ROYAL PHARMACEUTICAL SOCIETY

Innovation in pharmacy: Roles that transform patient care

Perspectives from
Pharmacists/Pharmaceutical Scientists in the
Pharmaceutical Industry

Disclosure

This presentation reflects the personal and professional experiences of the speakers. The views expressed are their own and do not necessarily represent those of employers.

ROYAL PHARMACEUTICAL SOCIETY

ROYAL PHARMACEUTICAL SOCIETY

Stephen Tomlin

Director of the Children's Medicines Research & Innovation Centre,
Great Ormond Street Hospital

Role Of Pharmacy In Medicine Development to Improve Clinical Practice



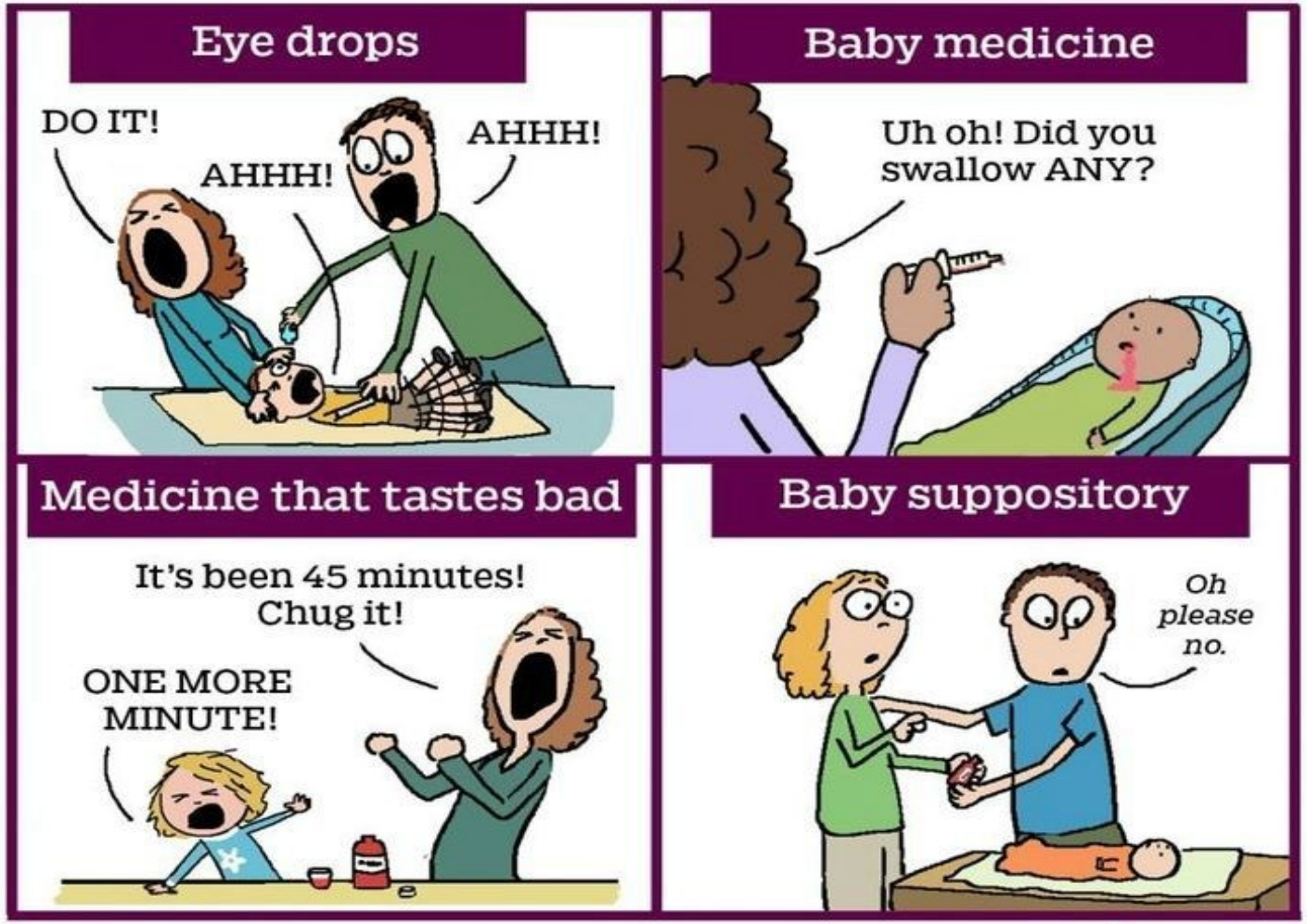


- **Steve Tomlin - FRPharmS FFRPS FRCPCH (HON)**
- Director – Children's Medicines Research & Innovation Centre
- Paediatric Consultant Pharmacist
- Professional Lead – NPPG
- Chair – Medicines Committee RCPCH

