Dr Shane Gannon, Sector Lead for Pharma and Life Science Consulting - PwC Ireland

Shane is the sector lead for pharma and life science consulting in PwC Ireland and has led engagements in Europe, the US and Ireland focusing on M&A, strategy and large-scale transformational change.

Shane is a former research scientist and holds a Ph.D. in Pharmacology from University College Dublin and a B.Sc. in Biotechnology from Dublin City University.

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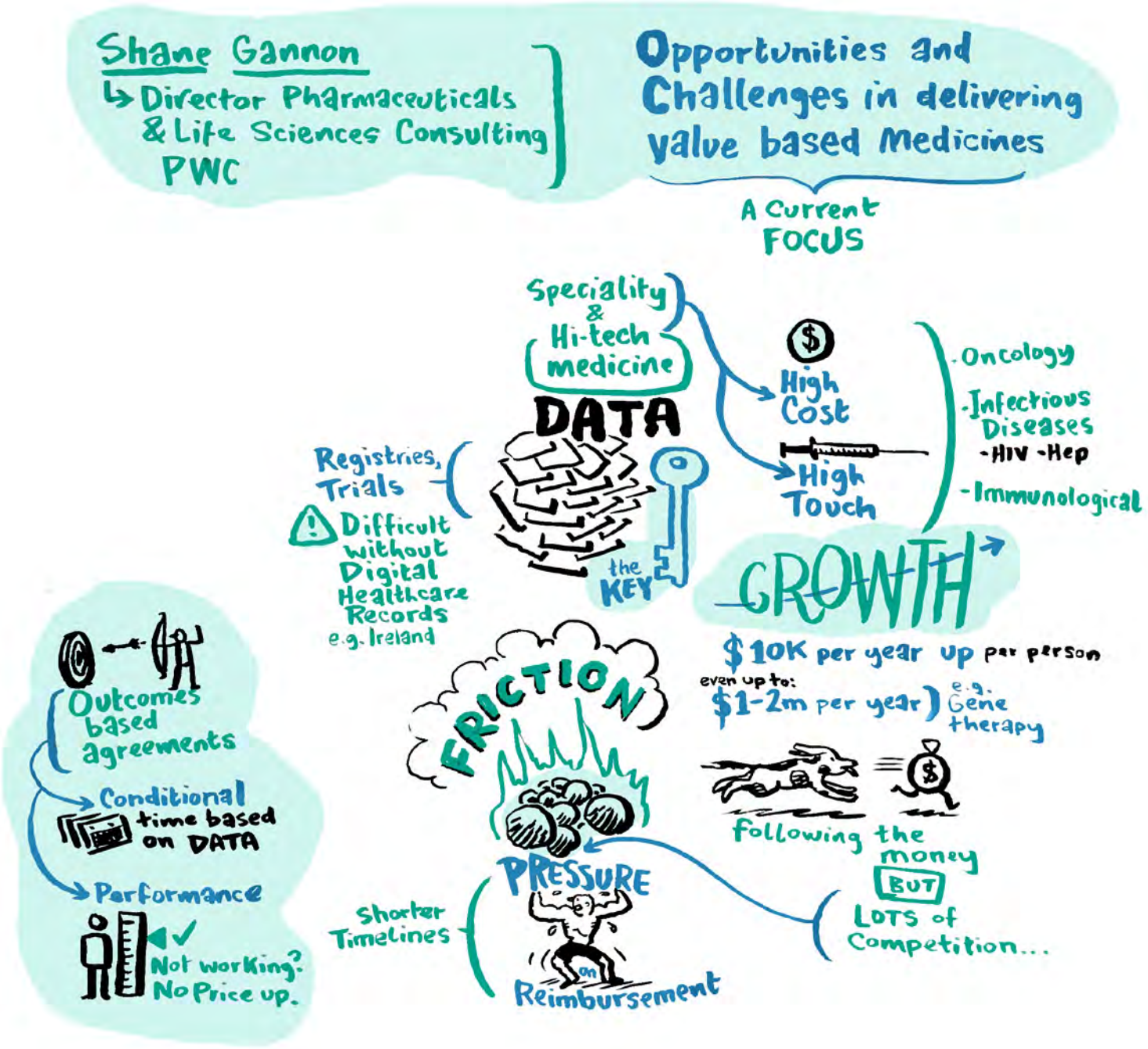
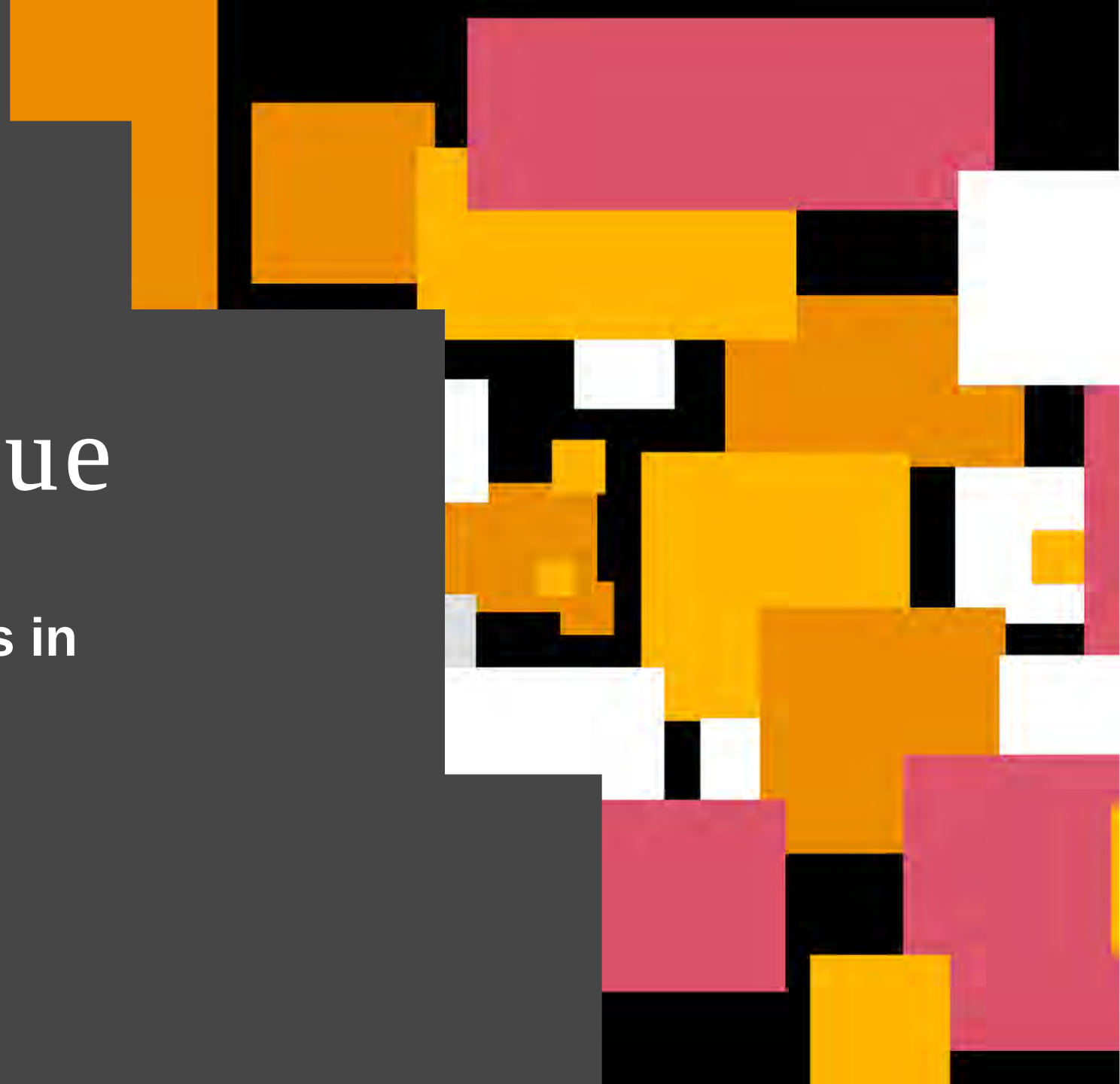

