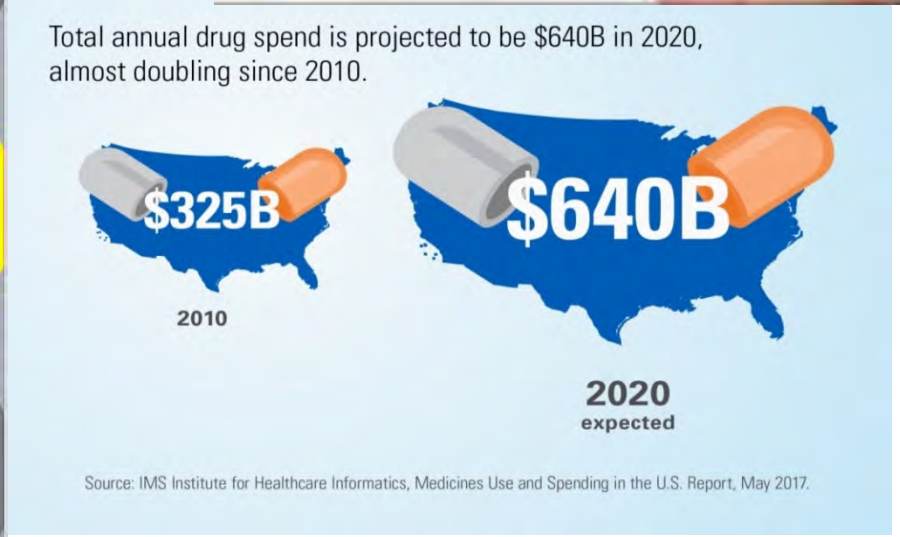
Session 126, Measuring the Impact of Emerging Health Technologies

SOA Health Meeting June 2019

In the News: Drug Headlines



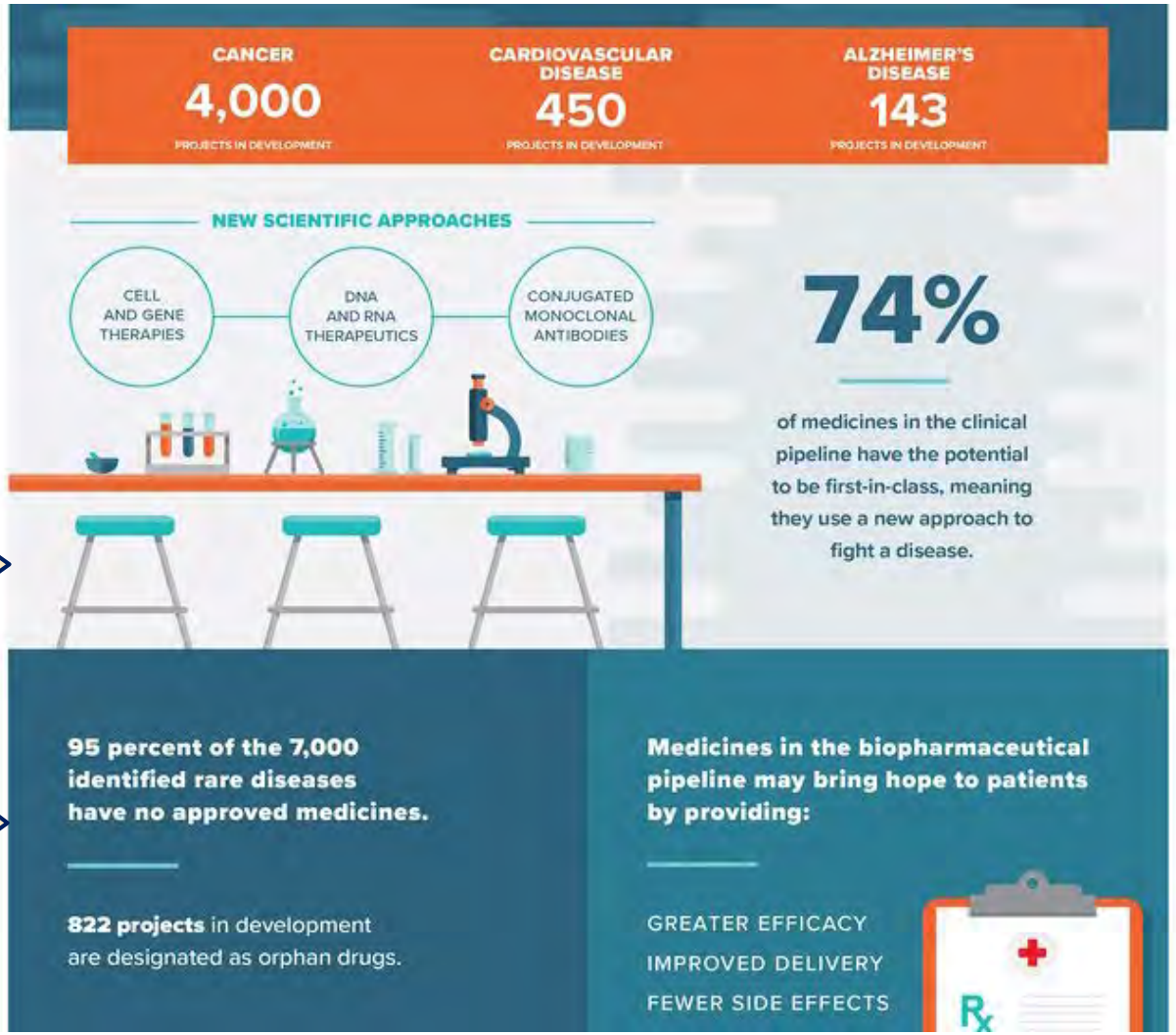
SOURCES: https://www.scoopnest.com/user/RepCohen/1093551210647425026-1-3-of-the-top-12-selling-drugs-had-price-spikes-of-over-100-since-2012-163-lyrica-155-enbrel-114-humira-144-lantus-its-time-to-stand-up-to-and-put-patients-over-profits/, https://www.barrons.com/articles/gene-therapy-is-nearing-a-major-breakthrough-1506140340, https://bcbstnews.com/insights/rising-drug-costs-are-taking-more-of-every-health-care-dollar/

