Course Overview

For drug and device developers, “blockbuster” opportunities are scarcer, regulatory hurdles are higher, and public and private payers are reducing reimbursement dramatically. All providers in the healthcare value chain are under pressure to reduce prices 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 and communicate that value potential to payers.

The exercise of forecasting provides a structured opportunity to identify 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.
- Indications studied will include Hepatitis C, immuno-oncology, and rare diseases.
- We will review the payer landscape, the changing reimbursement environment facing providers, and how to anticipate market access for drugs and devices.
- We will review the key strategic decision points in the development and marketing process, and discuss types of forecasts that inform those decisions.
- Advantages and disadvantages of using forecasts will be explored.
- We will survey and use analytic techniques for forecasting value and risk, from the perspectives of manufacturers, providers and payers.
- This course will provide an introduction to standard industry data 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 areas such as global market access challenges, clinical trial operations, probability of clinical and regulatory success, trial costs, patient adherence and portfolio optimization.

The emphasis is on the range of factors influencing value, rather than on building deep technical modelling skills. However, students will have the opportunity to practice and develop practical Excel tools for building models, performing sensitivity analysis, challenging forecasts, and sourcing 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 (e.g., Microsoft Excel) is required.
Format and Approach

The format of this course is in-class lectures and discussion, with assignments to be completed out of class. Classes will typically include an initial lecture, a technical demonstration and discussion, and a guest speaker discussing aspects related to the topics that week.

Students will carry out basic, desktop research to identify data and assumptions for some of the exercises. In addition to class participation, graded work will include a final (independent) assignment, including an Excel model, a PowerPoint presentation of analytic results with supporting information, and a written essay.

Materials

This course will require 3-4 case studies and other readings on the healthcare industry, which will be posted on Canvas the week before each class. Readings will be posted or distributed pertaining to specific class sessions. A list of supplementary materials and reference books will also be posted on the course web page. Students will also use Excel or another spreadsheet program.

Course Requirements and Evaluation

Class participation (25%): 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.

Final Paper/Analysis (75%): The final project will be a case study. The deliverable will be a Powerpoint presentation, describing the results of analysis, with exhibits and documented assumptions. An additional short essay will also be required (about 2-4 pages), to be completed individually. The final project will be assigned in mid February, and collected in mid March.

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

W1  Course Introduction, Industry Landscape
    - Introductions
● Global and US healthcare
  ○ Sources and uses of healthcare spending
  ○ Payers, providers, manufacturers
● The role of drugs and devices in healthcare
  ○ Scale of US expenditure, by payer
  ○ Historic and future drug spending trends
  ○ US drug plan characteristics
    ▪ Commercial, Part D, Medicaid
  ○ Prescription drug value chain
    ▪ Manufacturers, regulators, wholesalers and distributors, PBM, retail and specialty pharmacies, physicians
● Pharmaceutical development process
● The uses of forecasts in pharma development
● Basic components of development forecasts
  ○ Clinical/Development
  ○ Commercial/Market Access
● [Speaker – Doyle/McKemey TBC]

W2 Forecasting and valuation; Risk factors; Data sources
● Hepatitis C Case study theme
● Forecasting and Valuation [Speaker – Andy Berens TBC]
  ○ Equity Valuation and the Wall Street Dynamic (Sell-side versus Buy-side perspectives)
  ○ Drivers of Pharmaceutical Equity Valuation
    ▪ Pharma and Biotech are event-driven sectors
    ▪ Forecasting used to determine impact of new catalysts on fundamental values
    ▪ Development Stage Companies Versus Commercial/Mature Companies
  ○ Methods of Valuing Pharmaceutical Companies
    ▪ DCF
    ▪ Multiples (PE, PEG, EV/EBITDA, Price/Sales)
    ▪ Sum of the Parts
  ○ Valuation for in-licensing and business development
● Risk analysis [Speaker - Jerry Rosenblatt TBC]
  ○ Net Present Valuation and Risk-Adjusted Net Present Valuation
  ○ Importance of risks in valuation
  ○ Types of risks
  ○ Historic benchmarks of risk
  ○ Factors that temper historic risk rates

W3 Forecasting Demand, Forecasting Non-Commercial Factors, Sensitivity Analysis
● Risk factors to consider in forecasts
  ○ Drug development risk
    ▪ Clinical risk
    ▪ Product uncertainties and the “therapeutic window”
- Timing risk
- Regulatory risk
  - Commercial risk
    - Market size/penetration
    - Intellectual property
    - Price/access risk
    - New contracting models
- Patient demand forecasting
  - Influencing clinical practice
- Patient share forecasting – competitive analysis
- Sources of data and “real world evidence”
  - Sales and Prescription data
  - Epidemiology
  - Claims and Electronic Medical Records
  - Pricing
  - Sellsicde/Consensus
  - International and Other
- Forecasting when there is little data
  - Orphan drugs
- Forecasting non-commercial factors
  - probability of clinical trial success
  - regulatory approval
  - launch timing
- Forecasts and analysis in private equity [Speaker – Bob Seltzer]

**W4** Forecasting Revenues – Market access and pricing
- Market access
  - Regulators
  - Payers, providers and patients
  - The changing US landscape
  - International considerations
- Health economic and pricing considerations
  - Real world data
  - Patient registries
  - Generics and bio-equivalents
- Information technology and health care strategy
- [Speakers – Doyle/McKemey TBC]

**W5** Forecasting Operational Drivers
- Cost of development
- Clinical trial timing and costs
  - Probability of clinical success
  - Readout and trial timing
● Preparing for submission
● Special topics in forecasting for development decision making
  ○ Adherence
  ○ Modeling drug efficacy and safety
  ○ Global factors
  ○ New technologies
● Emerging challenges for development strategy
  ○ Bundled payments
  ○ Accountable care organizations
  ○ Health data and direct patient communities
● [Guest lecture – TBC]

W6  Influencing Drug Development Strategy
● Using evidence-based forecasts to influence strategy
● Special topics
  ○ Adherence
  ○ Portfolio management
● Open issues and topics that arise in earlier sessions
● [Speaker – TBC]