Session 2: Market Assessment Needs for MPTs

The Human Factor: Applications for Product Development & Early Stage Clinical Trials

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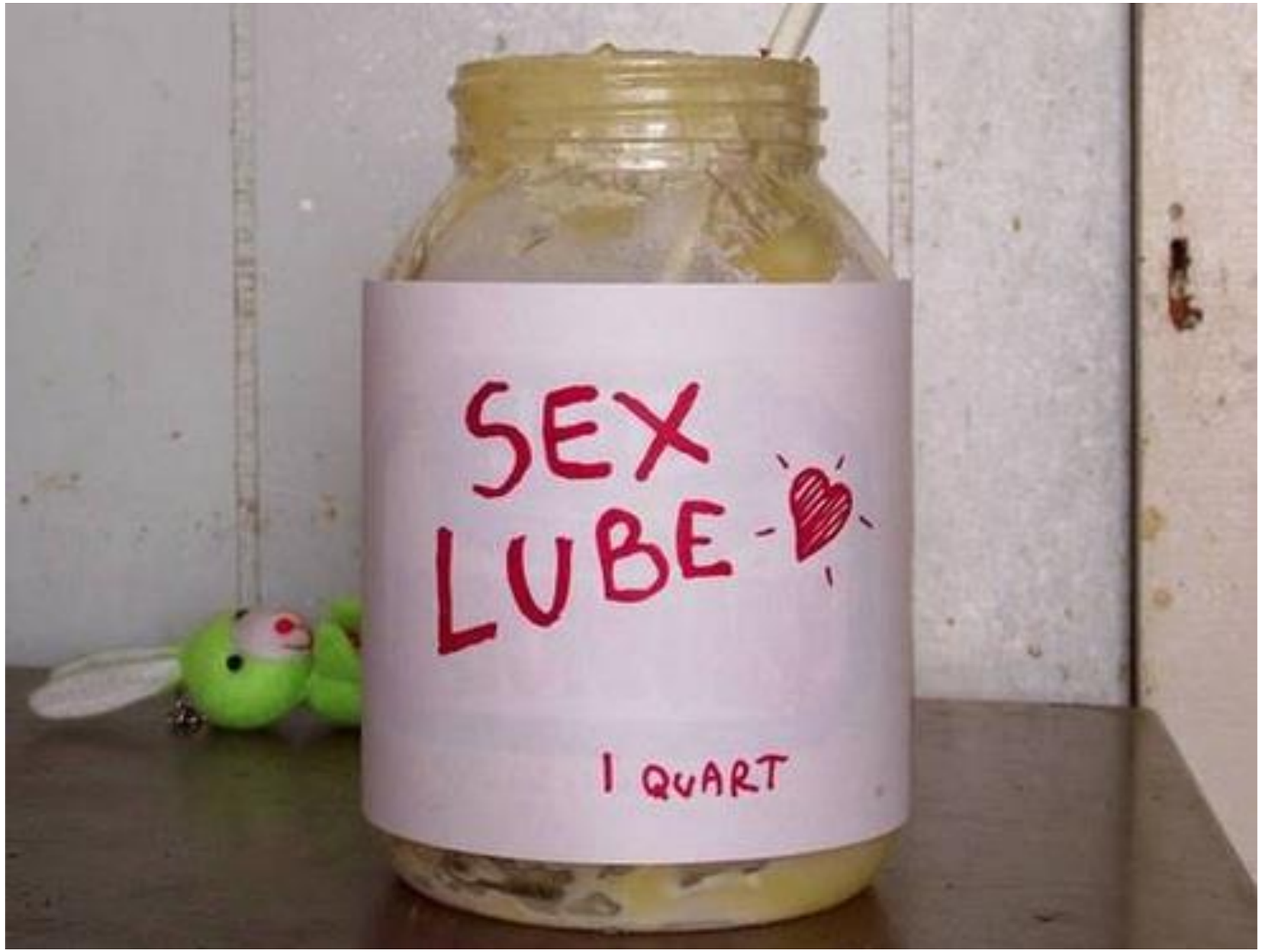
Injecting the human factor earlier on in product development, alongside the science

Scientific innovation provides great tools, and checking these tools against the everyday needs, lives and systems already in situ enhances their application

