Course Overview

For health technology developers, blockbuster opportunities are more elusive than ever. Regulatory and clinical hurdles are rising, and public and private payers are challenging prices and patient access. The entire structure of the US healthcare system is in flux. Drug and device manufacturers are not alone. All providers in the healthcare value chain face significant uncertainty and are also under pressure to reduce cost and take on more risk.

Investors and those working in the business of bringing innovative health services to patients need to quantify value propositions early in development, and they need to provide evidence to communicate that value potential to payers. There is an urgent need for new frameworks and tools for forecasting and communicating the value of new innovations in healthcare. This course is extremely practical, providing opportunities for students to use existing data sources and traditional business modelling tools to develop decision-relevant insights that reflect the value perspectives of decision-makers in this rapidly changing environment.

We recognize that Big Data and analytics are seen as critical strategic assets in the life science industry, and are attracting significant attention and investment. While high-profile investments are being made in new health data sources, mobile technologies, and analytic services, few organizations have fully exploited the value of their existing data resources. We emphasize the opportunity that existing resources offer to those who want to optimize value in health care.

This course provides a structured approach to identifying and quantifying the key factors that will create value for patients, payers, providers and for shareholders. By identifying these factors early, teams can invest in strategies that provide faster routes to the best opportunities for their health technologies.

- The primary emphasis of this course will be on the top drivers of value and risk for healthcare products.
- We will review the key strategic decision points in the development and marketing process, and discuss types of forecasts that inform those decisions.
- We will review the payer landscape, the changing reimbursement environment facing providers, and how to anticipate market access for drugs and devices.
- Disease areas will be discussed in case studies to illustrate more general concepts.
- Advantages and disadvantages of using forecasts will be explored.
- We will survey and use traditional analytic techniques for forecasting value and risk.
- We will innovate new forecasting approaches to reflect the changing industry structure and new contracting models.
- This course will provide an introduction to some standard industry data sources (eg, NHANES, MEPS, WHO and other public health sources, IMS data, EHR/EMR data, claims data), but we will also cover analytic approaches in areas where little market or clinical data exists.
- We will cover other topics such as clinical trial operations, patient adherence and portfolio optimization.

The emphasis is on considering the range of factors influencing value, rather than on building deep technical modelling skills. However, students will have the opportunity to use and extend a general
forecasting model (in Excel) to perform sensitivity analysis, challenge forecasts, and source healthcare data.

This course will be useful for students interested in careers in pharma and biotech, payers and providers, as well as management consulting, investment banking, equity research, venture capital, and private equity, given the large and growing life sciences practices of such firms.

**Important Note:** this course is designed for students with at least a basic understanding of the pharmaceutical industry. Some basic business modeling experience (eg, Microsoft Excel) is required.

**Format and Approach**

The format of this course is in-class lectures and discussion, with readings and some modelling to be completed outside of class. Classes will typically include a lecture and class discussion, and some sessions may include technical demonstration and group work. Guest speakers in one or two sessions will relate to the topics that week.

A range of readings will be suggested, covering lecture topics. While almost all readings are optional, students are expected to understand the range of topics covered by the readings, and be able to reflect this understanding in class discussion.

Data will be provided for all case studies, but students may need to carry out basic, desktop research to identify and support additional data and assumptions for some of the exercises.

In addition to class participation, graded work will include weekly “quizzes” on Canvas. These quizzes will be simple - they will emphasize one or two points that were clear insights discussed in the lecture that week. A final (independent) project will have two parts; a “quiz-based” portion and a PowerPoint presentation of analytic results with supporting information.

**Materials**

This course will require case studies and other readings on the healthcare industry, which will be posted on Canvas following each class. Students will also use Excel or another spreadsheet program.

**Course Requirements and Evaluation**

**Class participation (40%):** Please come to class fully prepared to engage in discussion and classroom activities. The class participation grade will reflect class attendance and the quality of your involvement in classroom activities and discussion, with an emphasis on the case study content.

**Quizzes (20%):** Six brief quizzes covering content covered in the lecture.

**Final Paper/Analysis (40%):** The final project will be a case study. The deliverable will be a canvas-based quiz, and a Powerpoint presentation, describing the results of analysis, with exhibits and documented assumptions. The final project will be assigned in late February, and collected in mid March. The final submission must be uniquely your own work.
Learning Goals

- To understand the challenges of market access, and how they relate to the value of drugs and devices in development.
- To understand the drivers of value and risk for payers, providers and manufacturers.
- To gain confidence using forecasts and healthcare analysis.
- To build a vocabulary and intuition for challenging analysis developed by others.
- To practice basic business modelling to build decision-relevant forecasts and perform sensitivity analysis.

Preliminary Class Schedule and Topics

Week 1
Course introduction - Forecasting for drug development strategy
Why “Forecasting”
Healthcare industry in numbers
  Global
  US

Week 2
Healthcare Industry and Drug development
Healthcare industry in the US
  EpiPen Case Study
Healthcare perspectives/stakeholders and flow of funds
  Patients
  Providers
  Payers
  Policymakers
  Pharmaceutical developers/manufacturers
  Pharmacists (and distribution)
Pricing Mechanisms and Terminology
Drug Development
  Key stages and shape of historic industry pipeline to launch

Week 3
“Traditional” pre-launch forecasting
TPP elements and relation to drug value
Key value drivers and uncertainties in drug development
  Cost
  Revenue
  Probability of success
  Launch timing
General model for classroom use
  Designing models for drug development strategy - best practice
Analytic area: Combining data sources, extrapolating to populations
- NHANES data
- Framingham Heart Study and risk calculator
- US Census population data and forecasts

Current issues: Outcomes - biomarkers vs events, Guidelines, Pricing and payment models, Adherence, Lifestyle modification

Week 4
**“New” Approaches**

Case Study: [TBD, eg Osteoporosis, Imaging technology and screening guidelines]

Payer perspective revisited: formulary design and decision making

New forecasting mindset

R&D strategies for approaching new challenges

Analytic area: Population health modelling, impact of prevention
- IMS sales data
- SEER data
- Outcomes data
- Data from peer reviewed publications
- Claims and cost data

Current issues: Medicare as a payer, Provider risk sharing, Generic entrants, 340B pricing

Week 5
**New approaches, part 2**

Case Study: Hepatitis C

Learning from old approaches

New contracting models

Analytic area: Strategic assessment of cost effectiveness, decision analytic models
- PROs
- Clinical outcomes

Current issues: Cost of care debate, Episode-based pricing

Emerging issues: CAR-T access and reimbursement challenges

Week 6
**Special topics**

TBD among:
- Orphan drugs, companion diagnostics, devices
- Drug access and reimbursement outside the US
- Real world evidence - possibilities and challenges
- Personalized medicine
- Why is there still upside value in life sciences?