

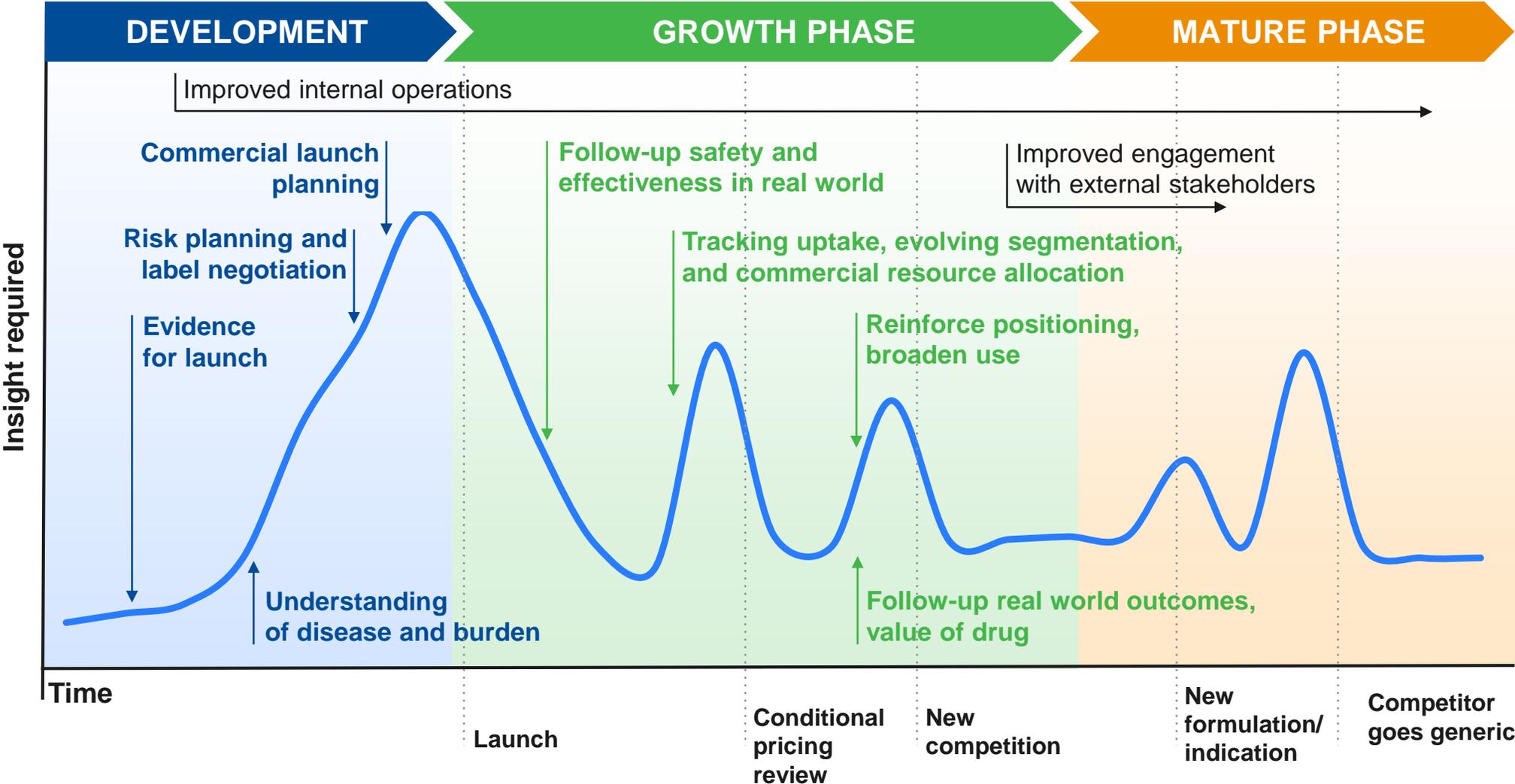
Key issues in the use of real-world data and how to avoid them – A project manager's perspective

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There are opportunities to leverage data in decision making throughout a product's lifecycle



There are some key challenges to realising the value of real world data

1

Inconsistent terminology – know what you say and say what you mean!