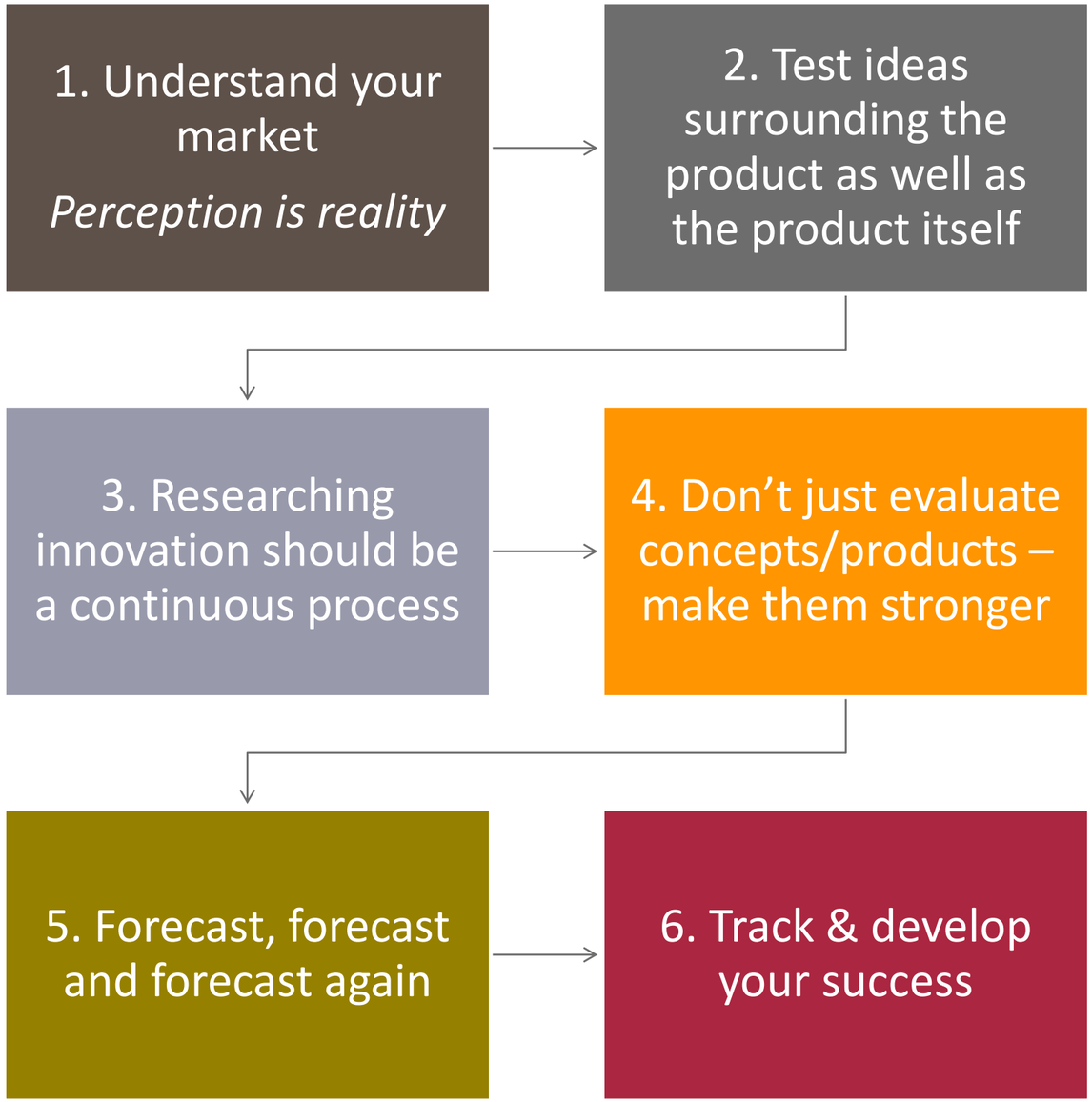
Not instead of but in addition to

Research can be planned for at the outset, and subsequently used alongside product development as a way to address and answer critical market and product-related questions



How to game success into your solutions

Pharma and commercial groups have historically Integrated market research into their thinking and throughout their decision-making/ product milestones



1. Understand your market

Don’t jump to ideas – uncover the consumer insights first

Perception is reality

I stopped explaining myself when I understood people only understand from their own perspective

Unpacking the impact of human-ness on the science

Integrating the human factor – ladder approach

2. Test ideas surrounding the product as well as the product itself

Understand perceptions of product attributes AND the environment surrounding the product

Does the style of language used in support materials make a difference in trial and adherence?