Health Technology Landscape

Over 7,000 health technologies are in development

U.S.–based biopharmaceutical companies invested nearly $90 billion in R&D in 2016.

By 2020, 9 of the 10 top-selling drugs will be specialty drugs and account for 50% of drug spend.



SOURCES: https://www.phrma.org/graphic/what-is-in-the-biopharmaceutical-pipeline, https://www.phrma.org/industryprofile/2018/, https://www.covermymeds.com/main/insights/scorecard/specialty/

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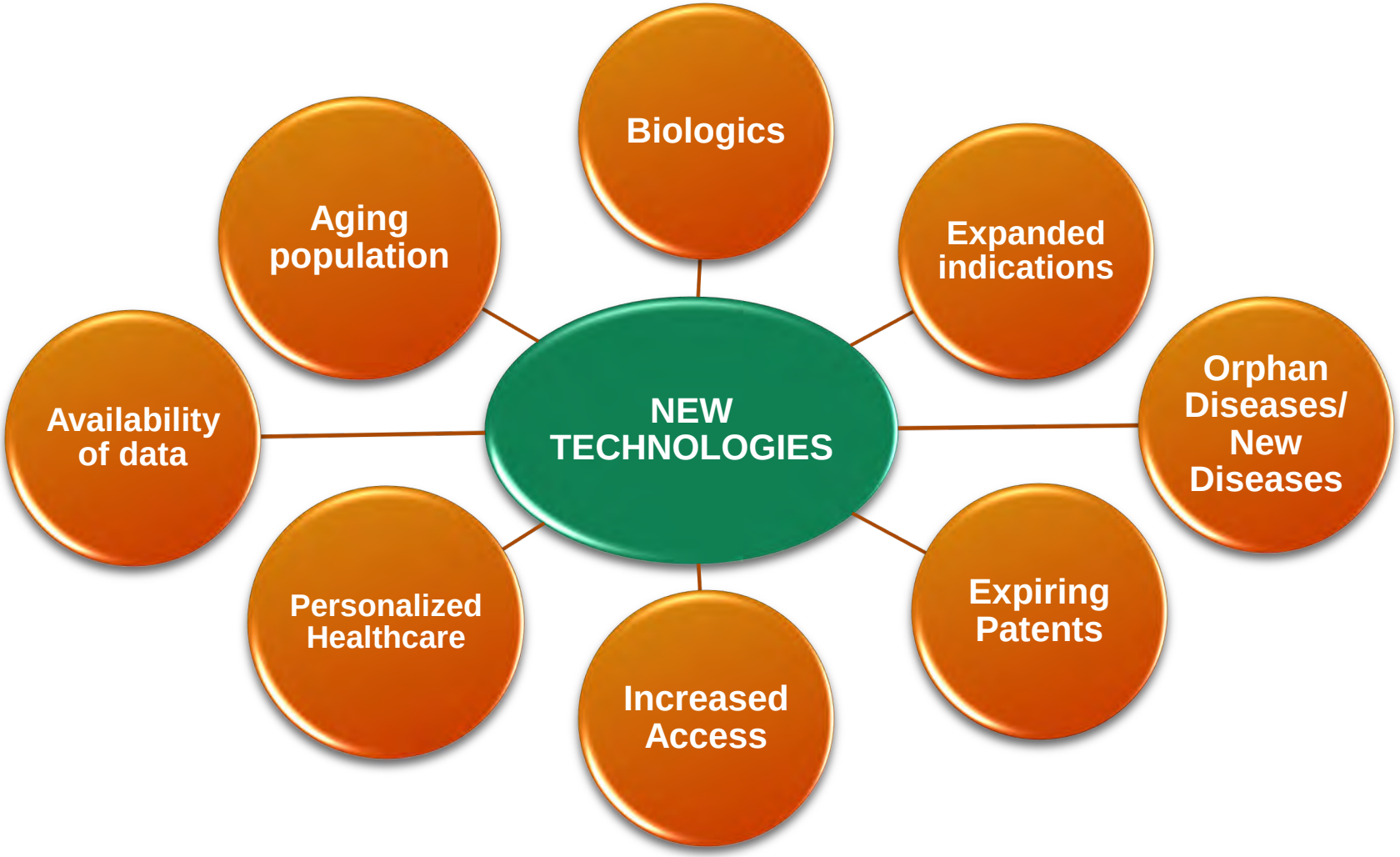
What Drives the Development of New Therapies?



New Therapies Result In…

Increases in Utilization
- Result of new technologies
- Overutilization
- Need for additional drugs due to non-adherence

Increases in the Cost of Drugs
- New brand drugs are often introduced at prices higher than the current drugs they aim to replace
- Specialty drugs comprise the fastest growing category
- Exclusivity periods

Changes in Drug Mix
- Shift to more costly drugs

Proactive pipeline monitoring is the key to anticipating the impact of new drugs

Optum Health Technology Pipeline (HTP): Overview

Created in 2003 to track potential "blockbuster" technologies expected to receive FDA approval within18-24 months

Used by major healthcare payers and pharmaceutical manufacturers in the U.S. to support various activities

- Trend forecasting, pricing
- Medical technology assessment, medical policy, reimbursement policy
- Management strategy, tier placement

One of the few available tools that provide estimated, unbiased per-member-per-month (PMPM) financial analyses of new technologies **before** they enter to market

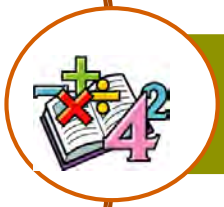
Categories of Selected Technologies include:

- New Medications
- New Medical Devices
- New Drug/Device Combinations
- New Cell, Gene, and Stem Cell Therapies
- New Screening, Diagnostic, and Pharmacogenomic Tests
- New and Revised Clinical and Treatment Guidelines
- Brand-to-Generic, Brand-to-OTC, and Brand-to-Biosimilar Switches

