

From Concept to Practice:

How to Tactically Design a
Feasible Outcomes-Based
Contract in Oncology

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NEW DIGS



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How to Tactically Design a Feasible Outcomes-Based Contract in Oncology

Discussion Lead



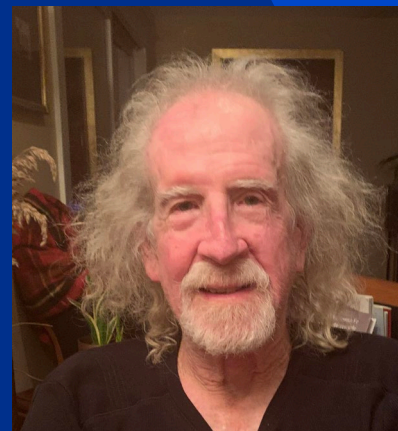
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Conflict of Interest

- Mark Trusheim is President of Co-Bio Consulting and has received personal fees from Janssen, Merck, Novartis, and Pfizer.
- Jamie Foley has no conflict of interest to report.
- Ann Nguyen has no conflict of interest to report.
- Ron Potts has no conflict of interest to report.



Agenda

- Opening Remarks
- Synthetic Oncology Case:
Astrorenoma
- Building an Outcomes Based
Contract for Launching
Astrotuminib
- Conclusion: Practical
Considerations and
Stakeholder Perspectives



Mark Trusheim

Strategic Director

Center for Biomedical System Design
NEWDIGS at Tufts Medical Center

I am speaking from my own personal viewpoint and not in an official capacity as an employee of Tufts Medical Center.



Managing Uncertainty: Financial Challenges Drive New Payment Models

Three financial challenges exacerbated



Payment timing
One-time high cost



Performance risk:
Effectiveness & durability



Actuarial risk:
Likelihood of encountering a case

Five Precision Financing solutions designed



Short-term
milestone-based
contracts



Multi-year
performance-based
annuities



Warranty
Model



Orphan Reinsurer and
Benefit Manager (ORBM)
and Risk Pools

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Subscription /
Netflix Model

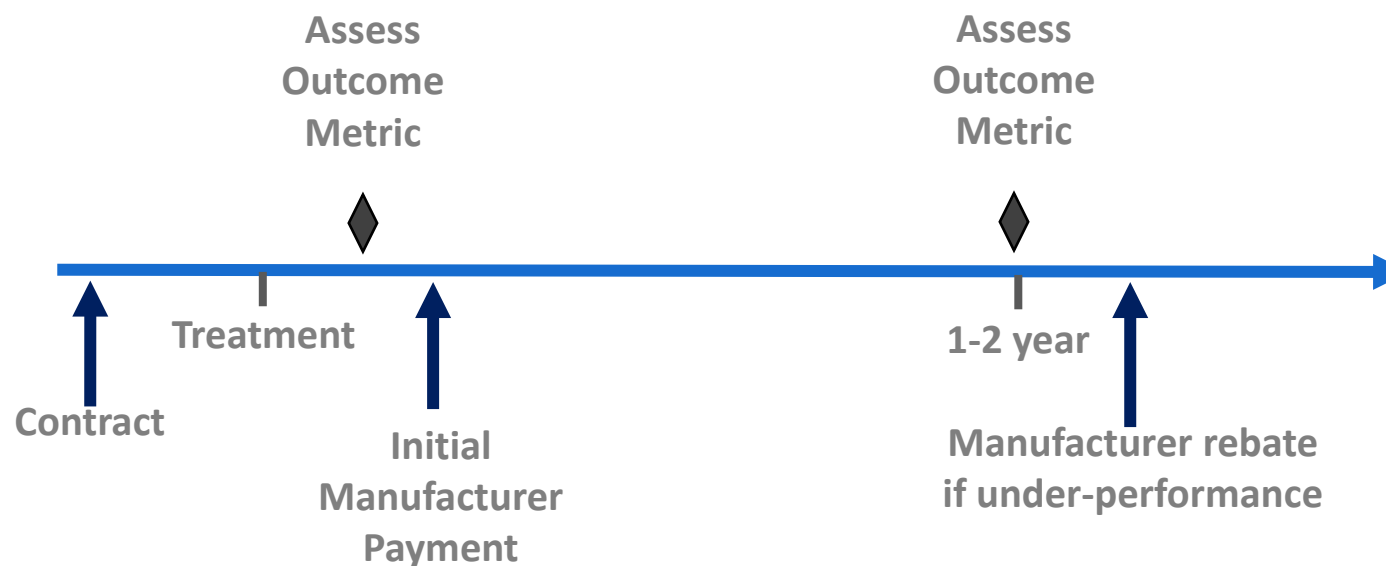
Outcomes-Based Designs



Milestone-based Outcomes Contracts



- Trigger rebates to clinical milestones
- In 2016, Italy AIFA used for gene therapy for SCID provided at Vita Salute San Raffaele University in Milano
- In US, used for cardiovascular (2017, PCSK9s) to a gene therapy for biallelic RPE65-mediated inherited retinal disease



AIFA: The Italian Medicines Agency

SCID: Severe Combined Immunodeficiency

PCSK9: Proprotein convertase subtilisin/kexin type 9

RPE65: Retinal pigment epithelium-specific 65 kDa protein



Jamie Foley

Global Director, Value-Based Innovation
Takeda Oncology

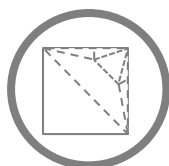
This presentation is based on my personal experiences and does not necessarily reflect Takeda's opinions about the topics being presented.