Shane Gannon
↳ Director Pharmaceuticals & Life Sciences Consulting PWC
Opportunities and Challenges in delivering value based Medicines
A Current FOCUS
Speciality & Hi-tech medicine
DATA
Registries, Trials
Difficult without Digital Healthcare Records
e.g. Ireland
the KEY
High Cost
High Touch
-Oncology
-Infectious Diseases
-HIV -Hep
-Immunological
GROWTH
$10K per year up per person
even up to:
$1-2m per year
e.g. Gene therapy
Following the money
BUT
LOTS of Competition...
FRICTION
PRESSURE
Shorter Timelines
on Reimbursement
Outcomes based agreements
Conditional time based on DATA
Performance
Not working? No Price up.


SECTION 2
GLOBAL challenges:
LOCAL SOLUTIONS

Focusing on value

Opportunities and challenges in delivering value based medicines



A focus on value for all stakeholders will be increasingly important given current trends in the industry

- The innovator pharmaceutical industry is increasingly focused on developing high tech specialty medicines
- Specialty medicines are often used to treat more serious diseases and are more expensive than traditional therapies
- Drug development pipelines and accelerated access programmes are increasingly focused on these indications
- Ensuring timely access and value for money for new treatments will increasingly require the use of additional data to validate effectiveness

Several large pharma companies have identified high tech or specialty medicines as a core driver of growth

New GSK to deliver step-change in growth and performance over next ten years driven by high-quality Vaccines and Specialty Medicines portfolio

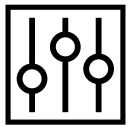
Our strategy is to build a leading, focused medicines company powered by advanced therapy platforms and data science.