The HTP Team

Writing and editing: Clinically-trained writers, peer reviewers

Modeling: Health economists, biostatisticians, actuaries, MPHs, clinical staff



Actuarial: Certified ASA and FSA modelers, peer reviewers

Clinical: Medical and pharmacy directors

Certified Coding: Health information management specialists

The HTP Process

Technology Identification

Horizon Scanning: FDA resources, journal subscriptions, meetings with Rx companies, newsletters, press releases, professional association websites, manufacturer websites, government websites (eg, CDC, NIH, clinicaltrials.gov)

Research and Clinical Information

- Extensive use of primary references
- Peer review by clinical experts

Data Analysis and Research for Modeling Assumptions

Reconciliation between external and internal data sources
Assumption-setting by clinical and actuarial staff

Projection Modeling and Customization

- View from both Private Payer and Medicare perspectives
- Peer review by actuarial staff

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What is Horizon Scanning?

- **Horizon scanning aims to identify emerging medical technologies that are expected to have a significant clinical and economic impact**

Factors Influencing Clinical and Economic Impact

- Size of the target population
- Availability of current treatments for a given condition
- Safety and efficacy compared to current treatments
- Mechanism of action
- Formulation and route of administration
- Cost of drug, administration, and testing
- Number of indications
- Site-of-service
- Buzz/hype - Media/public interest

Horizon Scanning Sources

- FDA resources
- Manufacturer websites
- Clinical trial websites
- Government websites
- Newsletters
- Meetings with Rx manufacturers
- Professional association websites
- Clinical experts
- Press releases
- National Center for Biotechnology Information

Biomedtracker
Pharma intelligence | informa

Medscape

The NEW ENGLAND JOURNAL of MEDICINE

PubMed.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA
FDA

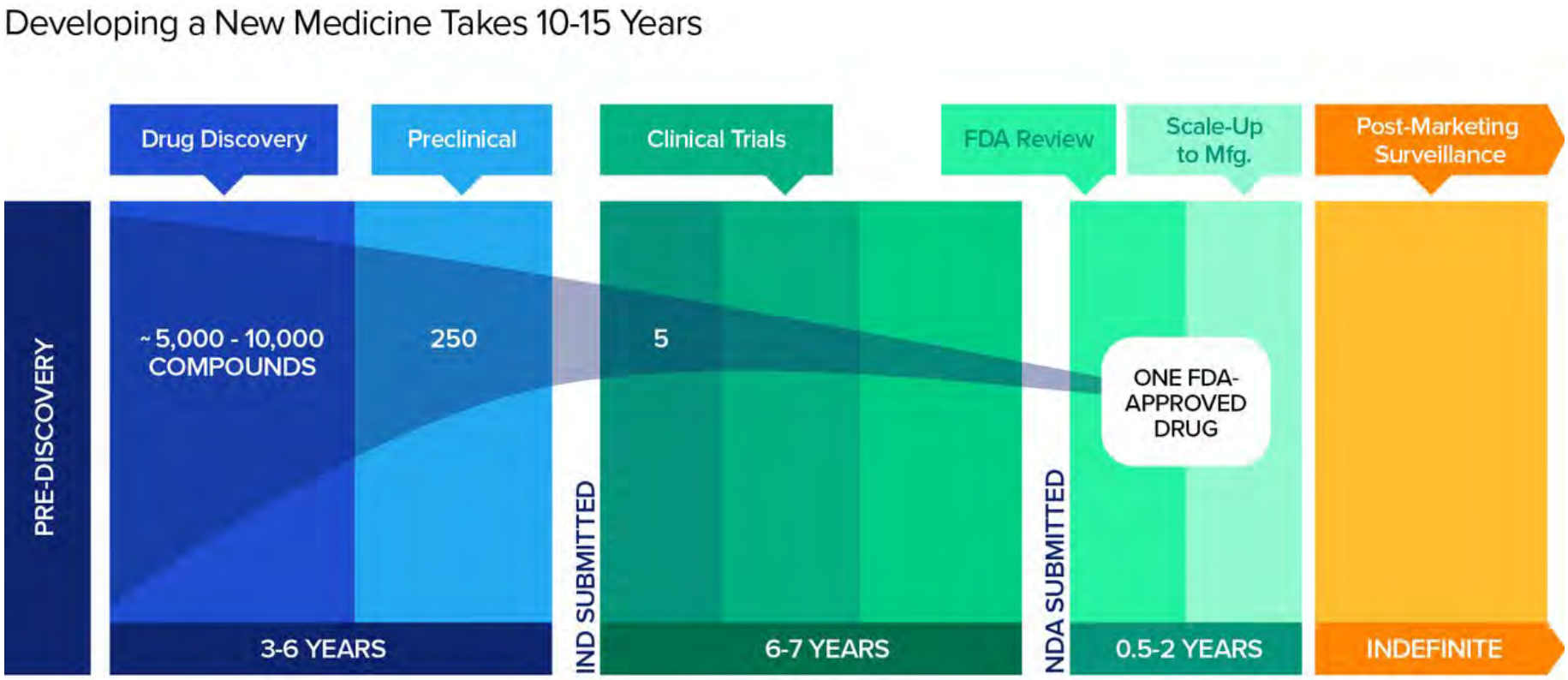
NIH U.S. National Library of Medicine
ClinicalTrials.gov

