager, Global Health Economics and Outcomes Research

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Learning Objectives

- Identify 3 evidence based medicine tools that payers can use to assist with decision making
- Understand components of the AMCP Format Dossier
- Discuss various types of economic models used
- Define outcomes analyzers and their importance in evidence based medicine

Pre-Test Question

- What types of tools can be used to assist payers with decision making

A. Economic models

B. Dossiers

C. Outcomes Analyzers

D. All of the above

Pre-Test Question

- What type of evidence do you think is most critical for formulary decision-making by payers?

A. Clinical data supporting FDA-approved indications

B. Clinical data supporting off-label usages

C. Product information

D. Health economic information, such as the model

E. Drug price

Pre-Test Question

- Which of the choices are considered economic models?
  - A. Cost utility analysis
  - B. Budget impact model
  - C. Cost-effectiveness analysis
  - D. Price calculator
  - E. All of the above

Pre-Test Question

- What is an outcomes analyzer?

A. Analytics and reporting instrument used IT departments

B. HIPAA-compliant software tool that uploads pharmacy / medical claims

C. Person that analyzes a person's golf swing

D. Web-based reporting tool that calculates the weather

Agenda

- Welcome and Introductions
- Pre-Test Questions
- Evidence Based Medicine for Decision Making
- Evidence Based Medicine Tools
  - Dossiers
  - Economic Models
  - Outcomes Analyzers
- Post-Test Questions

Footnotes in Arial font, 9pt

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Evidence Based Medicine for Decision Making

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History of Decision Making

- Historically, P&T committees make decisions based on
  - Reports in the medical literature
  - Promotional materials provided by drug manufacturers
  - Anecdotal information from physicians
  - Discounts
- Decisions focused on consequences to pharmacy budgets, rather than on broader health and economic consequences
- Recent trends are moving toward
  - Evidence-based medicine
  - Cost-effectiveness or “value for money”

Decision Making Globally

Australia

- Requires cost-effectiveness evidence

United Kingdom

- Optional cost-effectiveness evidence
- National Institute for Clinical Excellence (NICE)
  - Initiates and conducts evaluations itself
  - Makes nonbinding recommendations to the National Health Service (NHS)

United States

- Formulary committees have informally evaluated pharmacoeconomic data with large variation across plans
- In 1998 the Regence BlueShield health plan in Seattle began asking drug manufacturers to submit standardized packages of clinical and economic evidence as a condition for formulary review.

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Evidence Based Medicine Tools

Dossiers

Economic Models

Outcomes Analyzers

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Dossiers

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What is a dossier?

dos·si·er

a collection or file of documents on the same subject, especially a complete file containing detailed information about a person or topic

What is the AMCP *Format* dossier?

A process to obtain a standardized set of data and information about a drug from its manufacturer to support reimbursement and/or formulary placement consideration

A Little History Lesson…

1990s

Plans recognize issues with new product information provided by PhRMA. Regional ‘guidelines’ developed.

2000s

AMCP *Format* v1.0 was born!

2002-2009, 2 major revisions to the format

2012

AMCP *Format* v3.1 with addenda recognizing the changing marketplaces

Xcenda has been involved since the beginning

Overview of AMCP Format v3.1

2.2.1 Disease Description (1–2 pgs)
- Epidemiology & relevant risk factors
- Pathophysiology
- Clinical presentation
- Societal & economic impact

2.2.2 Approaches to Treatment (1–2 pgs)
- How is disease currently treated?
- How does the new product fit into standard or existing therapy?

2.2.3 Treatment Guidelines
- National and international bodies

1.0 Executive Summary (3 pgs)

2.0 Product Information and Disease Description (20 pgs)

2.1 Product description

2.2 Place of product in therapy

2.3 Evidence for pharmacogenomic tests and drugs

3.0 Supporting Clinical Information

3.1 Key Clinical Study Summaries (2 pgs)

– On-label evidence

– Off-label evidence

– Evidence table spreadsheet

4.0 Modeling Report (20 pgs)

5.0 Other Supporting Evidence

5.1 Summary of other relevant evidence

6.0 Supporting Information

– References

– CD-ROM of spreadsheet models

- May include retrospective studies, meta-analyses, systematic reviews, quality-of-life or economic studies, comparative observational studies, adherence/persistence studies, patient preference, others