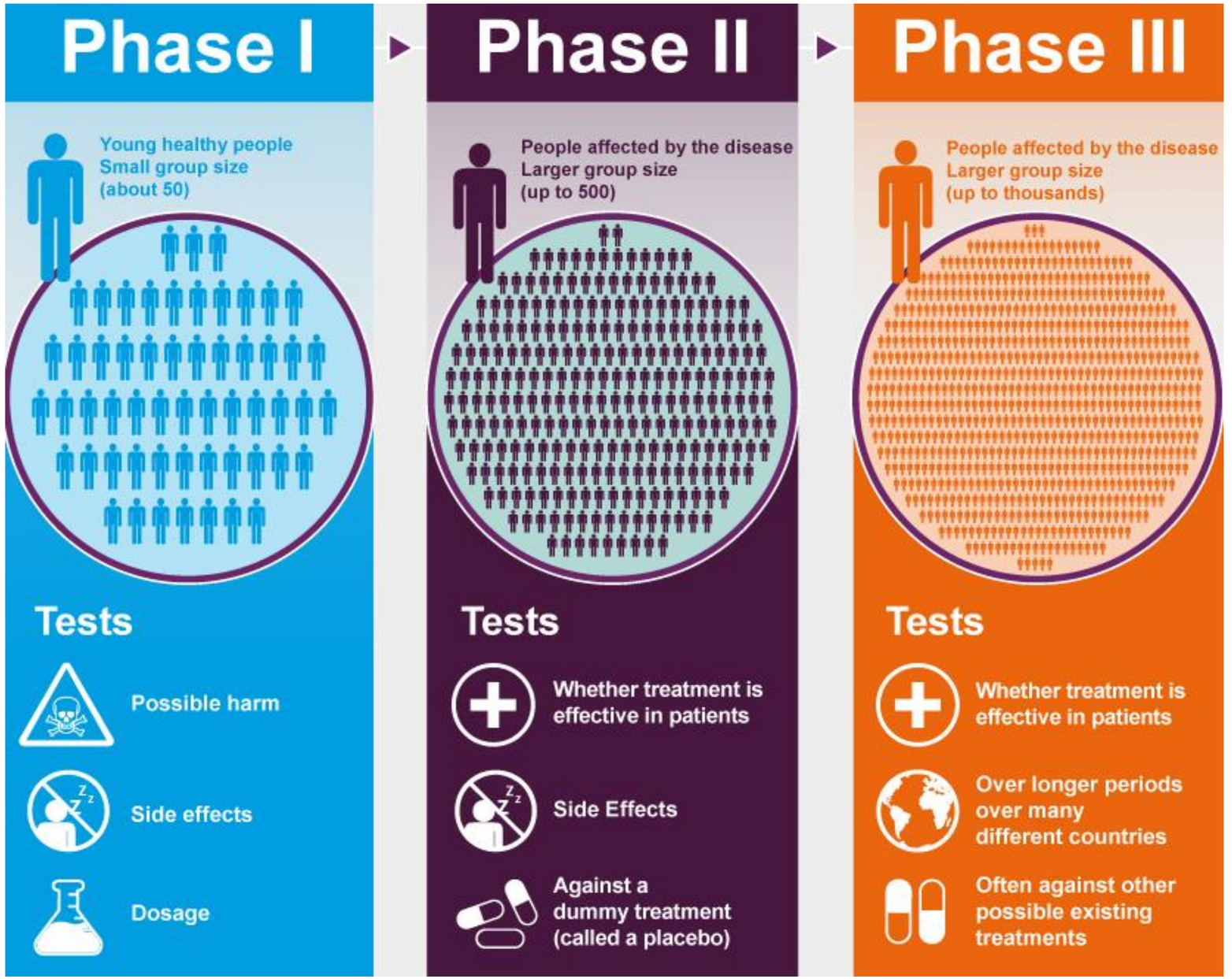
Dr versus nurse makes a difference to adherence?

What are uptake growth effects when community/ family/ relationship ripple benefits beginning to become visible?

Packaging has built in trigger for adherence?