FiercePharma

Challenges in Horizon Scanning

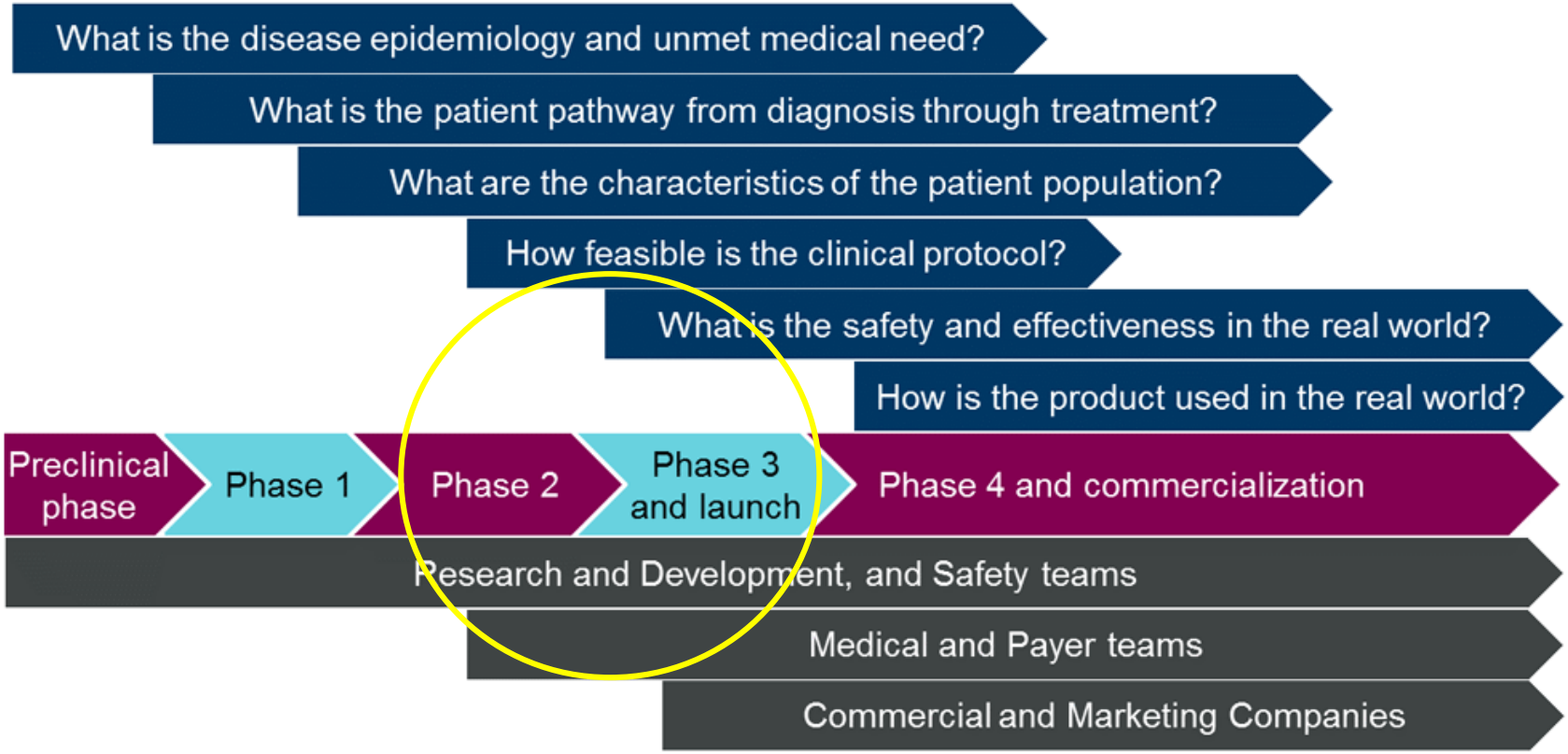
- Conflicting Information
- Identifying Eligible Population
- Unknown Costs
- Confidentiality issues
- Regulatory Delays
- Different approved Indication
- Uptake/Grade-In