ROYAL PHARMACEUTICAL SOCIETY

The Special Hell of Giving Kids Medicine

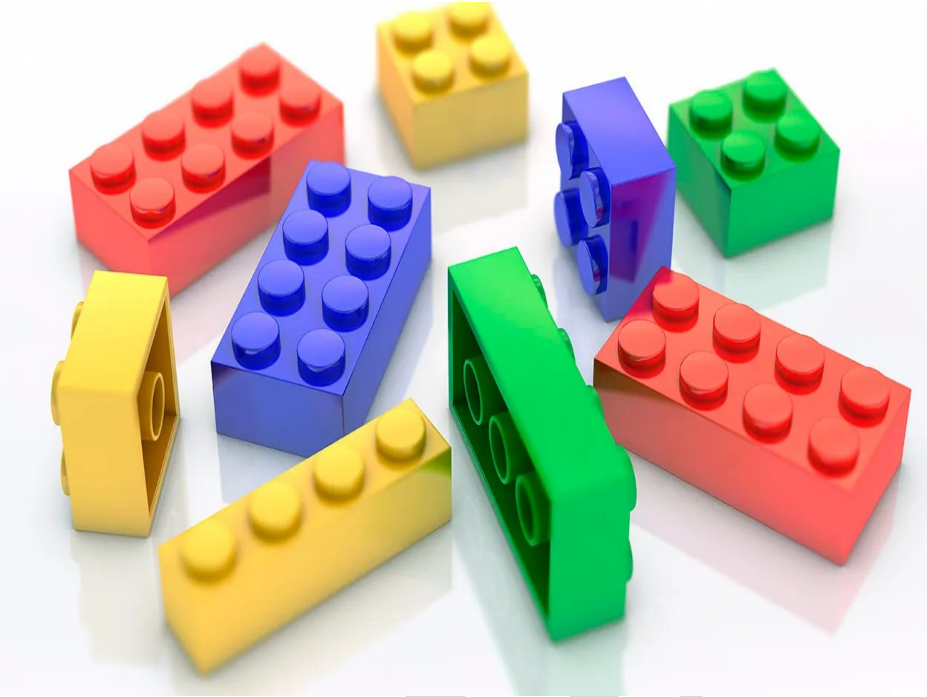




nickmom
Every night at 10pm ET

PH CAL

Things That Shaped Me







The Lancet
Volume 338, Issue 8770, 28 September 1991, Pages 798-80

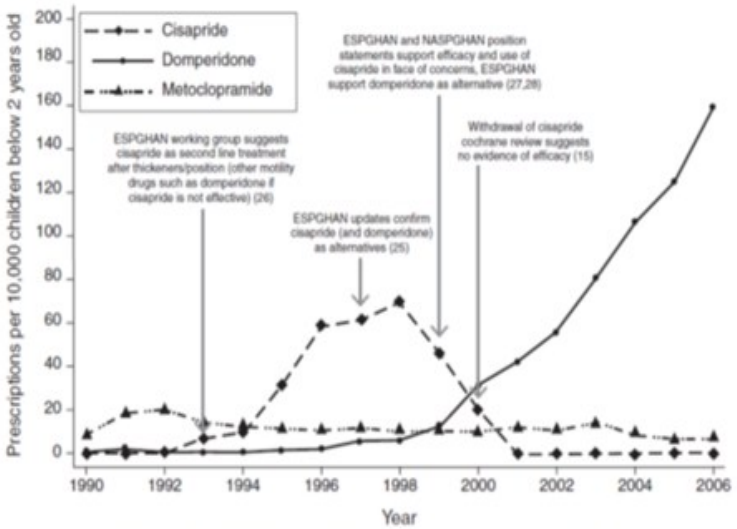
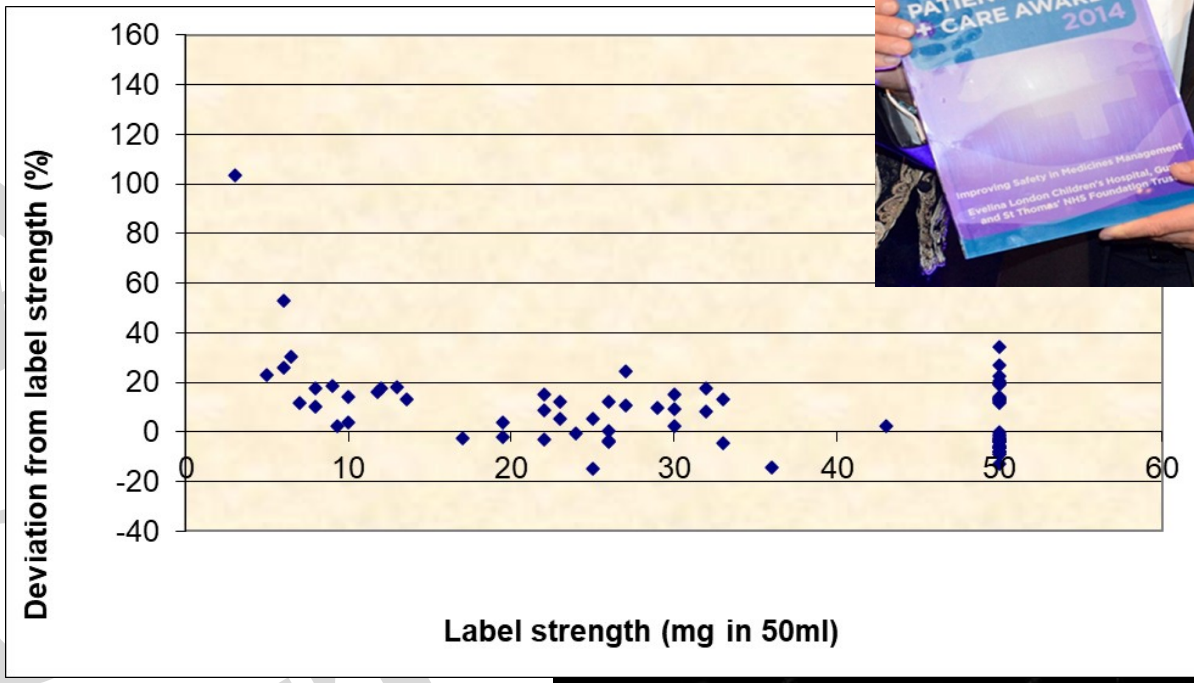
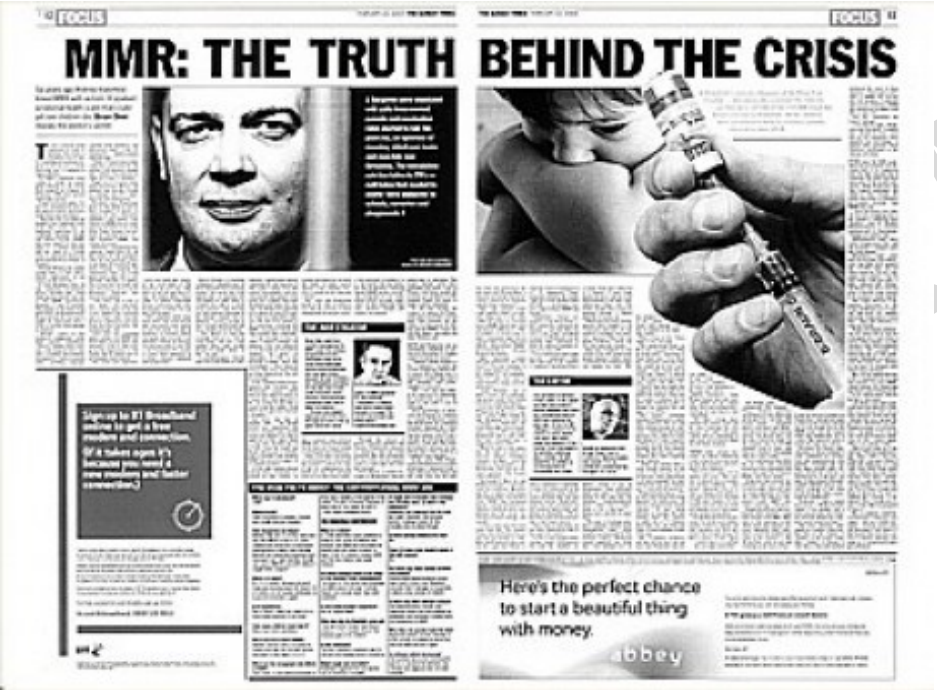


FIGURE 4. Number of prescriptions of cisapride, domperidone, and metoclopramide prescribed per 10,000 children <2 years old by year and temporal events.

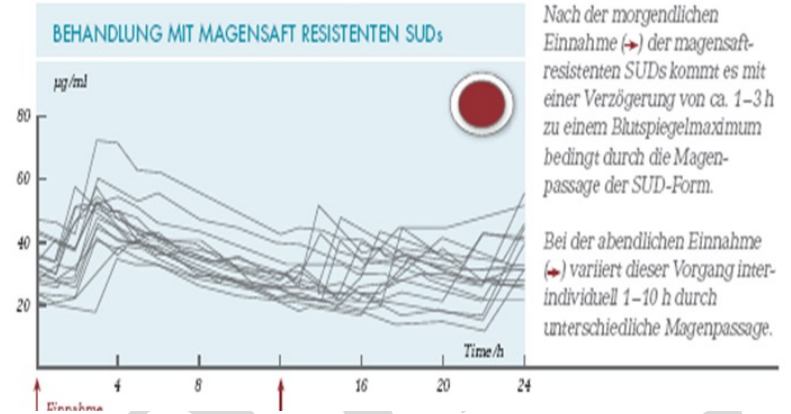






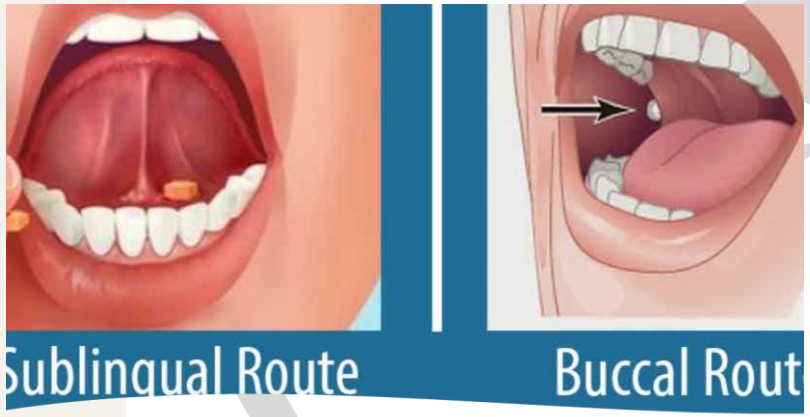





BEHANDLUNG MIT MAGENSAFT RESISTENTEN SUDs
µg/ml
80
60
40
20
Time/h
4
8
16
20
24
Einnahme
Nach der morgendlichen Einnahme (→) der magensaft-resistenten SUDs kommt es mit einer Verzögerung von ca. 1–3 h zu einem Blutspiegelmaximum bedingt durch die Magen-passage der SUD-Form.
Bei der abendlichen Einnahme (→) variiert dieser Vorgang inter-individuell 1–10 h durch unterschiedliche Magenpassage.

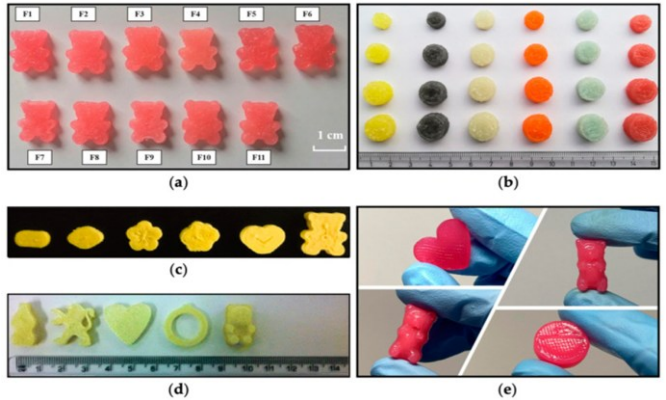



Full of Christmas Spirits
VODKA
Triple Distilled
GIN
TEQUILA
Whiskey


Sublingual Route
Buccal Rout

Exciting & Current







cMRIC

Children's Medicines Research & Innovation Centre





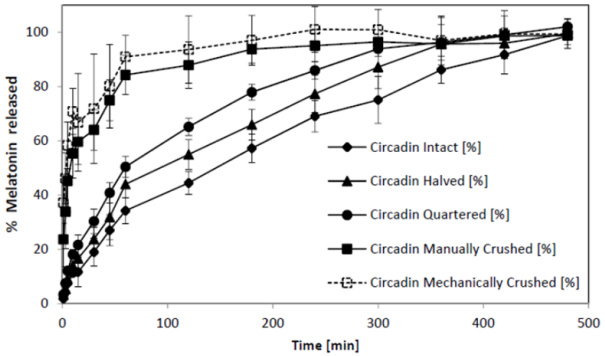
ROYAL PHARMACEUTICAL SOCIETY

Collaboration

*"It's Not Them and Us – It is just **us**"*

- Patients
- Academics
- Industry









ROYAL PHARMACEUTICAL SOCIETY

ROYAL PHARMACEUTICAL SOCIETY

Annika Boloz

Eligible QP/ Associate Director, MSD

Career path

Role overview and typical day

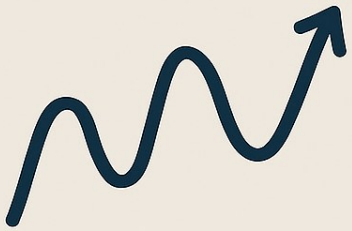


Current Role

Associate Director, Global Development Quality MSD UK

Enjoy the process

CAREER PATH SUMMARY



NON-LINEAR



PROBLEM SOLVING



TIME MANAGEMENT

1 DAY AT A TIME

LIFE HAPPENS

ROYAL PHARMACEUTICAL SOCIETY

Professor Kendal Pitt

Visiting Professor,
Strathclyde Institute of Pharmacy & Biological Sciences,
Strathclyde University

Honorary Professor,
Leicester School of Pharmacy, De Montfort University



Kendal Pitt BPharm FRPharmS FAPS AFIChemE PhD

Career to date

Nottingham University:
(BPharm):
Summer intern in Industry
Guy's Hospital: Pre-Reg
UCL School of Pharmacy: PhD
CASE award Boots Industrial

Manufacturing or R&D at:
Wellcome
Roche
MSD/Merck (UK and US)
GlaxoSmithKline (2006-22)
Consultant & Author (2022+)

"Pitt Equation"

Thoughts and observations

Best Groups Multidisciplinary:

Chemists, Chemical Engineers, Pharmaceutical Scientists, Statisticians, Material Scientists, Pharmacists

All have professional qualifications:

CChem, CChem Eng , MRPharmS, FAPS, FIChemE,

Most of my bosses have not had Ph.Ds !