Our R&D pipeline positions us with a clear focus on becoming a global specialty innovator in oncology, immuno-oncology, neurology, and immunology

We focus on researching, developing and marketing specialty-focused innovative medicines that provide significant clinical benefit and value

What are specialty medicines?

What are specialty medicines



Highly complex:

- Treatment often initiated by specialists
- Generally injectable and/or not self-administered
- Often biologics

High touch

- Require extensive or in-depth monitoring/patient counselling
- Require an additional level of care in the supply chain (e.g. refrigeration, specialised handling and distribution)

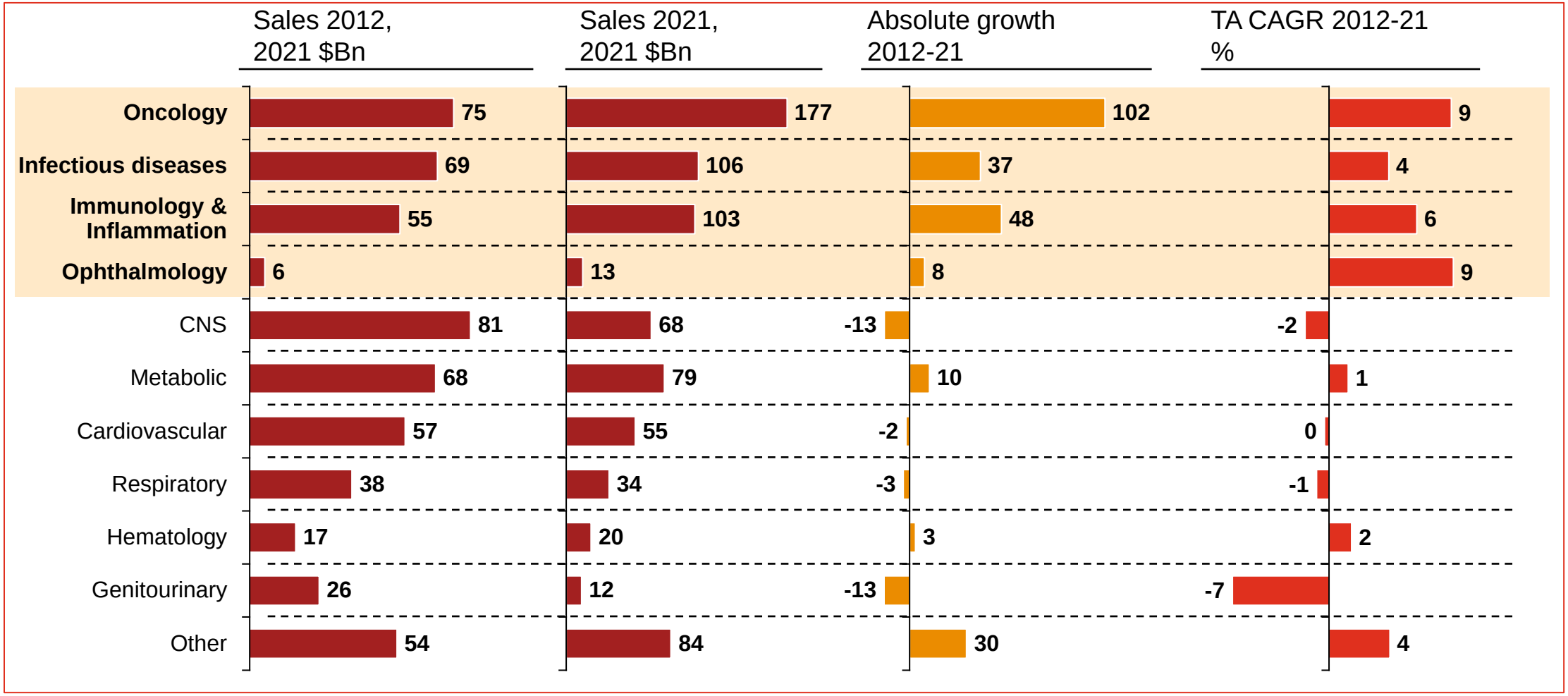
High Cost

- Typically very expensive in both total and per patient cost
- Often used to treat very costly diseases

Leading specialty medicine areas

- Oncology
- Rare diseases
- Cell and gene therapies
  - Neurodegeneration
  - Inherited retinal dystrophy
- Immunology and inflammation
  - Multiple Sclerosis
  - Psoriasis
  - Rheumatic disease
- Infectious diseases
  - Viral hepatitis
  - HIV antivirals
- Ophthalmology
  - Macular degeneration