Drug Development and FDA Approval



SOURCE: Pharmaceutical Research and Manufacturers of America, Drug Discovery and Development: Understanding the R&D Process, www.innovation.org.

Modeling Considerations



SOURCE: https://f1000research.com/articles/7-111/v2

Technologies Included in HTP

Inclusion Criteria

- Novel mechanism of action/first-in-class technology
- Game-changing technology for diseases with few, if any, effective interventions
- New treatment for a large patient population
- Improvement over standard-of-care or available therapies
- High expected cost
- New/potentially-new indication(s) for an existing medication
- New or expanded screening or treatment guidelines for a given condition
- Potential to reduce costs
- Recognized by the FDA as constituting an important therapeutic advance

Technologies Excluded from HTP

Exclusion Criteria

- Agents with a very small affected population that would not appreciably impact PMPMs
- Technologies which would have a minimal PMPM impact due to having a price/expected price similar to that of currently-available devices and drugs
- Marketplace entry of a technology in a class that is no longer considered disruptive
- Complete conversion from one technology to another (no significant PMPM change)
- Technologies unlikely to receive health plan coverage

Clinical Content

Snapshot Articles

- Include epidemiological statistics, clinical information, trial results, and references

- Discuss pipeline technologies' competitive environments

- Updated frequently with information on regulatory developments, indications, prescribing information, and launch dates