ROYAL PHARMACEUTICAL SOCIETY


There is a person at the
end of our supply chains...
Everything we do is to ensure they can
do more, feel better, live longer

PI AL

Maxalt™ Clinical Profile

- For the acute treatment of migraine attacks
  - Single dose treatment
- Dose: Rizatriptan 5 mg and 10 mg
- Patients predominantly young people: Mobile and working

ROYAL PHARMACEUTICAL SOCIETY

Maxalt™: Development Goals

Compound to be selected had to be better than current options as likely be 4th to reach marketplace

Approaches:

More efficacious: Clinical

Product formulation: Pharmaceutical

- Existing products only oral tablets or injections

Migraine: Nausea and Vision disturbance

ROYAL PHARMACEUTICAL SOCIETY

Formulation approaches investigated for MAXALT™

Buccal Tablet

Intra-Nasal https://doi.org/10.1023/A:1007590501540

Rectal

Oral dissolving dosage form:

- Taste?

Majority of early clinical studies conducted in UK for speed of development

ROYAL PHARMACEUTICAL SOCIETY

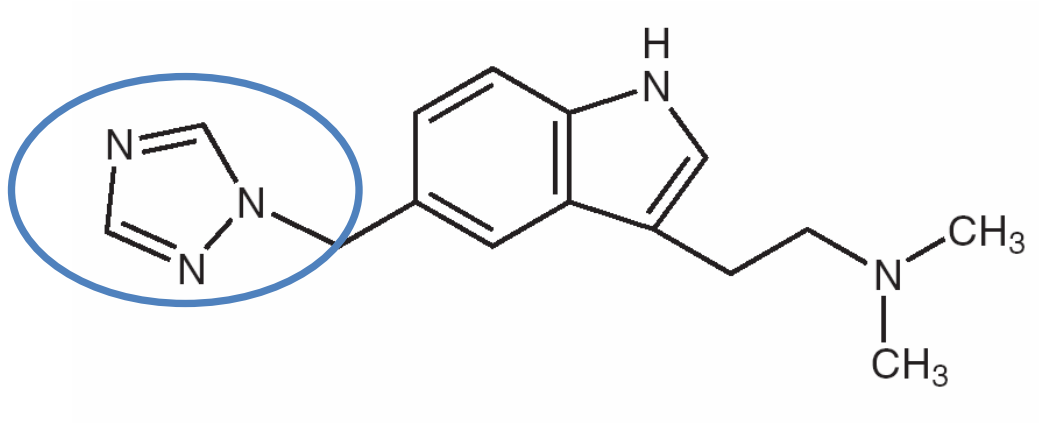
Rectal Discussions
Pharmacokinetic & Practical

- Pharmacokinetic issues: T ½ and site of absorption
- Practical:



ROYAL PHARMACEUTICAL SOCIETY

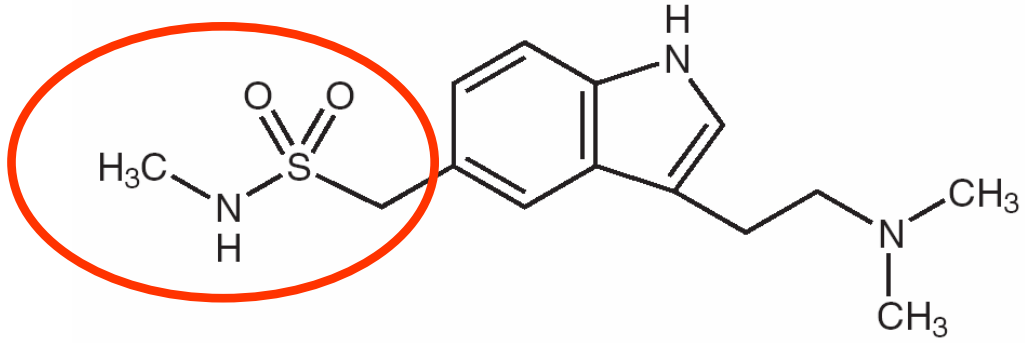
Taste and Triptan structures



Rizatriptan:

Triazole:

Group



Sumatriptan:

Sulphonamide

Group

Source: Merck Index

Zydis/RPD/MLT selected as:

Known technology to MSD

PEPCID™ and VASOTEC™ developed with Catalant (Novo):

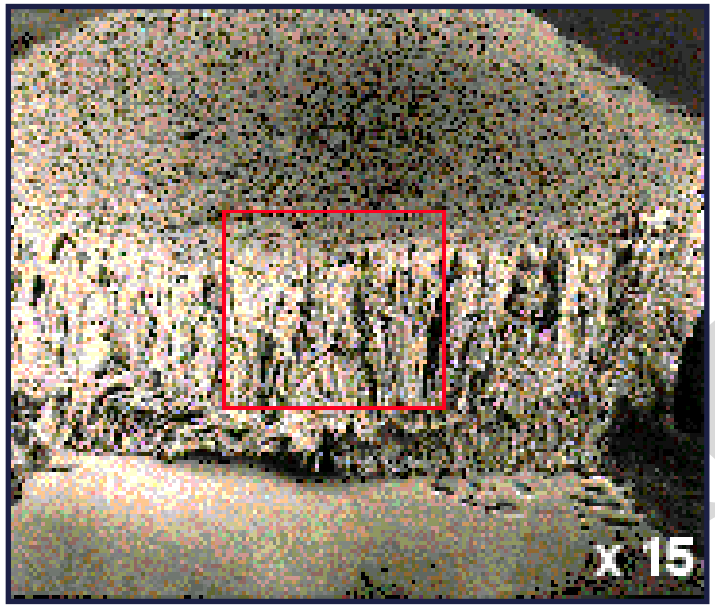
Drug properties amenable
Proven scale-up

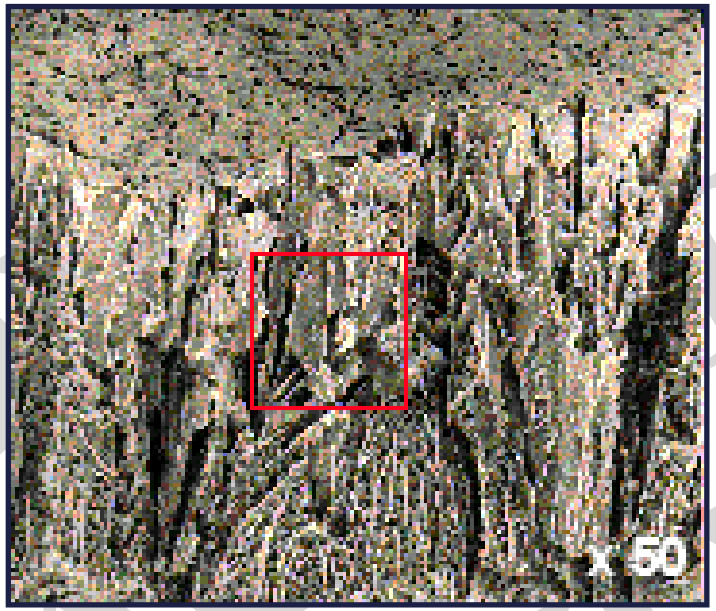
Other rapid dissolve technologies at time not as advanced:

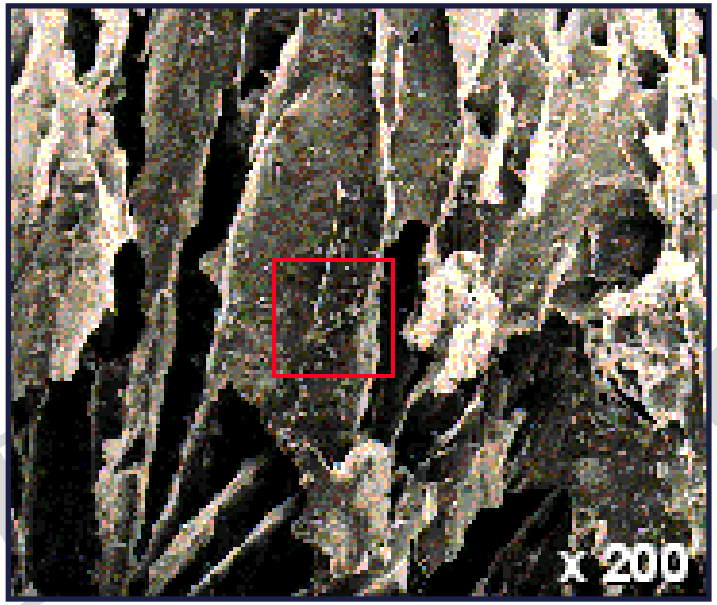
Unknown technical-transfer risks

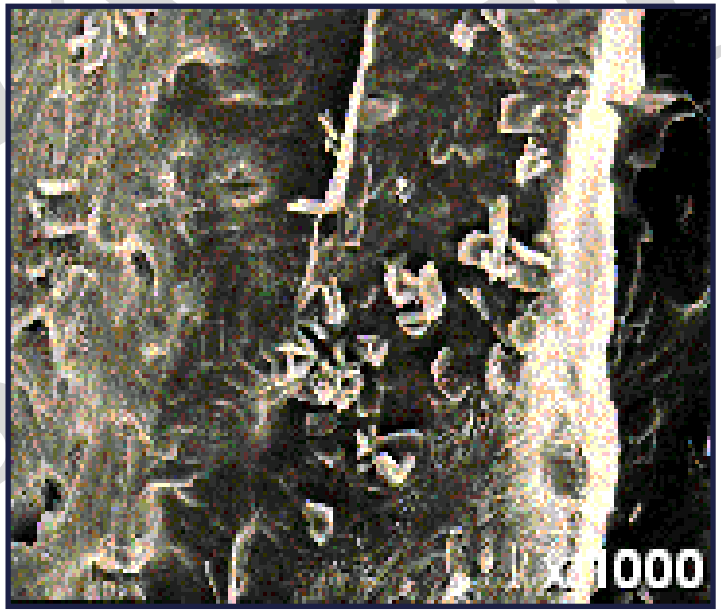
ROYAL PHARMACEUTICAL SOCIETY

Zydis/RPD/MLT SEM Structures









Mannitol +

Gelatin

Freeze-dried Matrix

PHARMACEUTICAL SOCIETY

Packaging: Brittle Wafer Protection

Ever changing market influences:

Green issues, Bulk dispensing, patient preference…

Carry around

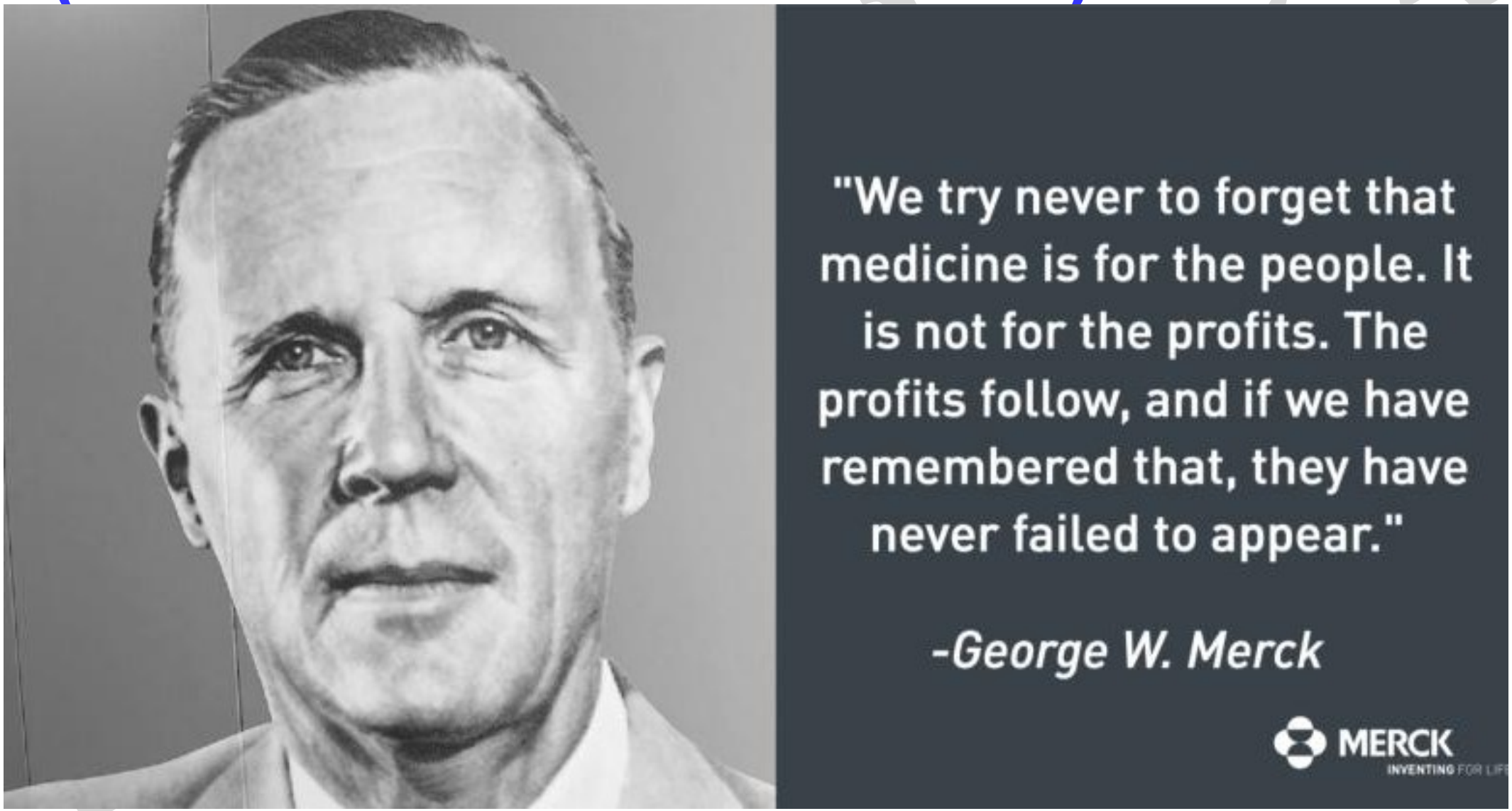
"Anywhere Anytime Concept"

- Small aluminium blister for tablets
- RAPIDISC™ was added blue plastic box

Then adopted for tablets: "Key Fob"

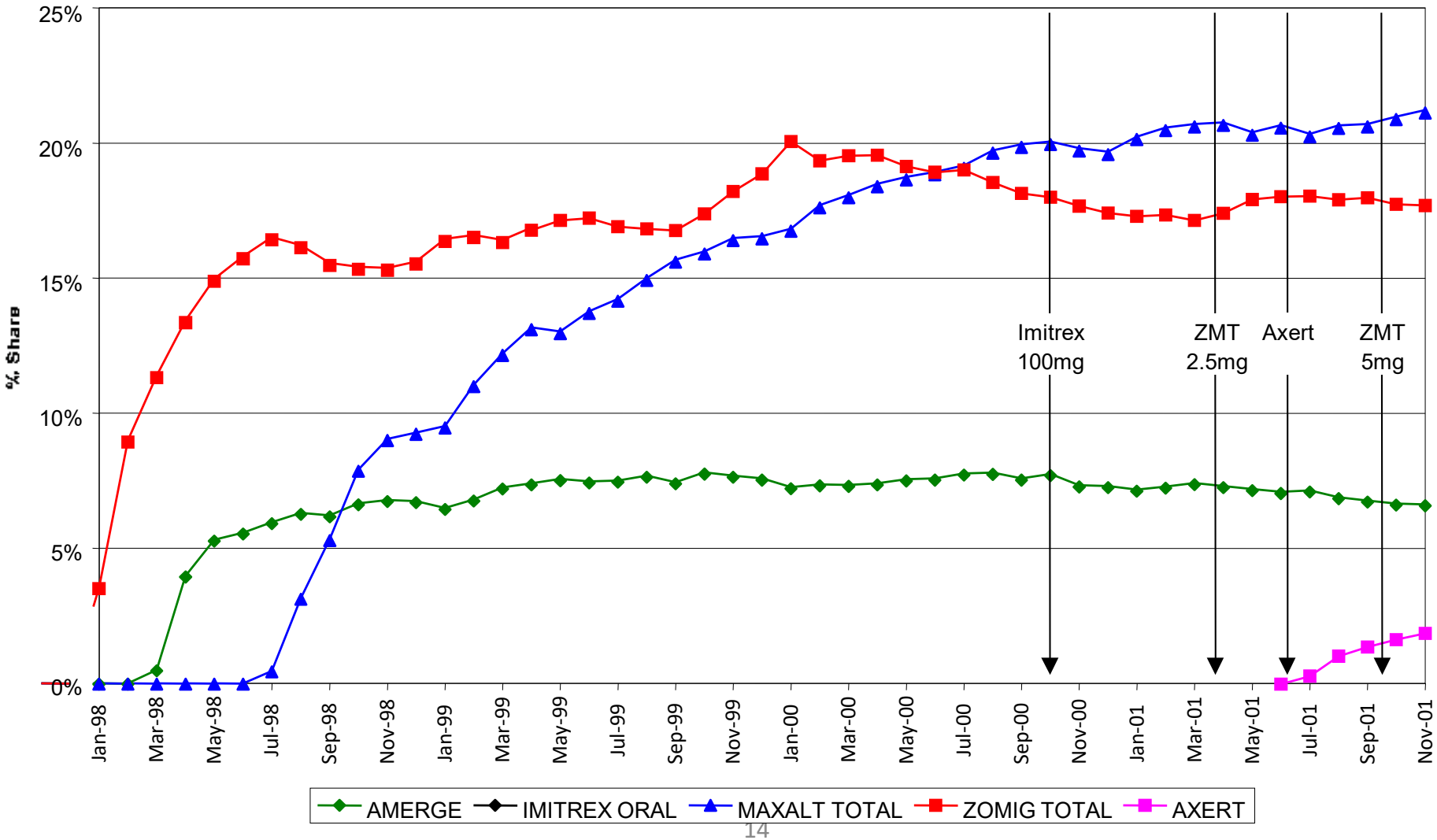
ROYAL PHARMACEUTICAL SOCIETY

George Merck Quote (Founder of Merck & MSD)



Acknowledgement: Merck & Co.

