The research and development journey

Life Science team

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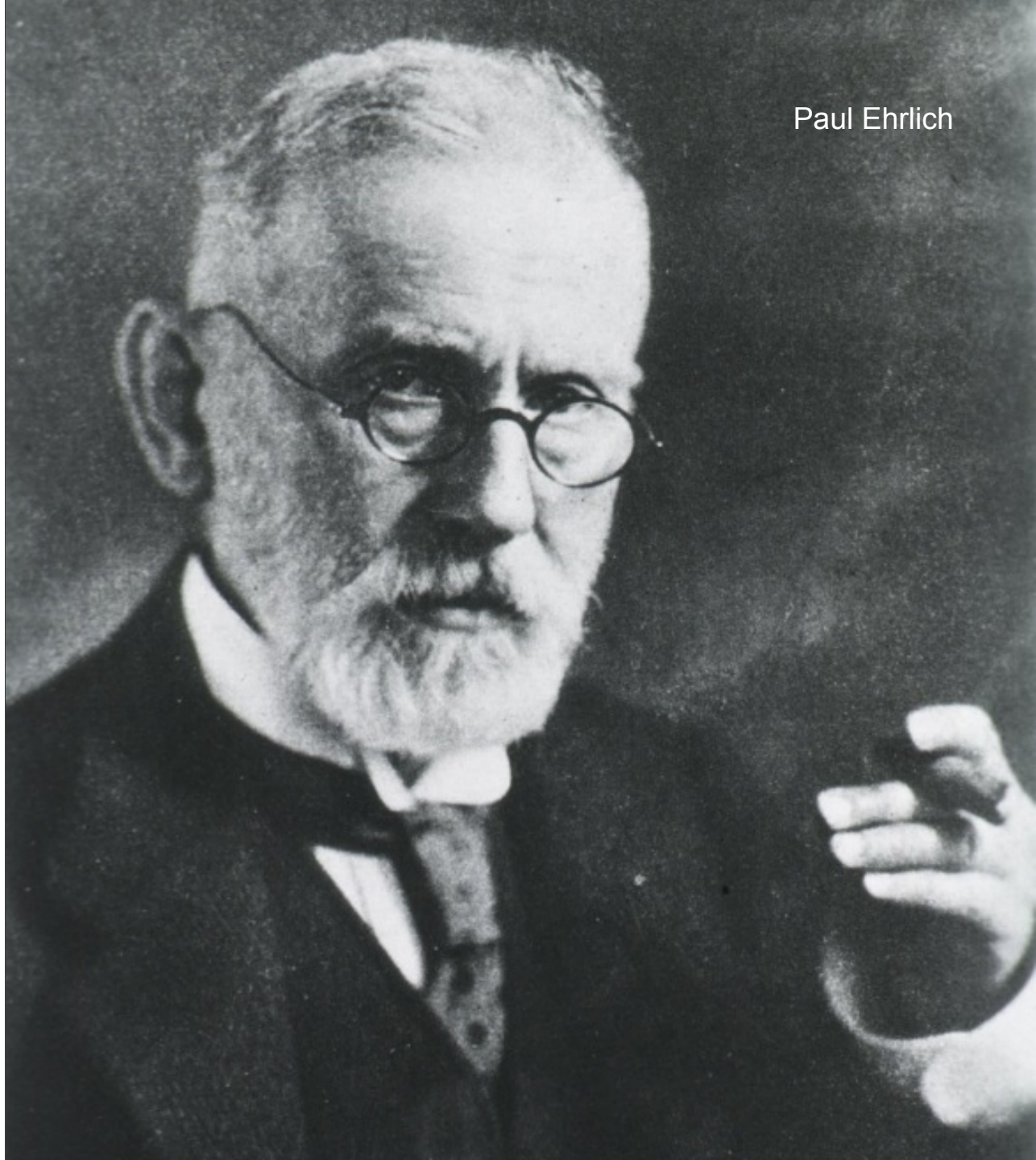
What is drug discovery?

What was the magic bullet and how has it shaped modern pharmacology?

What are drugs trying to alter?

How do drugs interact with our bodies?



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What is the R&D journey?

Discovery to commercialisation

Initial idea / discovery

Basic research into the disease itself

Development

The process of choosing a molecular target and confirming the molecular target

Pre-clinical testing

Completion of testing before human clinical trials. The aim to determine the safe dose for first-in-man study and assess a product's safety profile

Trials approval process

The clinical trial submission must be scientifically sound

Clinical testing

Clinical Trials Phase I to IV to determine efficacy and safety of the product.

Product approval

Central or national route?

Drug discovery

What's the big idea?

What exposure do they face?

Drug development

Time to optimise

Have the exposures changes?

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Central or national route?

Pre-clinical testing

Why do we do pre-clinical testing?

Types of testing:

- *In Vitro*
- *In Vivo*

Pre-clinical testing

CFC therapeutics
What do they do?
Exposures

Contract research service
What do they do?
Exposures

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Central or national route?