Following the AMCP *Format* Dossier footsteps

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Unsolicited request from payer*

Manufacturer determines need for dossier…

…and calls Xcenda

Dossier is developed and approved

Manufacturer provides the dossier to the payer*

Payer uses the dossier in sound clinical evaluation

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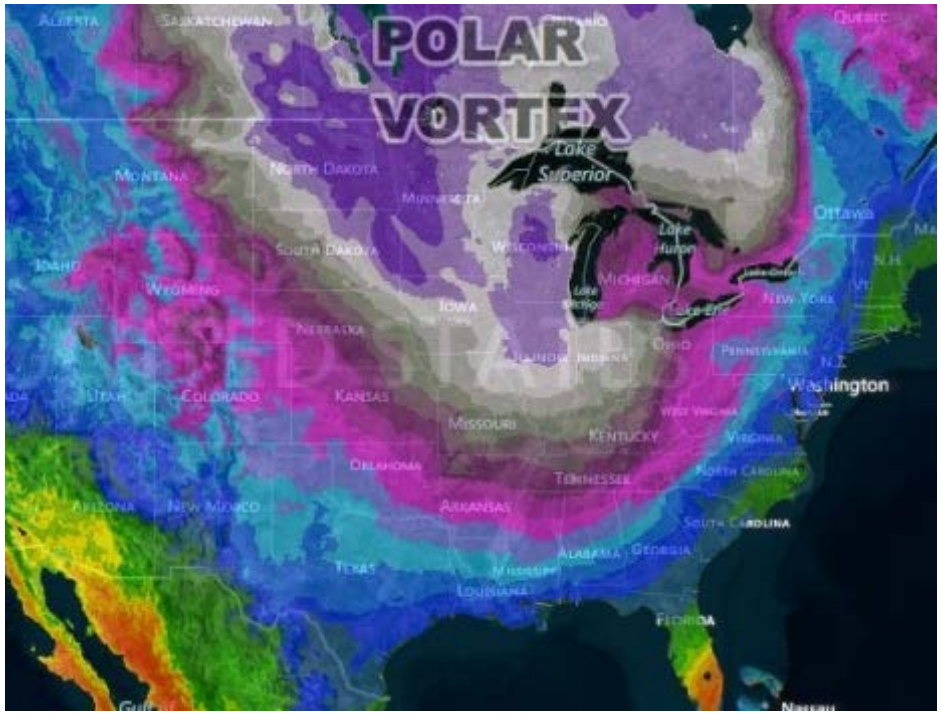
Economic Models

What is a Health Economic Model?

- A model is a predictive tool to help decision makers make better more informed decisions
  - Example of weather models
- Health economic models synthesize clinical and economic evidence from:
  - clinical trials
  - observational studies
  - insurance claims databases
  - case registries
  - public health statistics
  - preference and quality of life surveys
- To make predictions about clinical and economic outcomes of health care interventions



Why Economic Modeling?

- Decisions must be made about:

Coverage and reimbursement for new health technologies

Formulary placement of pharmaceuticals

Cost-containment strategies

- No clinical trial meets all of the following conditions:
  - Includes all relevant comparators
  - Reflects a health plan's real-world population
  - Has a time horizon long enough to capture all relevant outcomes
  - Includes clinically meaningful patient outcomes and costs
  - Makes results available in a few months at minimal cost
- Economic modeling is a tool to assist in decision making
  - We do not have a crystal ball
  - Models are better than a hunch or wild guess

Value of Economic Models

- AMCP dossier
  - AMCP dossier guidelines (v3.1) recommend dossiers should include an electronic copy of a working model
  - A cost-effectiveness and budget impact model is recommended
- Field use with managed care payers
  - Used by account managers and medical science liaisons to demonstrate product value to decision makers
- Publications
  - Abstracts, posters, and manuscripts can communicate value to a broader audience of clinicians and payers
- Internal decision making
  - Can assist with pre-launch product value strategy and pricing decisions

Types of Health Economic Models

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Cost Calculator

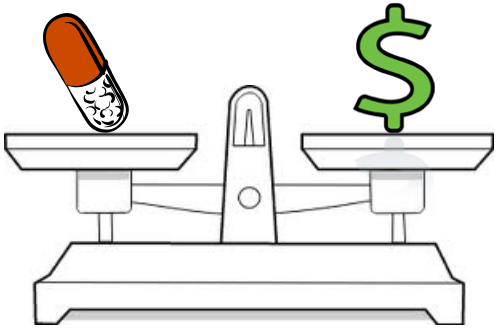
(How much does a health technology cost?)