Oral Triptan Market
New Prescription Share 50% due to MLT



Source: IMS NPA Plus with Mail Order Adjustments


There is a person at the
end of our supply chains...
Everything we do is to ensure they can
do more, feel better, live longer

PI AL

ROYAL PHARMACEUTICAL SOCIETY

Dr Mandy Wan

Lead Paediatric Research Pharmacist,
Evelina London Children's Hospital

My journey



Pharmacist

Paediatric Pharmacist

Paediatric clinical trials pharmacist

Lead Paediatric clinical trials pharmacist



Pre-registration



‘Clinical Academic Paediatric Pharmacist’

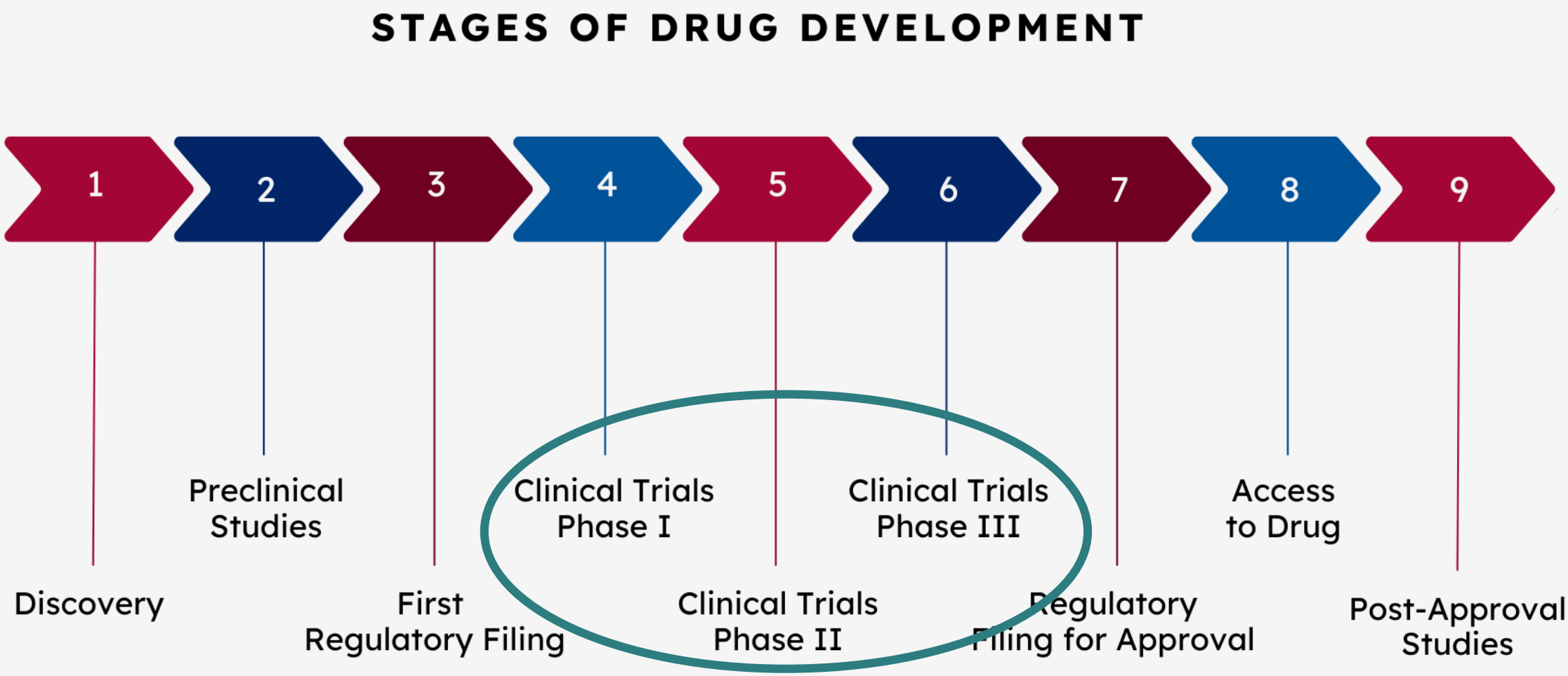
- Lead Paediatric Research Pharmacist
- Deputy R&D Lead – Children’s Research
- Honorary Senior Lecturer

NHS NIHR | National Institute for Health and Care Research

King’s College London

PHARMACEUTICAL SOCIETY

Clinical Trials Pharmacists & Pharmacy Technicians



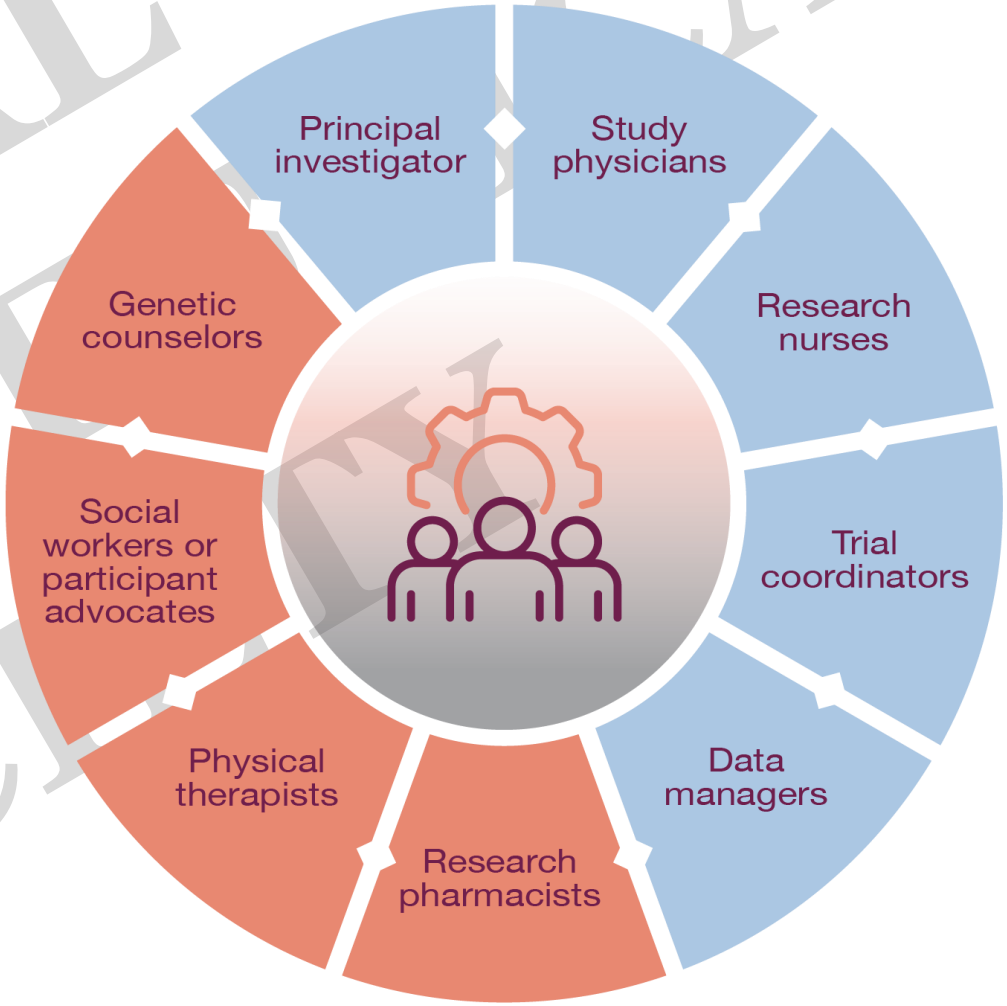
A medicine on paper has no efficacy



Clinical Trials Pharmacists & Pharmacy Technicians

Operationalise science at the bedside by ensuring trial medicines are:

- Stored correctly
- Prescribed correctly
- Prepared correctly
- Administered correctly
- Monitored correctly



Deliver high-quality data that underpins regulatory approval and practice change

ROYAL PHARMACEUTICAL SOCIETY

Personal experience and impact

Tocilizumab in Paediatric Patients With Active Systemic Juvenile Idiopathic Arthritis

- Observed low platelet count in a trial participant
- First case in the trial
- Worked closely with the pharma industry to develop the patient-monitoring plan, manage dose interruptions, and collect study data.