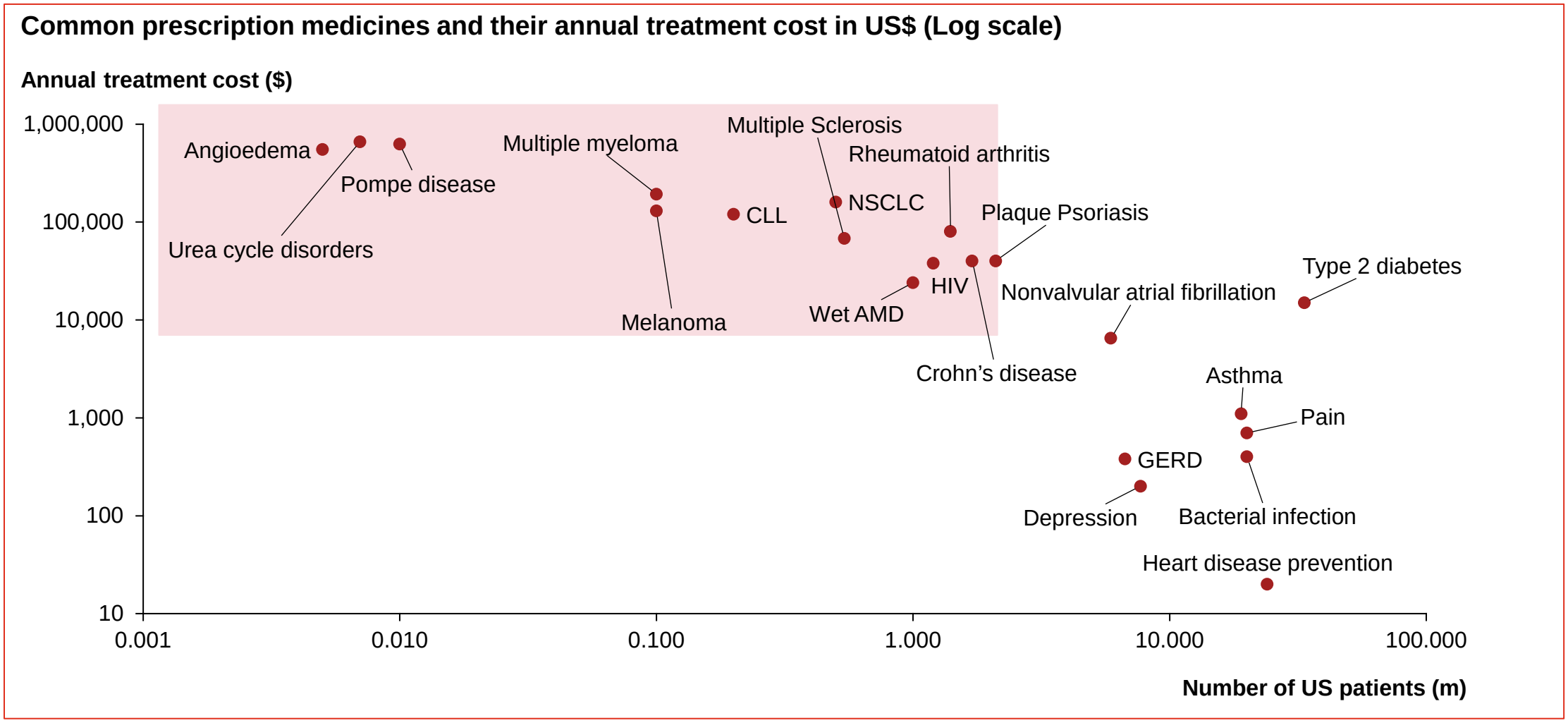
Specialty indications have been significant industry growth drivers in the last decade



Notes:
- Projections exclude COVID vaccines and therapeutics
- Other category includes: musculoskeletal, gastroenterology, toxins and legacy product portfolios