Budget impact

(How much does a health technology cost across a patient population?)

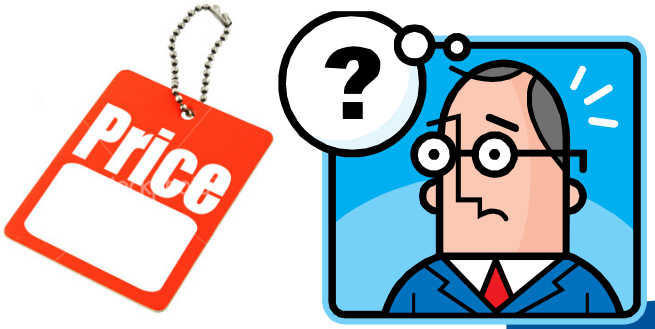
Cost-effectiveness

(How much value does a health technology provide for the money?)



Pricing

(How much can a company charge for a health technology?)



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Budget Impact Models

- Payer Question
  - "What is this going to cost me?"
- Provides a snapshot of product adoption/market dynamics and financial impact on the health plan
  - Pharmaceuticals
  - Devices
  - Diagnostics
  - Procedures
- Budget impact model outcomes include
  - Cost per-member per-month (PMPM) – difference between baseline and new scenario
  - PMPM provides a concise overall impact on costs given market share changes