SmPC

· Low platelet count

Laboratory Value (cells x 10^3/µl)	Action
50 to 100	Modify the dose of the concomitant MTX if appropriate. Interrupt RoActemra dosing. When platel[e] Tocilizumab 100 x 10^3/µl resume RoActemra.
< 50	Discontinue Tocilizumab . The decision to discontinue Tocilizumab in sJIA for a laboratory abnormality should be based on the medical assessment of the individual patient.

There are insufficient clinical data to assess the impact of a tocilizumab dose reduction in sJIA patients who have experienced laboratory abnormalities.

Available data suggest that clinical improvement is observed within 6 weeks of initiation of treatment with Tocilizumab Continued therapy should be carefully reconsidered in a patient exhibiting no improvement within this timeframe.

Clinical Pharmacy Knowledge

ROYAL PHARMACEUTICAL SOCIETY

Personal experience and impact

Phase 1/2 Trial for the Treatment of Neuronal Ceroid Lipofuscinosis Type 2, a Form of Batten Disease

- First in human trial in a child
- Intracerebroventricular administration over 4 hours every 2 weeks for at least 48 weeks.
- Worked closely with the pharma industry on the practicality and equipment used for drug administration



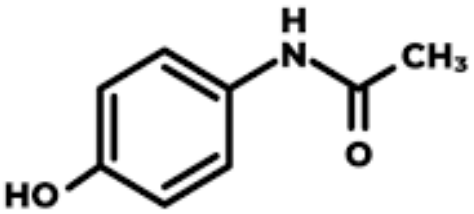
Pharmaceutical Knowledge

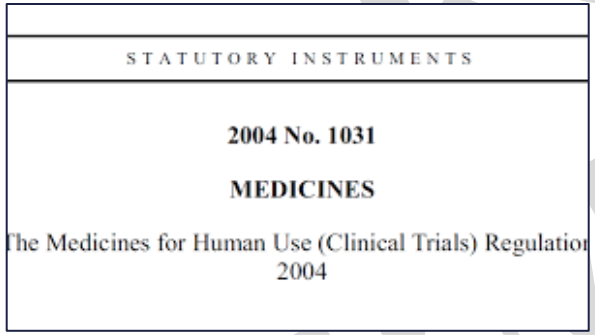
- **Drug compatibility**
- **Dead space**
- **Infusion rate**
- **Line flushing**

ROYAL PHARMACEUTICAL SOCIETY

Clinical Trials Pharmacists & Pharmacy Technicians

Dynamic Environment





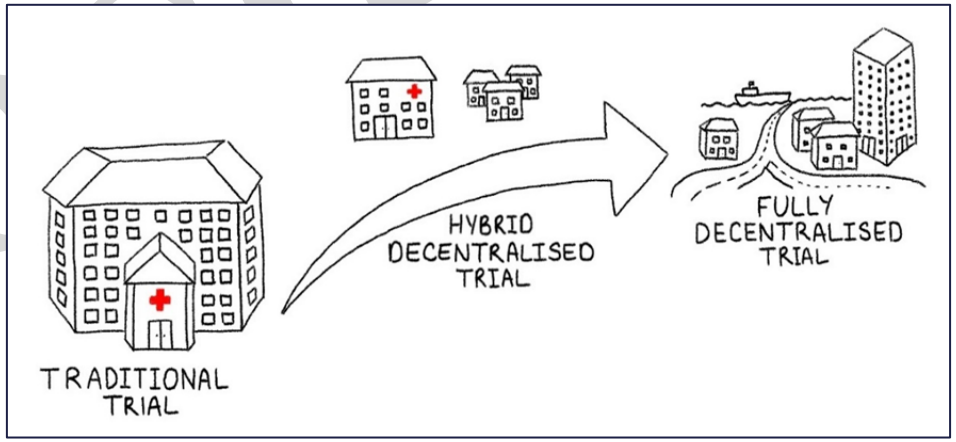
STATUTORY INSTRUMENTS

2004 No. 1031

MEDICINES

The Medicines for Human Use (Clinical Trials) Regulation
2004





PHARMACEUTICAL SOCIETY

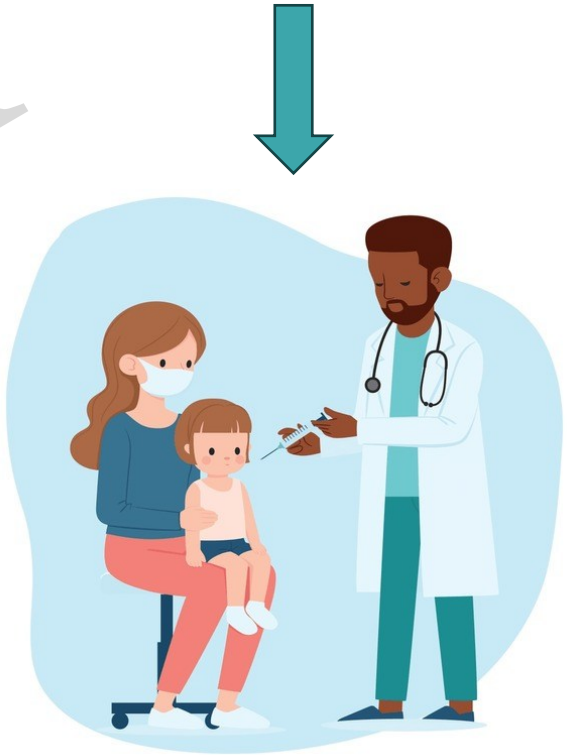
Clinical Trials in the UK

~ 50 to 60 drug clinical trials are approved per month by the MHRA

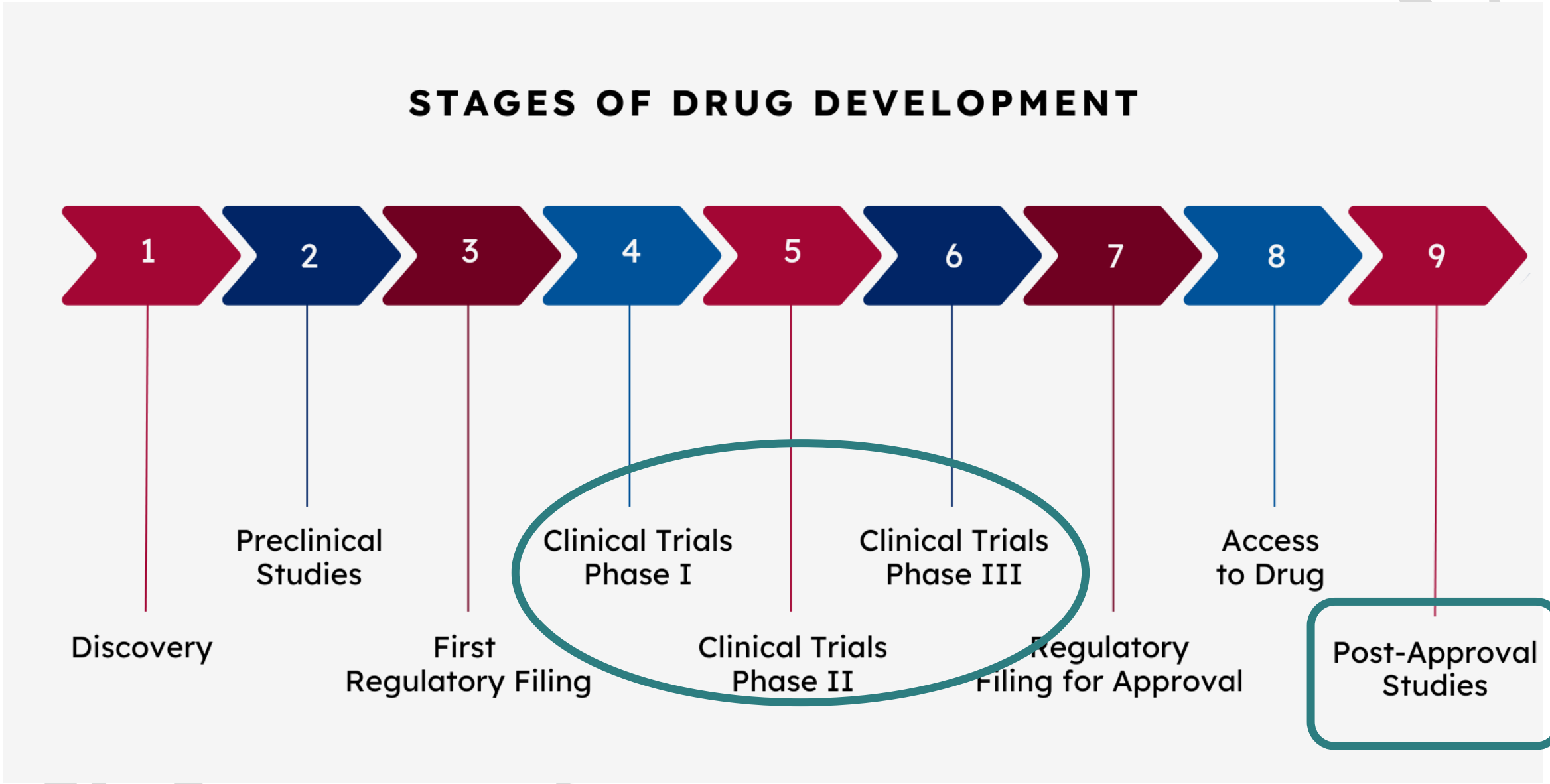


Clinical Trials Pharmacy Professionals

- **Generate knowledge through contributing to clinical research**
- **Knowledge are translated into the development of recommendations to support safe medicine use in clinical practice.**
- **Translate the science in clinical trial protocols into healthcare interventions**



ROYAL PHARMACEUTICAL SOCIETY


STAGES OF DRUG DEVELOPMENT
1
2
3
4
5
6
7
8
9
Discovery
Preclinical Studies
First Regulatory Filing
Clinical Trials Phase I
Clinical Trials Phase II
Clinical Trials Phase III
Regulatory Filing for Approval
Access to Drug
Post-Approval Studies

Post-approval research

- We still have much more to learn
- Generates evidence that can optimise real-world practice and improve outcomes across diverse patient groups
- Re-purposing medicines

Investigator-led clinical trials

- Study conception
- Grant application & Funding
- Develop trial protocol
- Trial drug supply
- Regulatory & Ethics approvals
- Trial delivery
- Analysis
- Dissemination



ROYAL PHARMACEUTICAL SOCIETY

Clinical Academic Paediatric Pharmacist

Efficacy and safety of ciclosporin versus methotrexate in the treatment of severe atopic dermatitis in children and young people (TREAT): a multicentre parallel group assessor-blinded clinical trial.