2

Purpose and use of data – these are not always aligned

3

Restrictions on access and patient confidentiality

4

Communicating the value for RWD generated insights to broader audience

1

Inconsistent terminology – RWD, RWE and RWI

If stakeholders use terms inconsistently it impedes communications and can present a barrier to utilising real world evidence

Real-World Data (RWD)

- Patient-level data, collected by any means other than conventional randomised controlled trials

Publication or other dissemination of information

- Evidence and insights generated are shared with other stakeholders and the healthcare professionals
- Generating discussion and new avenues for research



Real-World Insights (RWE)

- Evidence generated from RWD using appropriate scientific methodology
- Primarily intended to support a claim or hypothesis as **published evidence** with external stakeholders

Real-World Evidence (RWI)

- Insights generated from RWD using any appropriate analytical techniques
- Primarily to inform strategic or operational decisions
- May lead to new need for RWE generation from RWD

1

Awareness of terminology

- Within each organisations there are varying terminology for project documents and stages
 - An awareness of this, and what is contained in each document is key
 - Align on definitions and scope at the start of a project
 - Make no assumptions of the previous experience (with your company terminology & processes) and clarify wherever possible



2

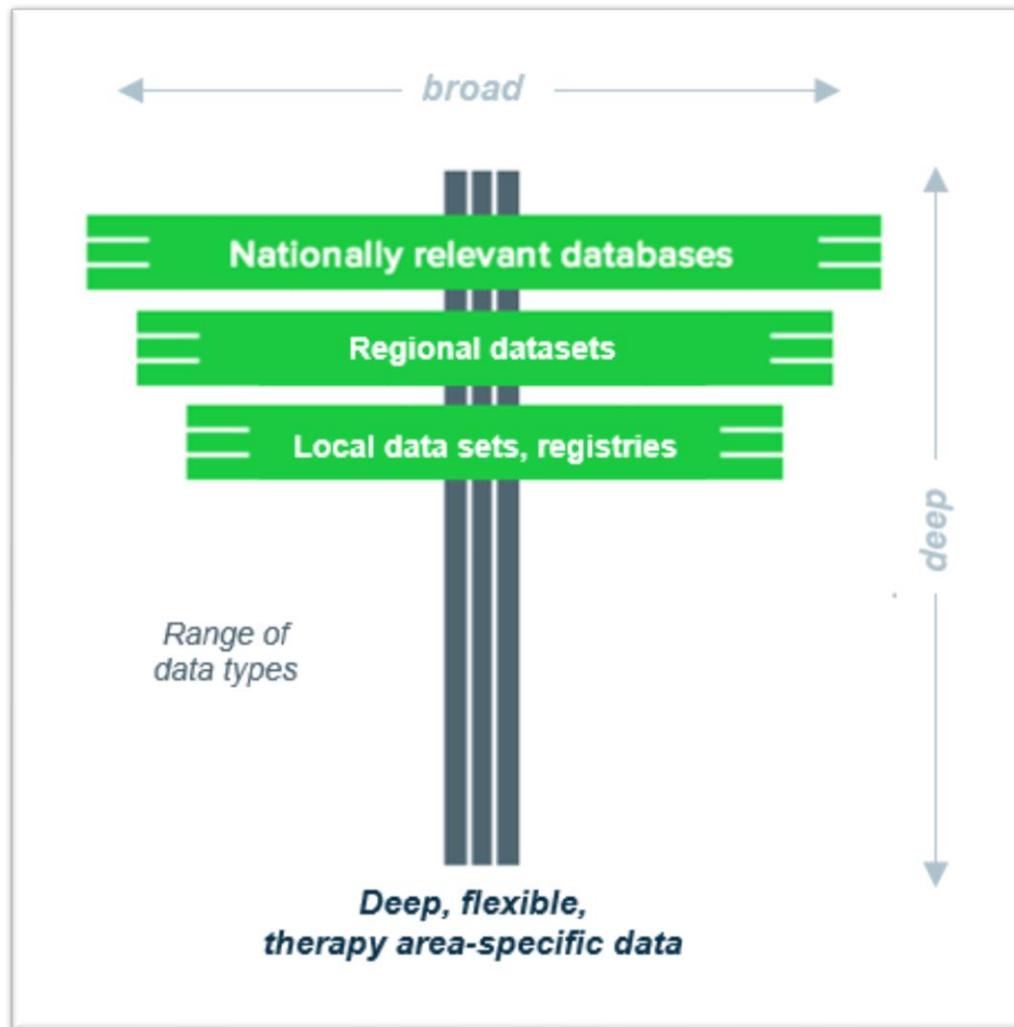
Purpose and use of data – these are not always aligned