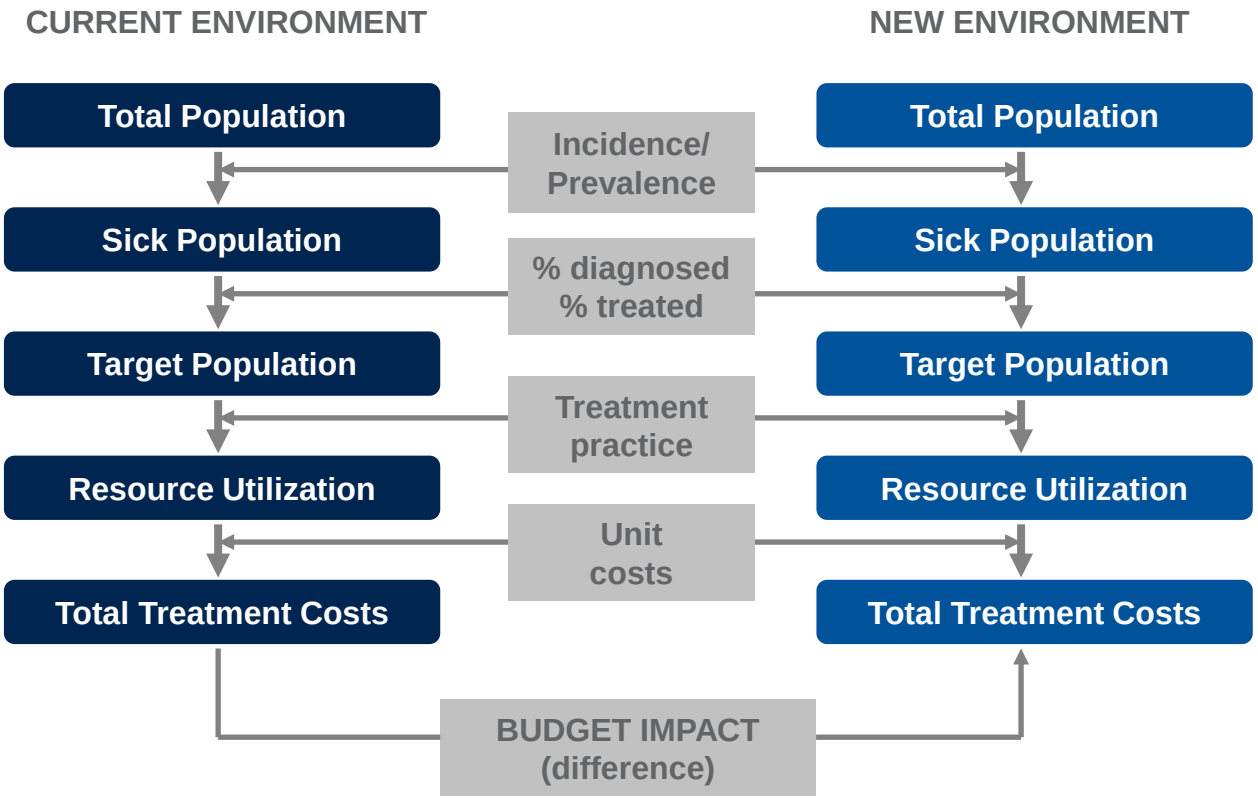
Budget Impact Models

"…are not intended to establish the overall value of healthcare technologies because they do not include the full impact of the technology on clinical and patient outcomes. They can be useful for estimating system-wide (eg, pharmacy and medical) budget impacts, however, and are commonly used by managed care payers. These models, as defined here, estimate drug costs, healthcare cost offsets, and adverse event costs, as well as the expected utilization in the healthcare system, to derive projected per-member per-month costs."

*– Academy of Managed Care Pharmacy**

* FMCP Format Executive Committee. The AMCP Format for Formulary Submissions, Version 3.0. October 2009.

Budget Impact Model Design



Cost-Effectiveness Models

- Payer Question
  - "What product provides the most value?"
- Cost-effectiveness models compare the value of alternative treatments
  - Within a target patient population
  - Over a specified time horizon
  - From a particular stakeholder perspective
- Cost-effectiveness model outcomes
  - Incremental cost per clinically relevant outcome measure
  - The payer's willingness-to-pay threshold determines if a treatment is cost-effective

Cost-effectiveness Models

"…are used to establish the value of a new technology relative to an appropriate comparator, and often use decision analysis techniques. They can be based directly on clinical trials. They are disease-based and account for the impact of new technology on clinical outcomes (efficacy, adverse events), resource use, and costs in the short and long term. They also reveal the relation between data inputs and assumptions and outcomes."

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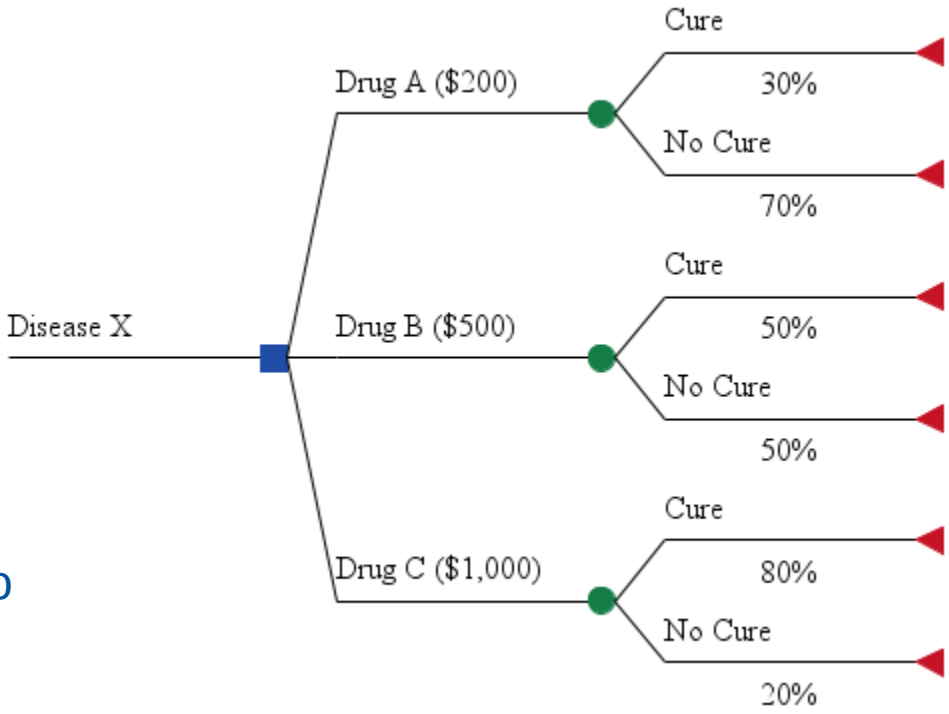
Cost-Effectiveness Model Design