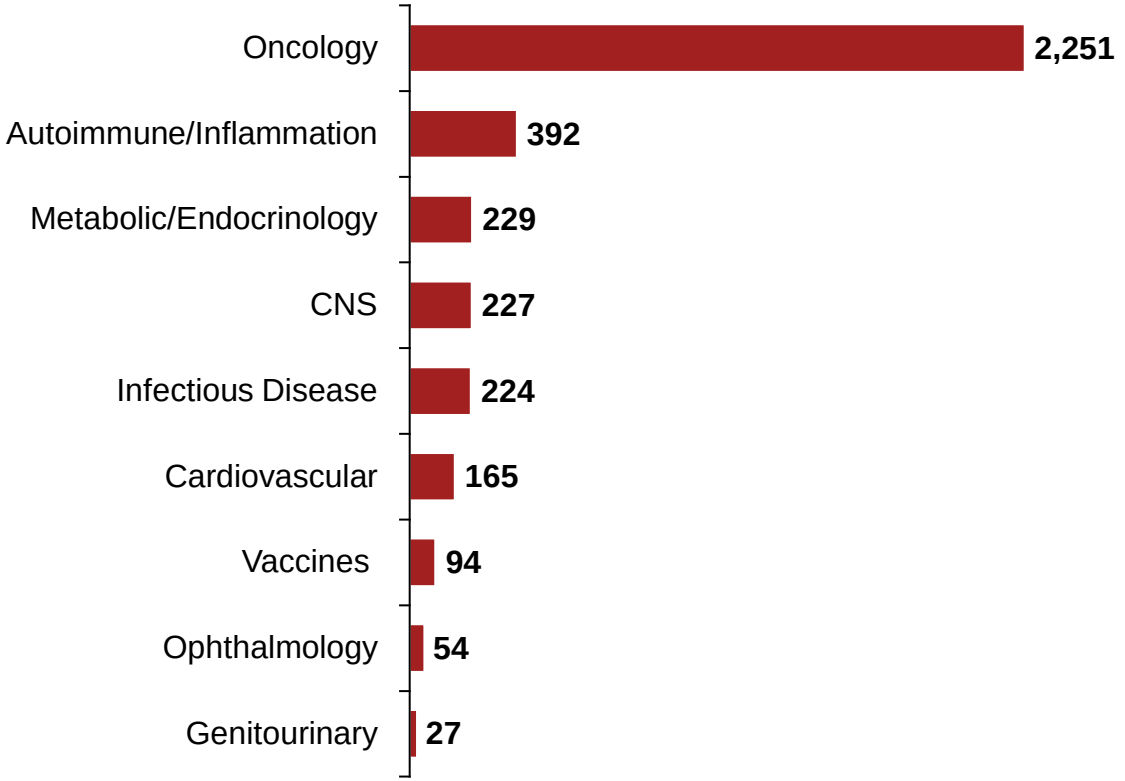
Source: Informa Datamonitor; Informa Pharmavitae

Specialty medicines tend to be more expensive and focused on smaller patient populations

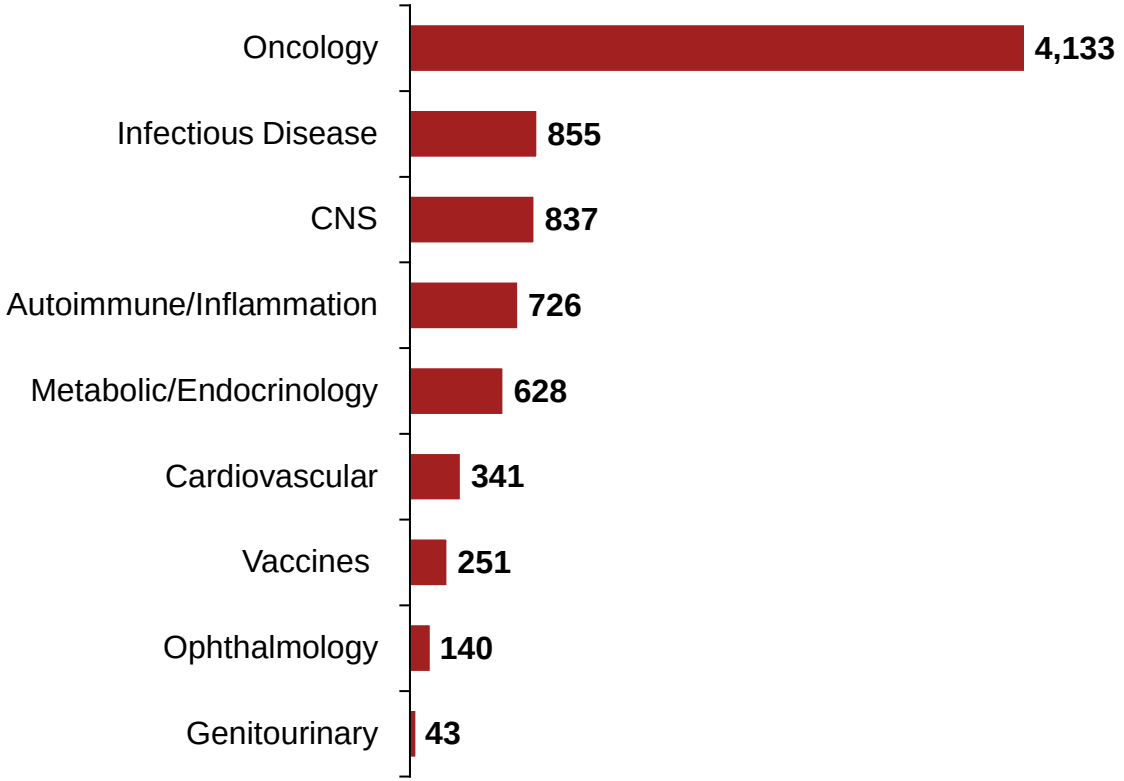


This has led to significant R&D competition particularly in Oncology

Number of open clinical trials, Phase I-III where a top 20 pharma company is listed as a sponsor