RWI has a wide range of applications, with tangible benefits to patients

	Pharma Needs	Pharma Benefits	Patient Benefits
R&D	<ul style="list-style-type: none"> Disease insights: Prevalence, diagnosis, treatment patterns, and unmet needs, 	<ul style="list-style-type: none"> ✓ Better targeted R&D investments, and study design for clinical trials 	<ul style="list-style-type: none"> ✓ Earlier identification of undiagnosed patients
Medical Affairs & Safety	<ul style="list-style-type: none"> Insight on how drugs are being used, patient safety, and drug effectiveness 	<ul style="list-style-type: none"> ✓ More sophisticated recommendations on who gets drugs, and how they are taken 	<ul style="list-style-type: none"> ✓ Fewer patient adverse events, and improved patient responses to drugs
Health Economics & Outcomes Research	<ul style="list-style-type: none"> Inform assumptions on disease prevalence, diagnosis, treatment, and burden of disease 	<ul style="list-style-type: none"> ✓ More sophisticated cost effectiveness models for drug funding applications 	<ul style="list-style-type: none"> ✓ Quicker, more positive funding decisions, quickening access to effective drugs ✓ Unlocking funding blocks
Commercial	<ul style="list-style-type: none"> Insight about how patients are diagnosed, monitored, and treated 	<ul style="list-style-type: none"> ✓ More effective and efficient brand promotion & education to the right doctors 	<ul style="list-style-type: none"> ✓ Earlier access to drugs for the most appropriate patients

2

However, RWD has not always been collected for the purpose of generating evidence



- **MOTIVATION:** Be aware of the motivations for collecting this data.
 - Hospital Episode Statistics (HES) data is for reimbursement
 - Clinical management of patients
 - Monitoring of specific disease population
- **IMPERFECT and INCOMPLETE:** Errors are more likely to arise where the variable used are not key to the purpose of the data
- **CODING v's CLINICAL PRACTICE:** an awareness of how and why data has been collected can help distinguish between clinical and coding practices
- **LINKAGE:** Linking data presents a sizeable challenge in reconciling different data recording techniques and technologies

Therefore **ALLOWANCES** have to be made to accommodate the “messy” world of RWD: Data cleaning activities, variables definitions e.g. defining “disease severity”

3

Restrictions on access and patient confidentiality

- Often there are strict data confidentiality principles to follow in order to use the data for scientific purposes.
- As researchers we must adhere to various rules and regulations safeguarding patient data

e.g.

GDPR



CAG



ISAC



Also local ethics boards at hospital sites, data specific ethics committees, country specific ethics processes.

- Can have a massive impact on timelines – ethics processes can last 4 weeks to 9-12 months to complete

4

Communicating the value for RWD generated insights to broader audience

Often a requirement of ethics application is the demonstrating the broader impact of your research – supporting clinicians in management of their patients

Main aim is through

- Publication and conferences
- Making a change to improve how patients are treated or how hospitals view efficiencies in their treatment pathways

These review institutions are often under large public and political pressure to reassure the public that their data is safe and being used for greater good

Security breach fears over 26 million NHS patients

f share | | | Save 16

Practices are struggling to deliver basic care within v
image CREDIT: ANTHONY DEVLIN/PA

Department of Health | Department for Business, Energy & Industrial Strategy

Making a reality of the Accelerated Access Review

Improving patient access to breakthrough technologies and treatments in a cost-effective model

November 2020

Sir John Bell's Life Sciences Industrial Strategy sets out the industry's vision to make the UK a world-leader in this **£64bn sector**

Building our #IndustrialStrategy

HM Government

So knowing about these key challenges up front, how do we avoid project pitfalls?