- Various methods to compare costs and clinical benefits
  - Decision tree (see example)
  - Markov process
- Would you choose Drug A, Drug B, or Drug C?
  - How would you choose?
- Incremental Cost-Effectiveness Ratio (ICER)
  - Quantifies the value for money of one treatment compared to another



Xcenda's Economic Models

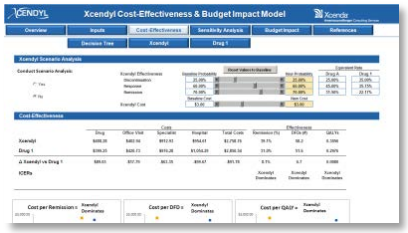
- Numerous designs

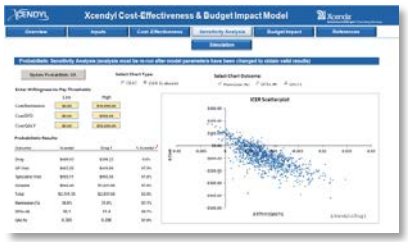
Burden of illness	Cost-effectiveness	Budget impact
Productivity impact	Value-based pricing	Return on Investment

- Various platforms

Excel-based models	Tree Age models	Software-based models (iPad)

- Diverse perspectives
  - US and ex-US
  - Hospital
  - Private payer
  - Medicare
  - Provider
  - Societal





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Outcomes Analyzers

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Overview of Outcomes Analyzers