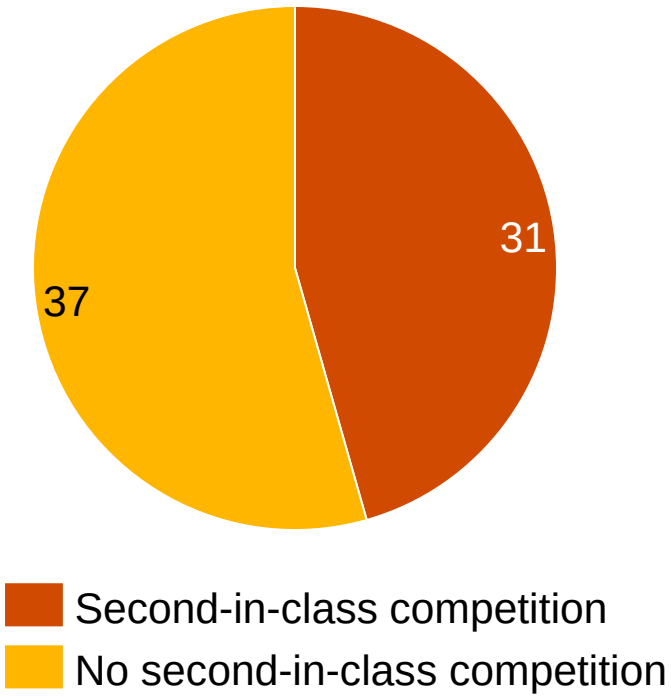
Number of open clinical trials, Phase I-III where a non-top 20 pharma company is listed as a sponsor



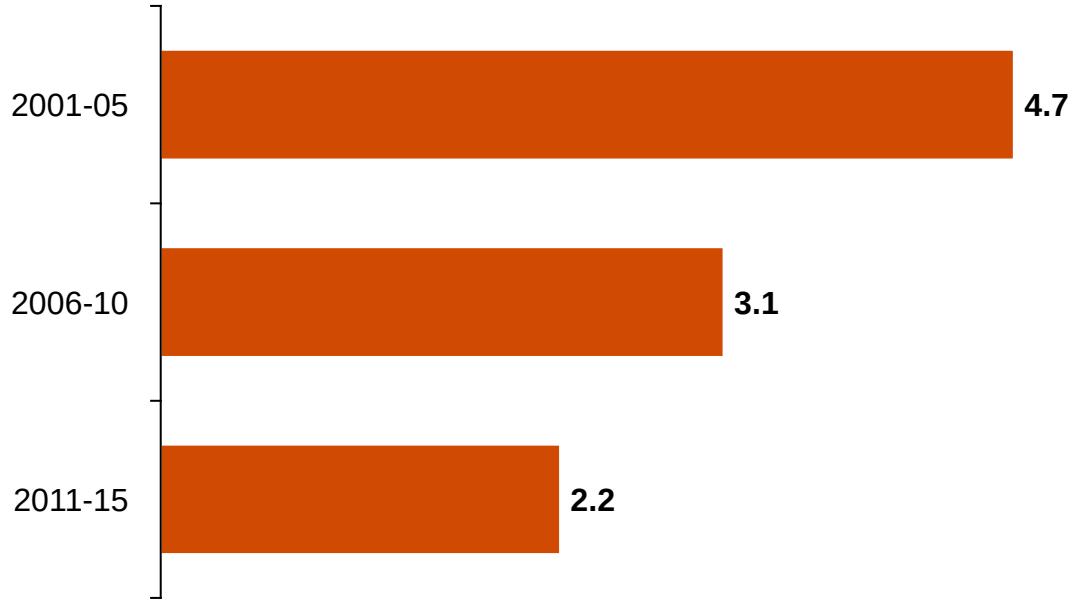
Source: Pharmaprojects

This competition is contributing to falling market exclusivity periods for many first in class products

Approximately 31 of the 68 blockbusters approved during 2001–15 have **in-class competition**; the remaining 37 do not have a competitor in their class