It is important to take a systematic, multi-step approach

I. ANALYZE

Understand the payers' **product value perception** and **uncertainties**



II. CONCEPTUALIZE

Identify **contracting options** which fit best with the brand strategy and responds to **payer uncertainties**



III. DESIGN & IMPLEMENT

Build operating model, **develop legal contract** and implement **the contract**





Ann Nguyen

Senior Vice President, Pharmacy Strategy & Product
UnitedHealthcare

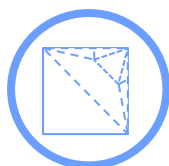
The opinions expressed in this session, any slides, and/or discussion herein, are that of my own, and not representative of UnitedHealthcare.



Using a Similar Systemic Approach Builds Trust and Advances Contract Acceptance & Execution

I. ANALYZE

Understand the biopharma's **product value perception** and **uncertainties** across different populations and lines of business



II. CONCEPTUALIZE

Identify **contracting options** which fit best with the payor's (plan) strategy and responds to **biopharma uncertainties**



III. DESIGN, IMPLEMENT, MEASURE

Build operating model, **develop legal contract** and implement the contract





Ron Potts

Chief Medical Officer
6 Degrees Health

I am representing my own views and not necessarily those of my employers or collaborators.



Cost Containment in Healthcare – Endless Opportunities

Self-funded Health Plans

- Covers 65% of workers in US

Affordable Care Act (ACA) Exemptions

- Exempt from ACA coverage requirements except preventive care

Optional Coverage

- Very expensive therapies for common or not-so common conditions may be optional

Risk Management

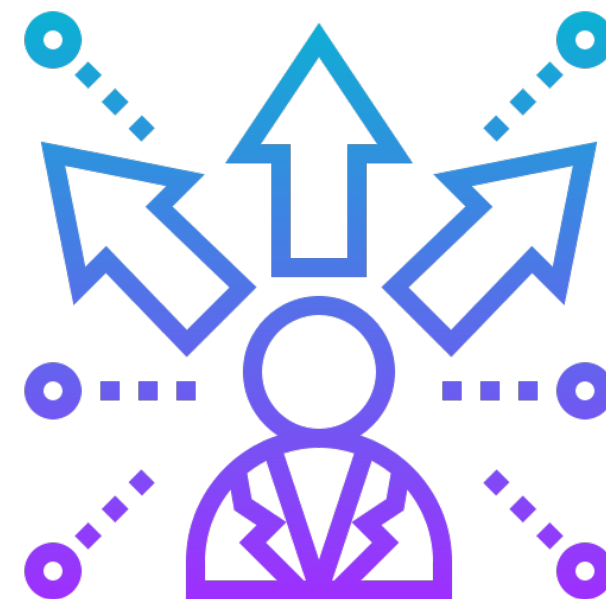
- Risks covered by pooling and/or re-insurance/stop loss

Cost Reduction Opportunities

- Reference-based pricing and clean-claims reviews

Innovative Cost Containment Options

- OBCs for high-cost therapies having incomplete data on effectiveness or durability





Building an Outcomes Based Contract for Launching Astrotuminib



Synthetic Oncology Case: Astrotuminib* for Astrorenoma



Condition

- Malignant tumor of the kidney, unrelated to renal cell carcinoma.
- Propensity for occurring in both kidneys or early metastasis.
- Late metastasis to brain primarily.
- Current standard of care is kidney removal/transplant



Population

- Onset in 40s-50s, gender agnostic
- Commercial insurer population
- Prevalence in this population is 1 in 30,000



Product

- Small molecule targeting the “Metaphor Pathway”
- Approved on an accelerated basis
- Used as first line treatment
- Price \$100-200K/year; ~\$20K/month



Clinical Evidence

- Responses evenly split between dramatic responders (30% sub-population) with 24-month Progression-Free Survival (PFS) and non-responders (70%).
- Possibility of preventing life-long dialysis or transplant has spurred early release and plans for capturing Real-World Evidence (RWE) in this population.

**The product expressed in this case study and certain case study details have been fictionalized and are not representative of any known product, either developed or in pipeline.*



Discussion: Uncertainties



Discussion: Metric Selection



Discussion: Metric Selection

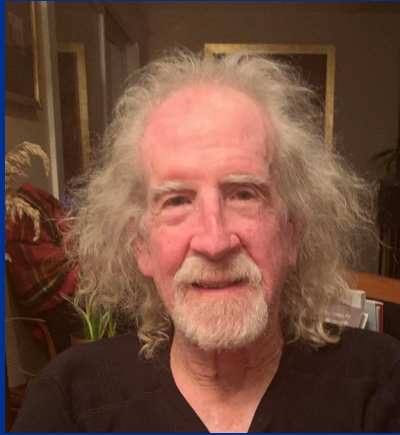


Discussion: Adjudication Challenges



Practical Considerations and Stakeholder Perspectives

Payer Perspective



Ron Potts

Payer Perspective



Ann Nguyen

Industry Perspective



Jamie Foley

Discussion Lead



Mark Trusheim



Thank you!

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