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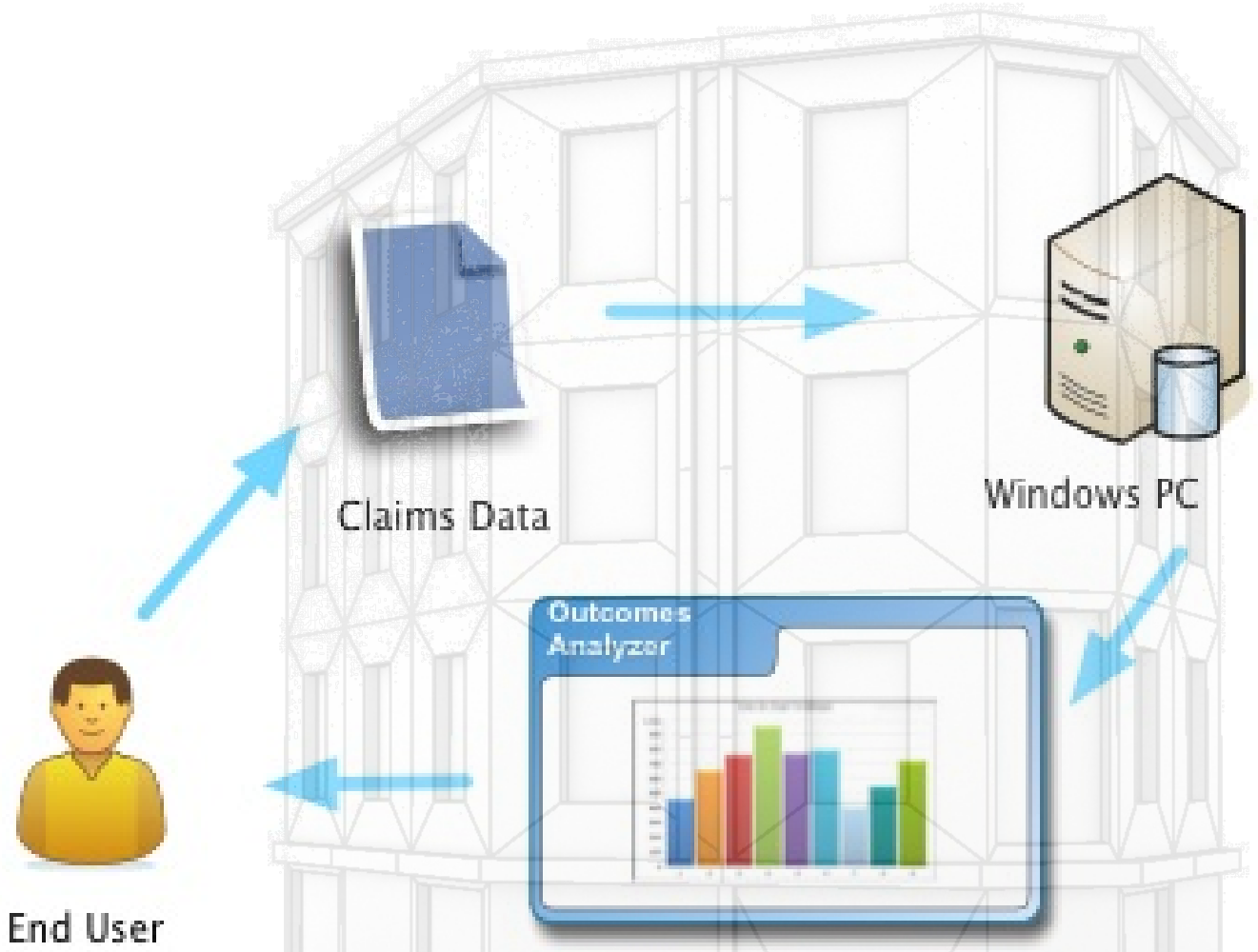
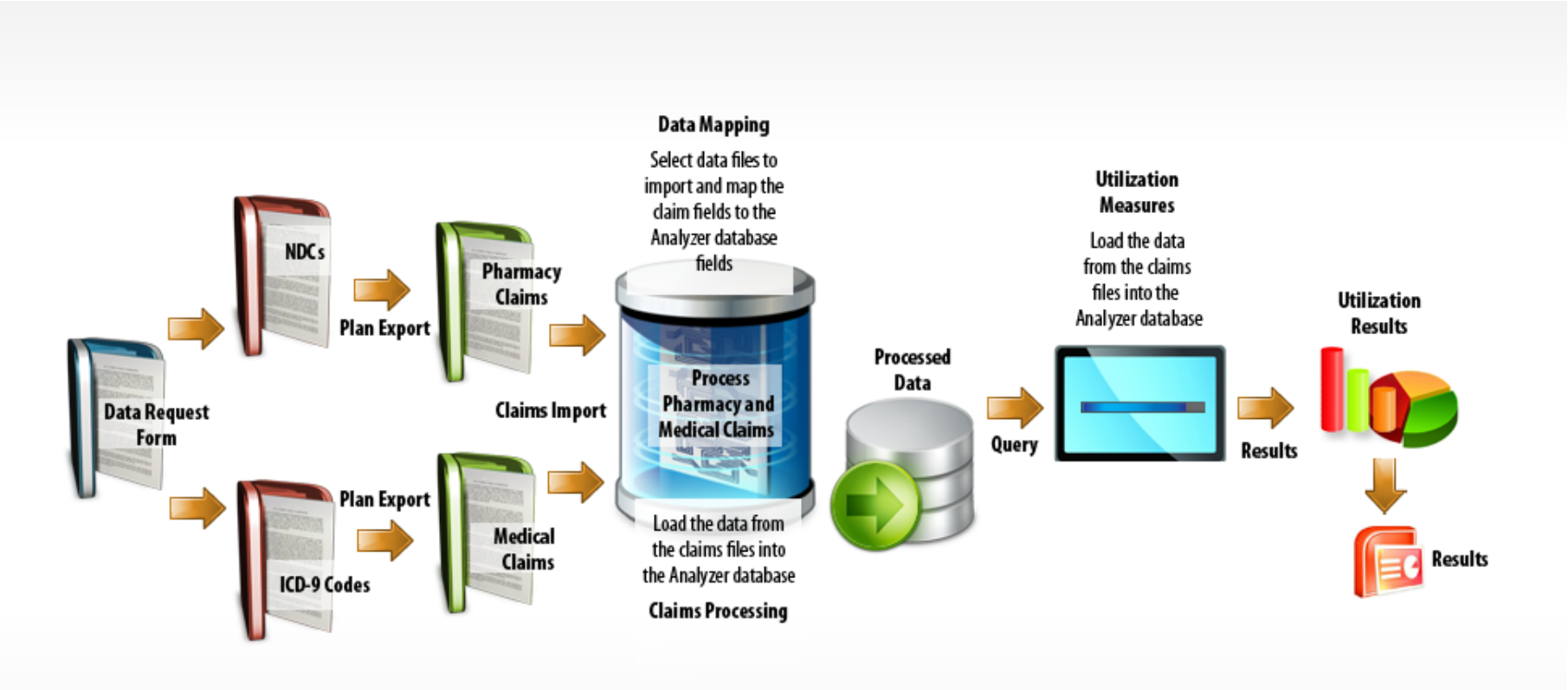
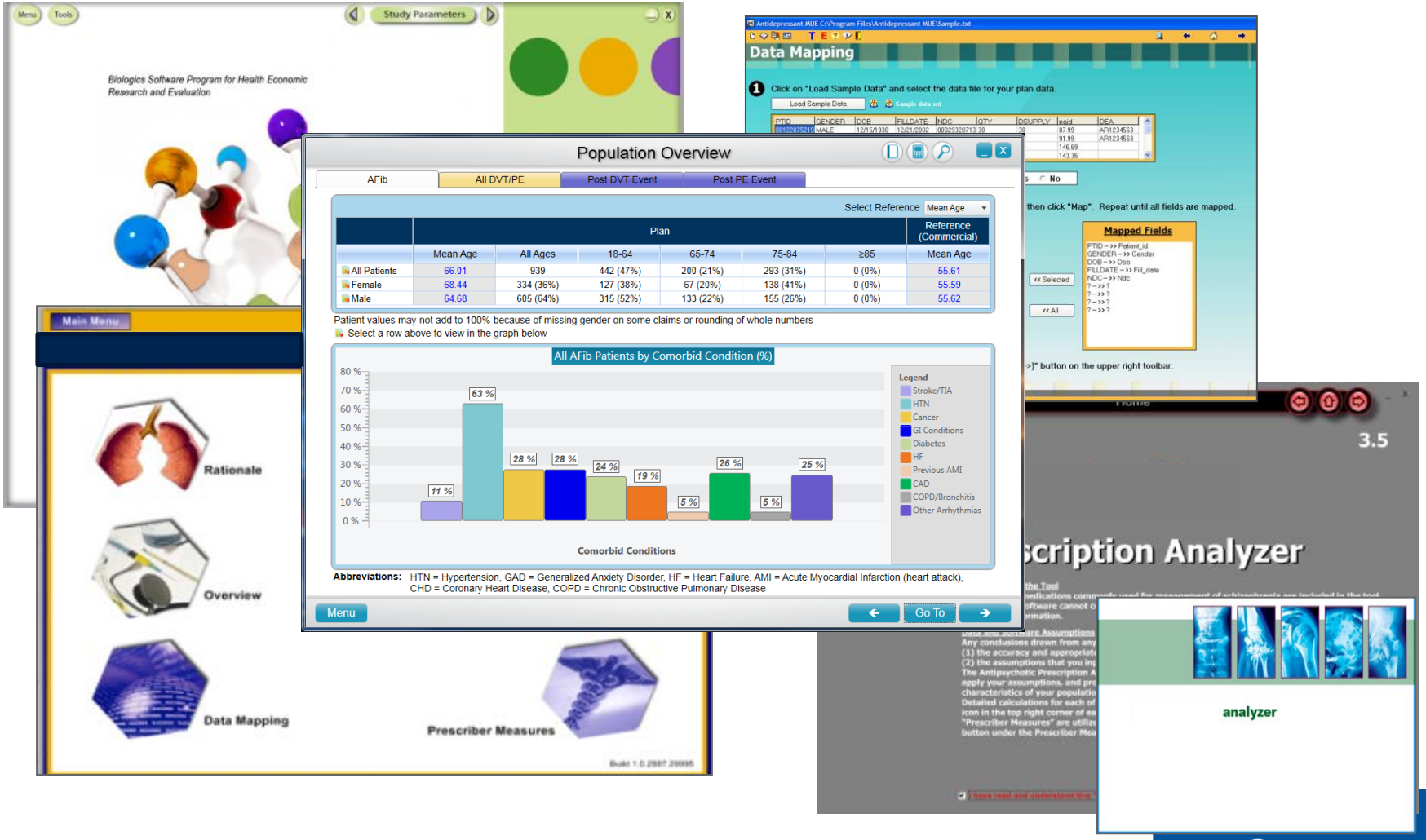
PC-based Analyzer



Analyzer Flow Diagram



History of Analyzers



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Post Test Questions

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Thank you

Jasmine Knight, PharmD, MS[2]

Manager, Global Health Economics and Outcomes Research

jasmine.knight@xcenda.com

727 – 771- 4100 x 203-4113

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