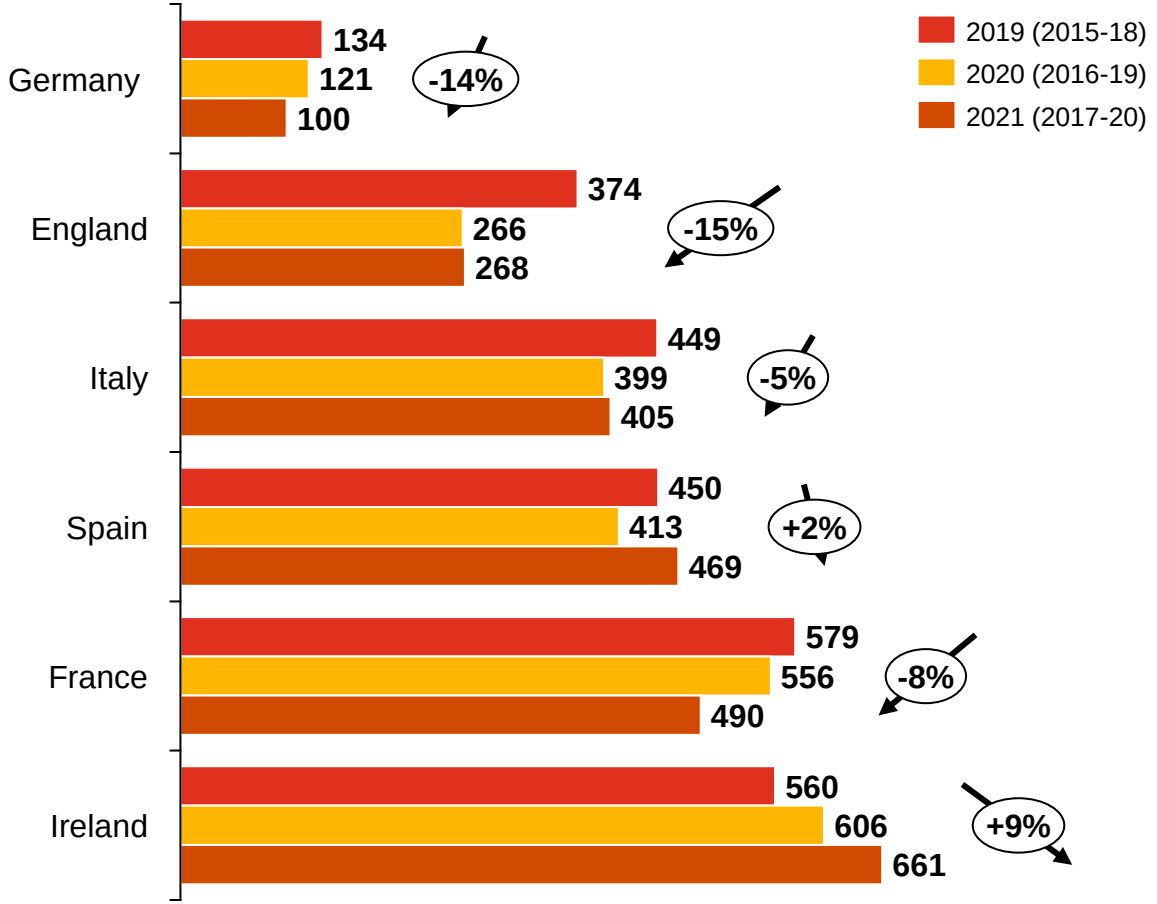
On average, **the more recently a drug was approved by the FDA, the quicker it has faced in-class competition**, meaning drugs are enjoying shorter monopolies



Source: Informa Pharmaintelligence

Securing access in Europe can be a time consuming process (Oncology example)

EFPIA reimbursement wait time trends for Oncology treatments are variable with Ireland being particularly long



Examples of issues causing reimbursement challenges

High Cost	Many treatments have a high cost
Uncertain long term efficacy	Several high medicines do not have long-term efficacy data
Lack of robust clinical data	Many treatments are approved on an accelerated basis or on the basis of open single arm trials

Source: EFPIA; IQVIA

Challenges in reimbursement have led to the increased use of managed access agreements

Finance based agreements		Outcomes based agreements	
Population level	Patient level	Conditional coverage	Performance based
Simple discount or rebate Free stock Cap on overall reimbursement costs Price/volume agreements	Dose cap Limit on treatment duration Per-patient cost threshold	Coverage with evidence development	Full or partial repayment of costs in patents where treatment outcomes

Source: Informa

Outcomes based agreements are becoming popular in the case of Cell and Gene Therapies

Country	Primary Reimbursement model	Price approach	Data collection for reimbursement
France	Upfront payment with future price adjustments possible	Future price can be adjusted based on subsequent clinical performance	Based on existing registries in place
United Kingdom			Long term clinical trial data and routine clinical data collected by the NHS
Germany	Changes in payments based on individual patient data	Price paid is based on individual patient response to treatment	Generally not disclosed or based on existing registries in place
Italy			Dedicated government registry/tool
Spain			