Clinical testing

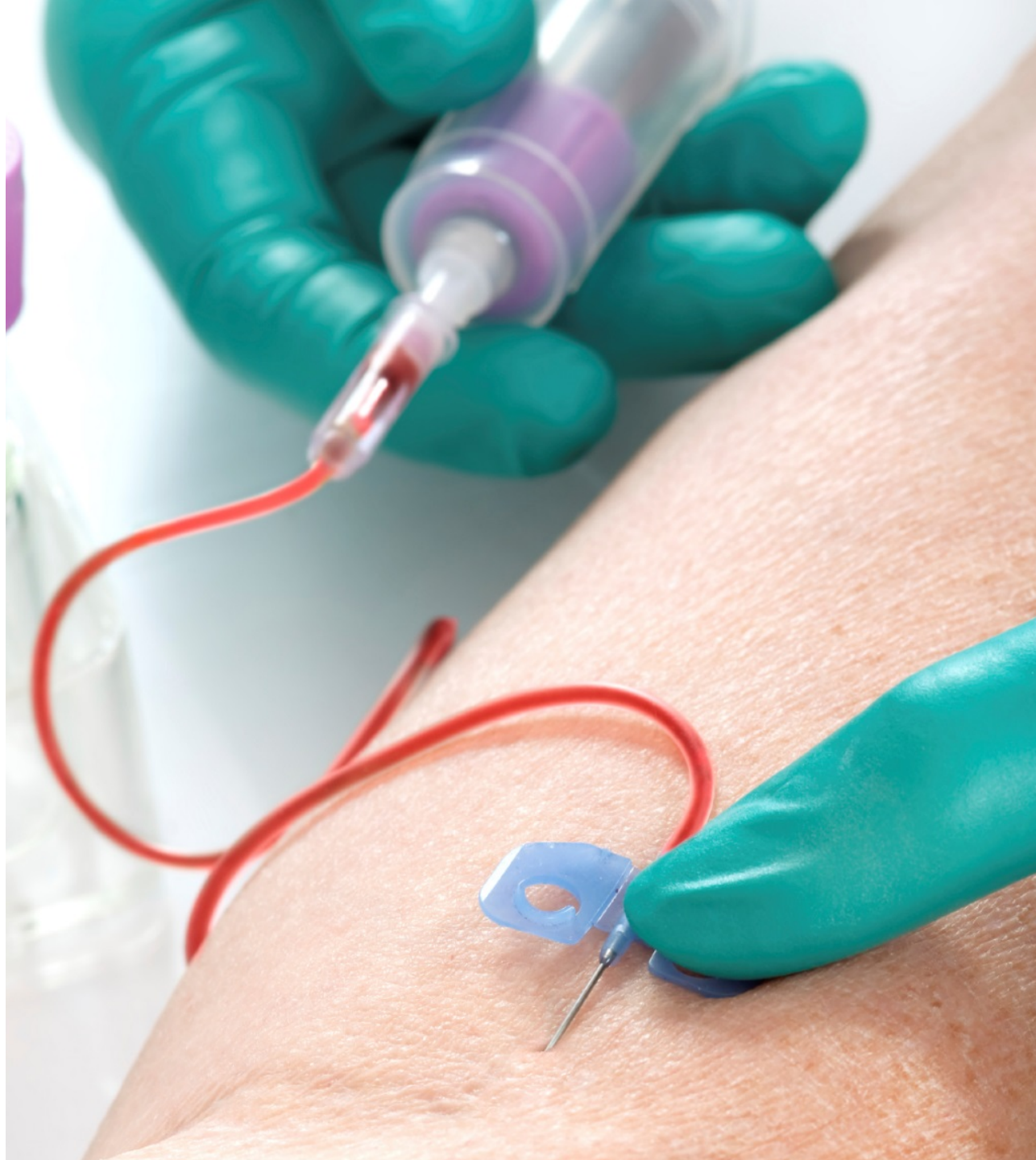
Clinical trials phases

	Number of participants	Purpose	Success rate
Phase I	20 to 100	Gathering information on how the drug interacts in the human body	70%
Phase II	Up to 300	This phase looks to establish efficacy and side effects	33%
Phase III	300 to 3000	Establishing less common side effects	25-30%
Phase IV	Over 3000	Post Commercialisation safety monitoring	N/A

Clinical testing

CFC therapeutics
What do they do?
Exposures

Contract research organisation
What do they do?
Exposures



Clinical testing

Queensland trial giving Viagra to pregnant women halted after Netherlands deaths

Researchers pause to gather information after 11 babies died in similar Dutch trial

Regulatory approval, stifling progress or saving lives?

The R&D journey

Exposure summary

	Summary
Product discovery and development	• Typically a company developing their own drug or medical device, receiving funding through grants and private investments • The main exposure for these companies come through their property and supply chain
Pre-clinical testing	• Most often a company called a Clinical Research Service sub-contracted to undertake the testing to establish safety in humans • The exposure for a CRS comes primarily through professional indemnity
Clinical testing	• Clinical testing often has two interested parties, the Clinical Research Organisation undertaking the testing and the Trial Sponsor • Both types of companies are exposed to bodily injury risks while Clinical Research Organisations are exposed to financial loss claims
Regulatory review	• At this point in the R&D process consultants are relied upon to provide knowledge on the convoluted approval process • Regulatory consultants are most exposed to professional indemnity claims

Any questions?

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