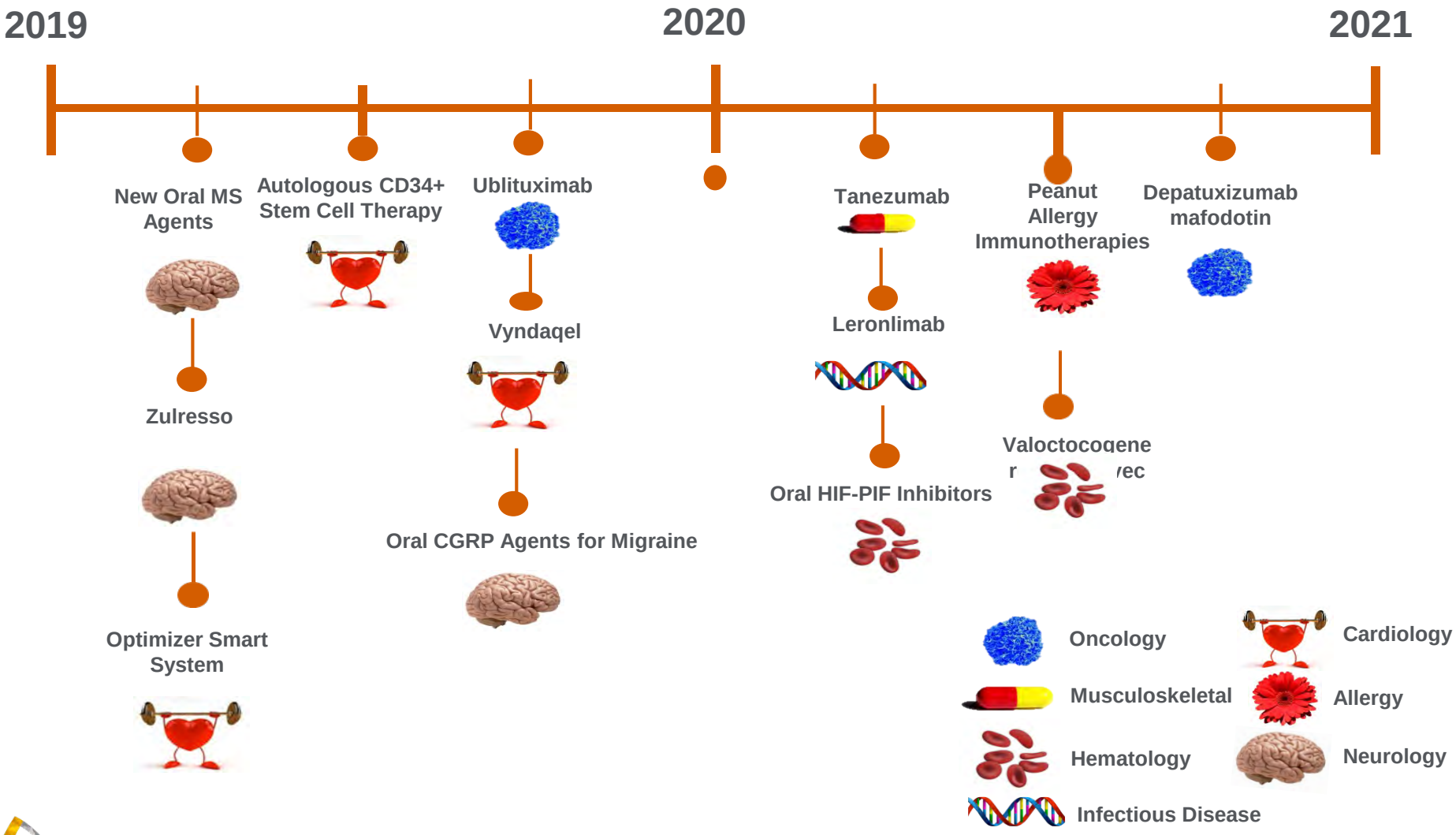
Operational Impact Articles

- Provide coding and administration guidance for complex HTP technologies

- Intended for use during the uncertain period between product approval and the assignment of permanent codes

- Contain best practices, expected practice descriptions, and coding scenarios

What is on the horizon?



Actuarial Models

Quarterly PMPM Forecasts

- By line-of-business (LOB), technology type, therapeutic class, and disease category
- Based on economic assumptions

New Models

- Approved by independent peer reviewers

Revised Models

- Updated with new information on approvals, regulatory changes, clinical trial results, cost information, and patent litigation

PHOTO: https://www.pexels.com/@breakingpic

Modeling Assumptions

Model Questions

Informed by Medical Director and Clinical Pharmacist expertise

1. Medical vs. Pharmacy Impact
2. Population Assumptions
3. Direct Costs
4. Offsetting Costs
5. Launch Date
6. Grade-In
7. Adoption Rate

Data

- Medical and Pharmacy administrative claims and membership data
- Over 18 million covered lives
- Externally-published statistics

Modeling Assumptions: Medical vs. Rx Impact

Model Type

- Drug, Device, Test, Biosimilar, Generic
- IP/OP/PHY/Rx

Medical vs. Pharmacy Impact

- Medical Impact
  - Intravenous or intramuscular injections
  - Subcutaneous injections administered in a health setting
  - Devices, procedures, and screening tests
  - Gene, cell, and stem cell therapies
- Pharmacy Impact
  - Pharmacy-provided prescriptions
  - Subcutaneous injections that can be self-administered
- Combination of Medical and Pharmacy inputs