Flohr C,
Hearn R
McPhers
M, Sach
Br J Der
PMID: 3

Methotrexate versus ciclosporin in the treatment of severe atopic eczema in children: an economic evaluation.

Sach TH,
Browne F,
Br J Derm
PMID: 392

The effects of ciclosporin and methotrexate on kidney function in the treatment of severe atopic dermatitis in children: results from the TREAT trial.

Bruce G, Rosa
Brown SJ, Ga
Ashoor F, Mcl
Irvine AD, Sin
Br J Dermato
PMID: 39009

Exposure-response of ciclosporin and methotrexate in children and young people with severe atopic dermatitis: a secondary analysis of the TREatment of severe Atopic dermatitis Trial (TREAT).

Wan M, Jones AP, Maskrey D, Arenas-Hernandez M, Rosala-Hallas A, Beattie PE, Baron S, Browne F, Brown SJ, Gach JE, Greenblatt D, Hearn R, Hilger E, Esdaile B, Cork MJ, Howard E, Lovgren ML, August S, Ashoor F, Williamson PR, McPherson T, O'Kane D, Ravenscroft J, Shaw L, Sinha MD, Spowart C, Thomas BR, Sach TH, Irvine AD, Flohr C.

Clin Exp Dermatol. 2025 Jul 24;50(8):1623-1627. doi: 10.1093/ced/llaf147.

PMID: 40168525 **Free article.** Clinical Trial.

Combining clinical practice with research and education

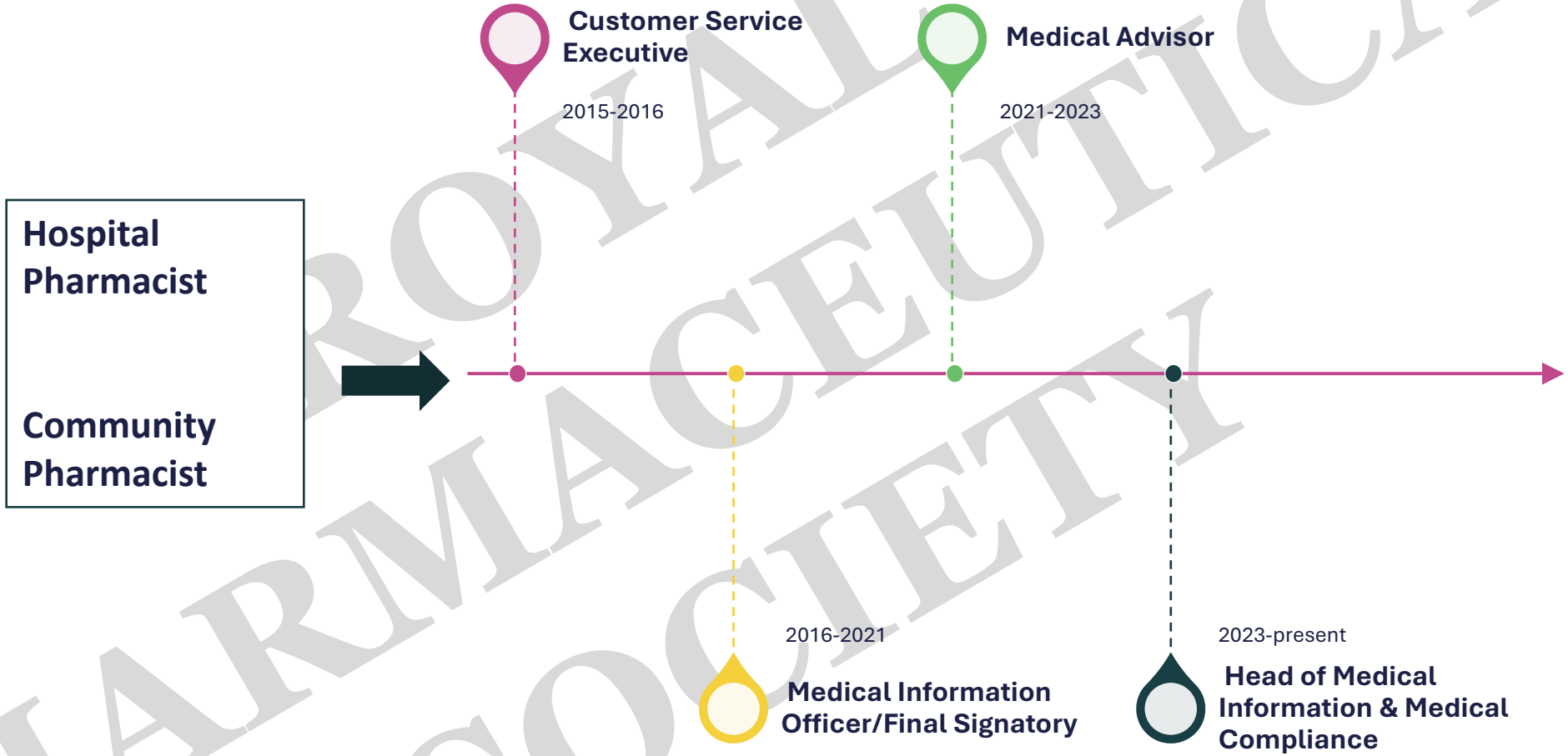
PHARMACEUTICAL

ROYAL PHARMACEUTICAL SOCIETY

Tazneem Anwar MRPharms

Head of Medical Information & Medical Compliance,
Johnson & Johnson

Career History



ROYAL PHARMACEUTICAL SOCIETY

Medical Information

- Respond to HCP and patient enquiries across
- Peer to peer conversation
- Compassionate use
- RMMs