	CHALLENGE	MITIGATION PLAN
1	Inconsistent terminology – know what you say and say what you mean!	<ul style="list-style-type: none">• Ensure consistency throughout project process• Define terminology up front e.g. Study protocol development – not limited to RWD/RWE but also all other terminology specific to the disease area, data, defined variables
2	Purpose and use of data – these are not always aligned	<ul style="list-style-type: none">• Understand the data BEFORE conducting analysis. Either through feasibility analysis so you know what the limitations are upfront and can plan accordingly or through researchers experienced with the dataset.
3	Restrictions on access and patient confidentiality	<ul style="list-style-type: none">• Understand the process for accessing data up front. Experience cannot be underestimated here. What may seem easy – in reality is drawn out, laborious, inflexible process.• Know what the ethics committee want up front so you can include it in your thinking.
4	Communicating the value for RWD generated insights to broader audience	<ul style="list-style-type: none">• Know what the purpose of your research is – what the end goal is both from “pharma perspective” as well as “patient/health service perspective”

Real-world project management key takeaways



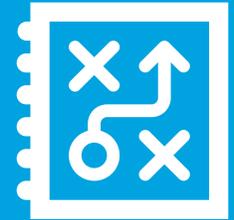
Be **flexible**, but be **orderly**.
Have plans ready to pick up but be prepared to stop and re-asses the situation



Communicate, communicate, communicate
Keep your team and your client on the journey with you



Document your decisions, this allows you to justify the route you have taken, making your research reproducible and defensible

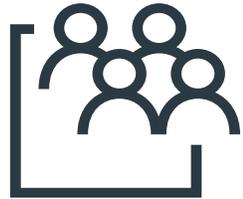


Be **pragmatic**, do not let perfection be the enemy of good. RWD is often imperfect but we gain RWI by working pragmatically with what we have

Case study challenge – multiple stakeholders

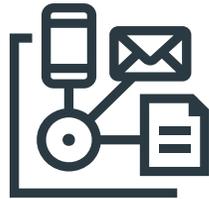
Large multi-country project with consortium of ~20 pharmaceutical

SITUATION



- Client needed to provide RWE for the safety of their product in offspring of exposed fathers
- PASS (Post authorisation safety study) for EMA
- All market authorisation holders were to be involved ~ 20 companies
- Risk of divergent thinking may delay tight project timelines

SOLUTION



- Clear channels of communication – email, consortium meetings, meeting minutes, ground rules.
- Organised and clear methods for providing feedback (e.g. Protocol review processes), with milestones that were kept.

RESULT



- Allowed for all members to have a voice and express view, challenge project direction, and have their input included
- Allowed for timely delivery of key documents to EMA, meeting MA holders obligations.

Case study challenge - inheriting a project with previous PM challenges

Aim:

Generation of RWD from delivery data

Challenge:

Consent to use data collected from patient and HCP portal only allowed the data to be used to manage patient deliveries

Issue:

The project goal was not communicated widely so a subsection of the development team were not thinking of the generation of new data when deciding wording for the consent

Resolution:

Re-consenting of patients and HCPs resulting in patient and HCP attrition as well as significant time and financial cost to the sponsor





Any questions?



Appendix

Counsel-identify suitable sources of RWE as early as possible in the product lifecycle

Speed

- RWE is not quick to generate, and depends on what is required, and how it can be generated.
- Those not expert in RWE are often surprised by, and frequently caught out by these timings
 - Retrospective dataset analysis – quickest
 - Retrospective observational studies based on primary data capture
 - Prospective observational studies based on primary data capture – slowest

Proactivity vs. Reactivity

- Proactively consider developing the RWE strategy earlier in pipeline development as part of their overall GTM, - initiating broad and flexible programmes of projects at the beginning of Phase III to consider current clinical practice, guideline adherence etc. as part of their programme to prepare the market for access rather than being reactive when asked to generate RWE in face of an HTA challenge for example

Patient and public engagement to ensure continued support for use of RWD for research purposes

What is being done with patients' data?

Do patients know that their data is being used?

Patient data opt-out clause

What is the difference between anonymised and non-anonymised data?

What is patients' data being used for?

National news stories about patient data

Welcome Understanding Patient Data Survey: 2000 participants:

- More people supported than opposed commercial access and that figure went up if there was no other way of conducting the research, if the commercial option was the only one otherwise the research wouldn't happen, then 61% of people were supportive
- 17% that didn't want commercial access under any circumstances – why an opt out approach is the most appropriate way forward
- People had four key tests, they wanted to know why the data was being used; who was using it; what kind of data; and how it was used. But really, the first and most important was that why. If there was a public benefit, then they were much more comfortable with the data being used
- There was mix of public and private benefit, then it was a bit more acceptable. They would have a conversation about the who and why and how. Solely private benefit, people were very uncomfortable – explains why insurance companies accessing data raises so many concerns

<https://www.kingsfund.org.uk/audio-video/nicola-perrin-understanding-patient-data> here is a significant minority of people