Modeling Assumptions: Population

Eligible Population

Pull one year of "annual prevalence" data using:

- LOB
- Diagnosis Codes
- HCPCS, J codes
- NDCs, AHFS class
- Exclusions

Expand to national level

Utilization

Election Rate

- Range of 20-30% - crowded market or less acute condition
- Middle range: 40-60% - other treatment options, expensive treatment
- High range: 70-80% - no other options, low survival rate or devastating disease

Adherence Rates

Modeling Assumptions: Costs

Direct Costs

- Factors that impact direct costs
  - Competition
  - First-to-market advantage
  - Professional and facility fees
  - Length of treatment course
  - Route of administration
  - Treatment efficacy
- Cost estimates use:
  - Currently-approved treatments with similar mechanisms of action (if available)
  - Dosing information
  - Sales projections

Offsetting Costs

- Foregone costs of currently-available treatments
- Factors that impact offsetting costs
  - Add-on therapy vs. replacement therapy
  - Professional and facility fees

Modeling Assumptions: Timeline

Expected Date of First Impact

- FDA approval date
  - Standard FDA review
  - Breakthrough Designation
  - Fast-Track Status
  - Priority Review = ~ 6 months
- Guideline implementation date
- Patent litigation/Generic market entry

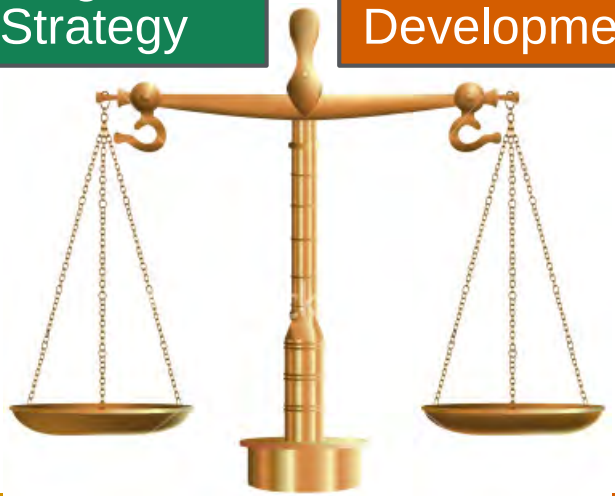
Grade-In Period

- Varies for Rx vs. Medical vs. Devices; Brand vs. Generic or Biosimilar
  - Device/Test = ~4-5 years
  - Drug = ~2-4 years
- Linear grade-in vs. Normal grade-in

Value of Pipeline Analysis

Enables U.S. payers and pharmaceutical manufacturers to proactively manage various activities:

- Trend Forecasting
- Medical Technology Assessment
- Management Strategy
- Medical Policy Development



Related Applications of the HTP Process

Some employers offer supplemental medical benefits to employees for care that is not covered by traditional medical benefits. These benefits help retain existing talent and attract new talent in competitive markets.

We are currently partnered with one client to identify new benefit recommendations for their supplemental medical to make sure they can offer the latest and greatest medical innovations. In order to accomplish this, we perform horizon scanning and develop cost and utilization projections based on their employee population.

New benefits can be things just hitting the market that the traditional medical policy is not likely to cover or may be items added after benefit managers have noted interest by the plan members. Frequently, we are asked to provide quick turnaround opinions on items that are making headlines.

Additional Considerations For Benefits

The fundamentals of the HTP process are leveraged and additional considerations are made when modeling the expected benefit costs for many new supplemental benefits. For example, coverage for a promising but not yet fully proven surgery that is not covered by traditional medical benefits is likely to have:

- Strict eligibility rules that prevent patients from receiving the procedure

- Limited rates of election because other treatments will likely be selected first and patients may be more weary of new treatments

- Low geographic dispersion because fewer providers that not everyone will have access to it because it's new

- Low utilization driven by limited benefit awareness