Examples of data tools include Valtermed and DoubleJump Interchange

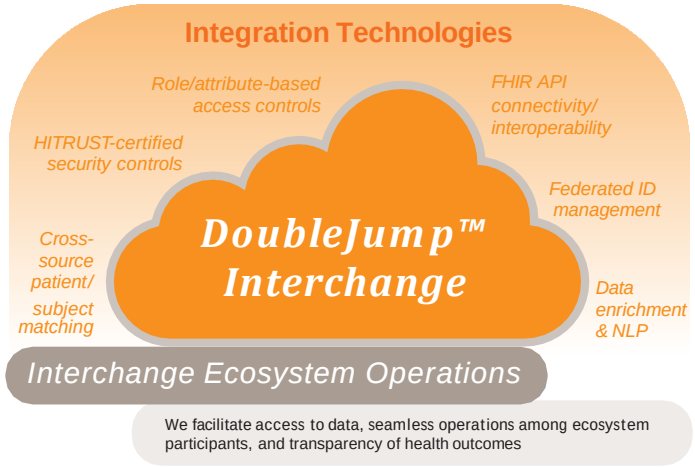
Valtermed

Web based tool that is a collaboration between the Spanish MoH, the regions (budget holders), healthcare professionals and the pharmaceutical industry

For CAR-T the tool collects:

- General patients details
- Disease characterisation at diagnosis and subsequent medical history
- CAR-T production and administration information
- Post infusion monitoring of disease status
  - Response and survival (evaluated using predefined criteria at set times)
  - Safety

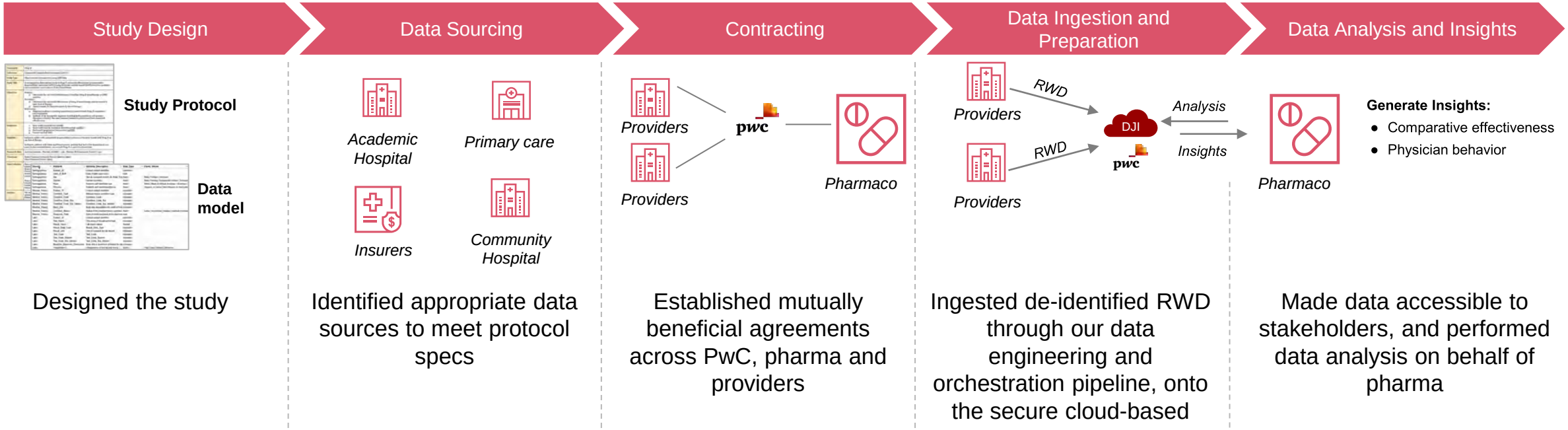
PwC DoubleJump Interchange



Contracts	• Defining roles and responsibilities • Agreement on data use and sharing terms
Operations Integration	• Data fluidity • Workflow interoperability
Shared Services	• Triaging and resolving technology and operating issues • Continuous monitoring to proactively identify vulnerabilities
Value Capture	• Tracking and measuring outcomes to drive program transparency • Program sustainability

PwC orchestrated a provider-pharma collaboration to use real world data to reveal comparative treatment outcomes

Clinical trials showed that an oncology treatment was effective as front-line therapy, but it was not being adopted rapidly by clinicians due to a lack of evidence for subsequent therapies. PwC delivered the evidence to address this challenge.



Outcomes

This study will reveal the full therapeutic sequence for this cancer type that's being used in the real world at both academic and community hospitals. Publication of these results will provide evidence to practicing clinicians that the client's drug can be used effectively with common subsequent therapies.