PHARMACEUTICAL SOCIETY

Medical Advisor



ROYAL PHARMACEUTICAL SOCIETY

Head of Medical Information & Medical Compliance

Final Signatory

- Pipeline assets

Lead the MI and Med. Compliance Team

- Sounding board
- Development
- Strategy
- Coaching
- Insights

Access

- Compassionate use
- Post trial access

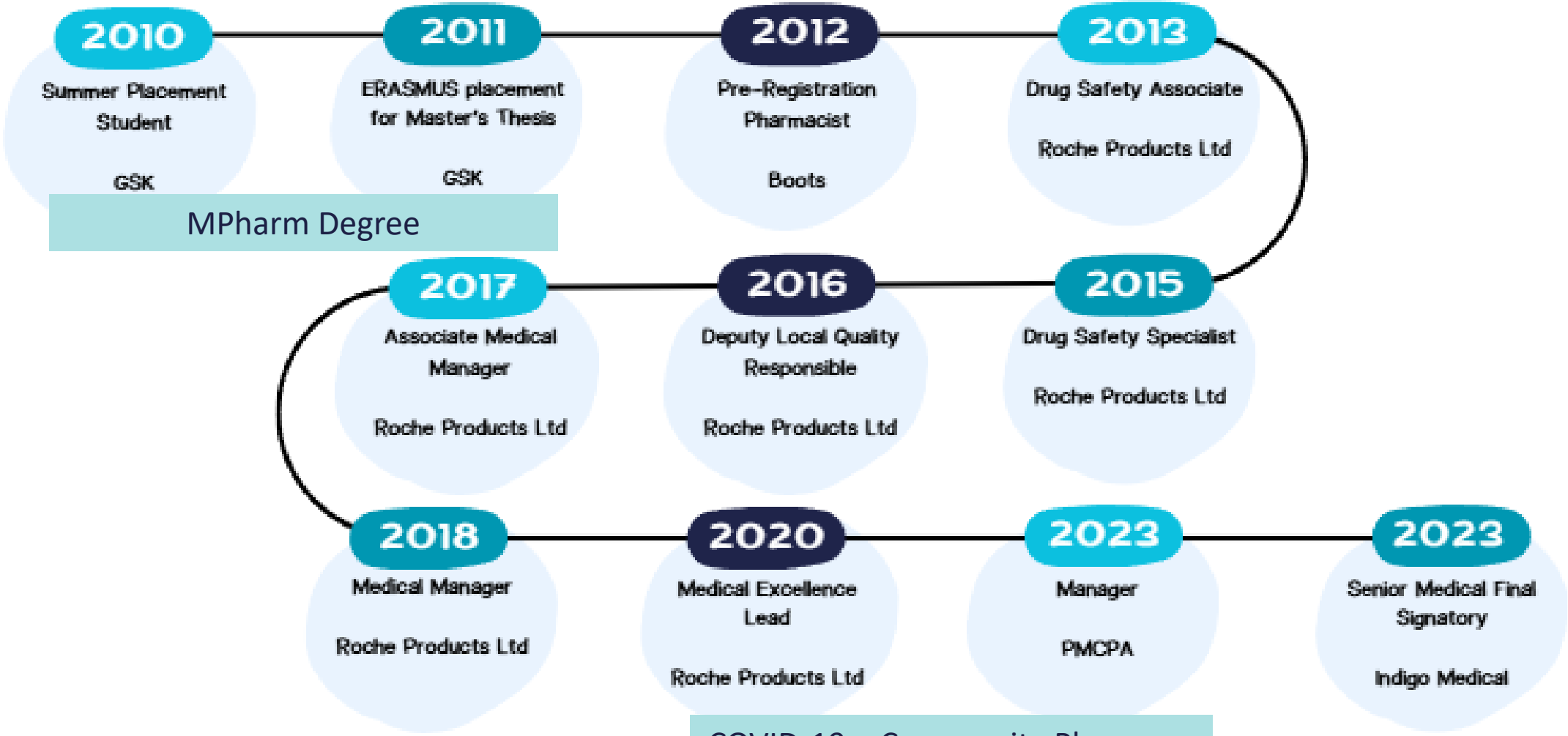
ROYAL PHARMACEUTICAL SOCIETY

ROYAL PHARMACEUTICAL SOCIETY

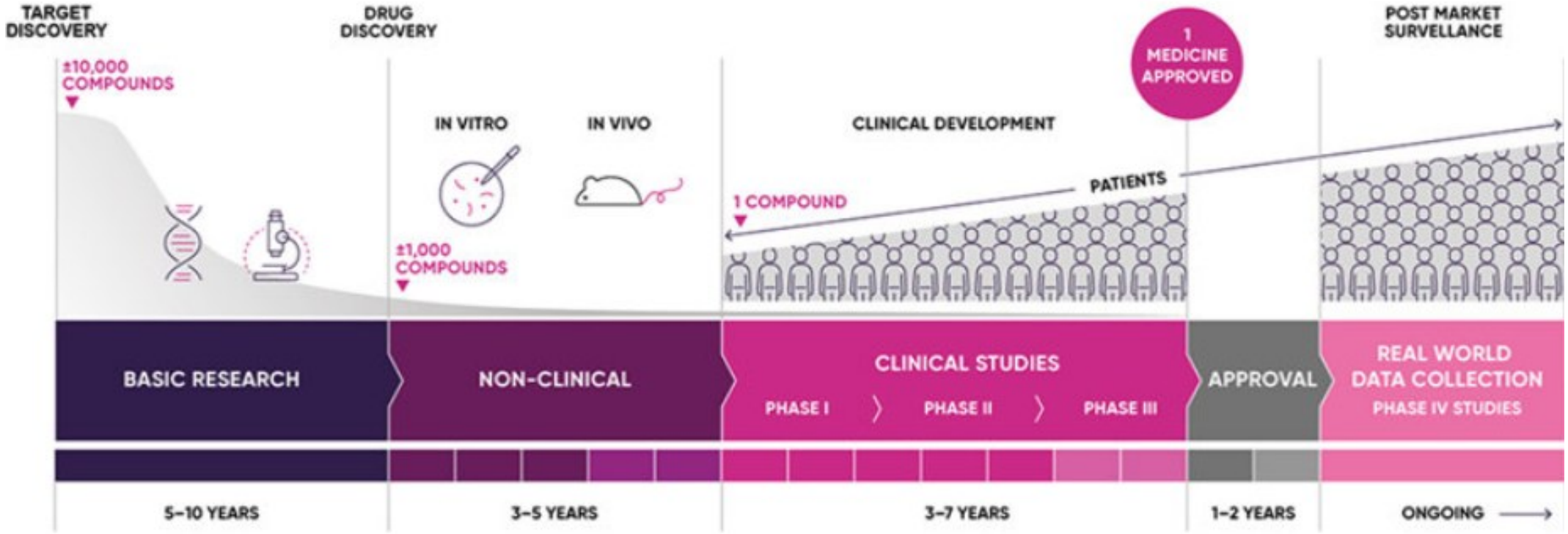
Ciara O'Brien

Senior Medical Final Signatory,
Indigo Medical

My career journey

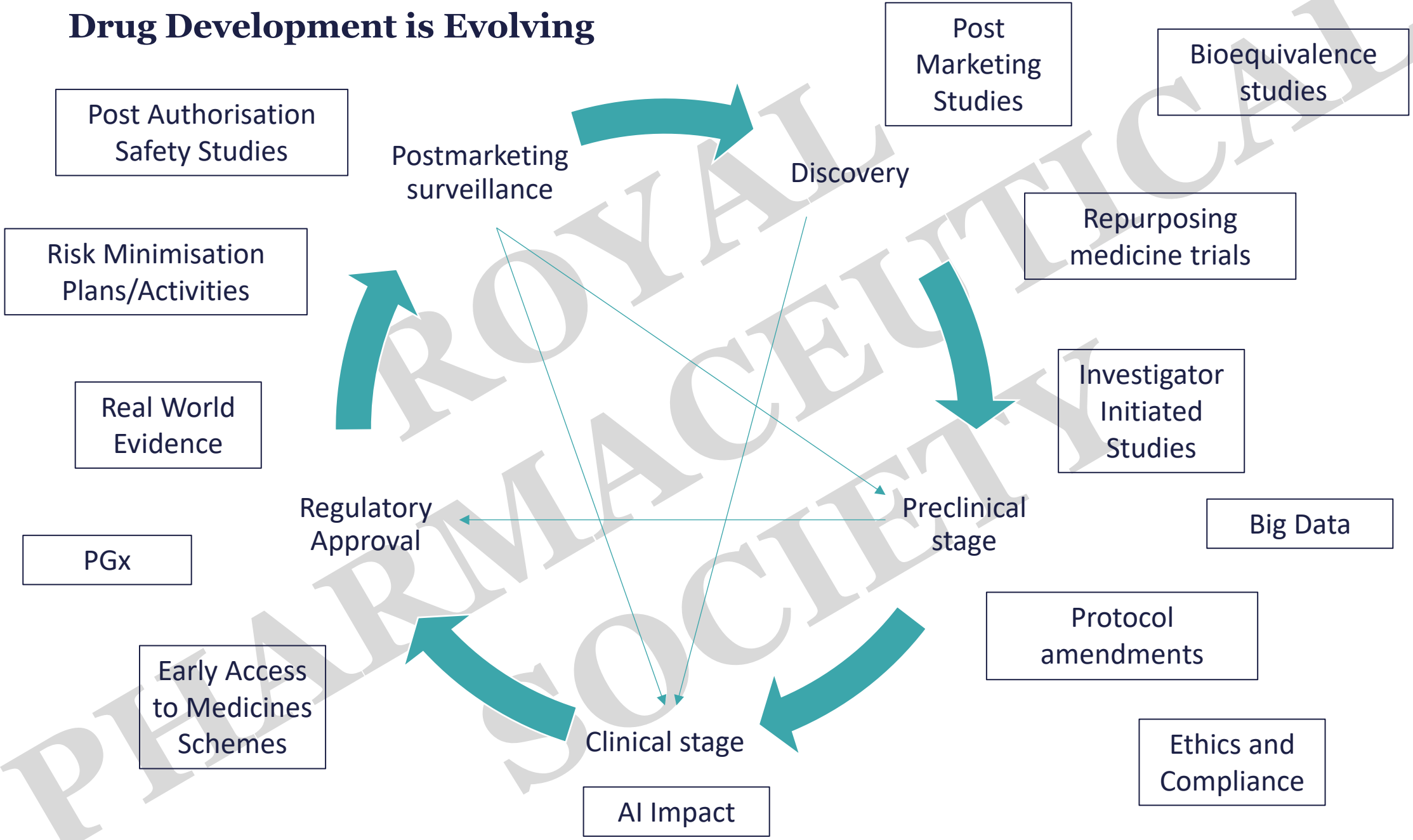


Drug development is evolving



PHARMACEUTICAL SOCIETY

Drug Development is Evolving



ROYAL PHARMACEUTICAL SOCIETY

Why the Pharmaceutical Industry?









ROYAL PHARMACEUTICAL SOCIETY

Dr Amit Aggarwal

Executive Director Medical Affairs & Strategic Partnerships,
The Association of the British Pharmaceutical Industry

Pharmacists and Pharmaceutical Scientists in Pharma

- About 4% of pharmacists working in the UK are employed by the pharmaceutical industry
- **Pharmacists and Pharmaceutical Scientists have a vital role in the complex processes of developing and supplying medicines to the market.**
- The ABPI exists to make the UK the best place in the world to research, develop and access medicines and vaccines to improve patient care.



ROYAL PHARMACEUTICAL SOCIETY

ROYAL
PHARMACEUTICAL
SOCIETY

Together,
we are pharmacy.