Clinical trials investigates subjects

Throughout each phase most investigations are around the science, with secondary objectives around the human factors



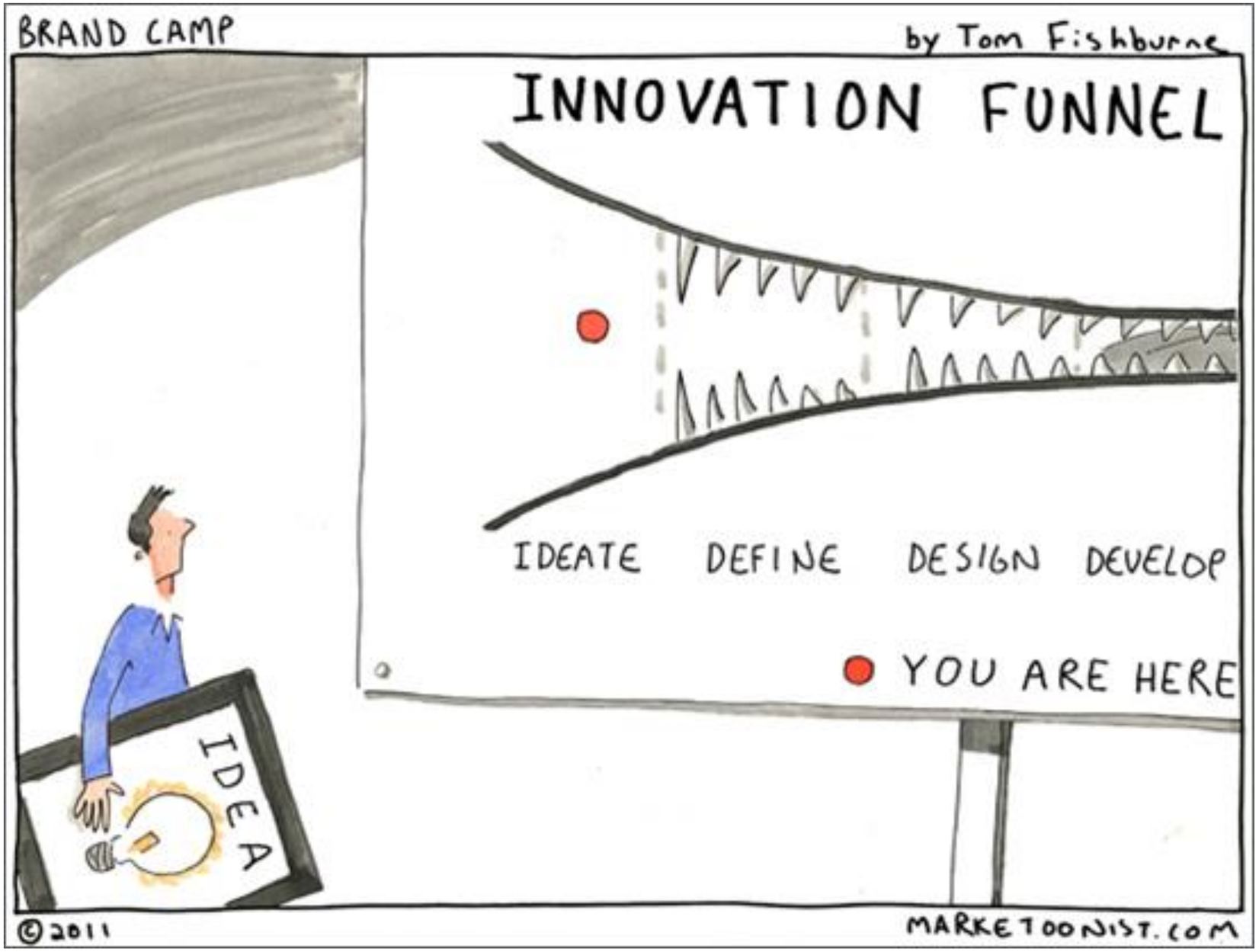
Source: Alzheimer's Research UK

Combining the two valuable lenses

Marrying the clinical and human lenses

3. Researching innovation should be a continuous process

1) Identify
2) Evaluate
3) Iterate
4) Maximize



4. Don’t just evaluate concepts/products – make them stronger

Make space for innovation and adaptations during evaluations

5. Forecast, forecast and forecast again

Forecasting market potential throughout the innovation process is both possible and informative

6. Track & develop success

Why did it work?

THANK YOU

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Session 6: Phase 3 Issues for MPT Products

Market issues for consideration: What can be done in Phase 3 trials, what should be done in parallel?

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Knowledge building

What we know and what we would like to know

Supporting clinical and academic knowledge during Phase 3 clinical trials

It is time to better understand adherence, and develop a nuanced appreciation of factors influencing HIV products and prevention

Engage, listen, appreciate

Current literature expresses this need, and equally the opportunity to build research into the current clinical trajectory for products

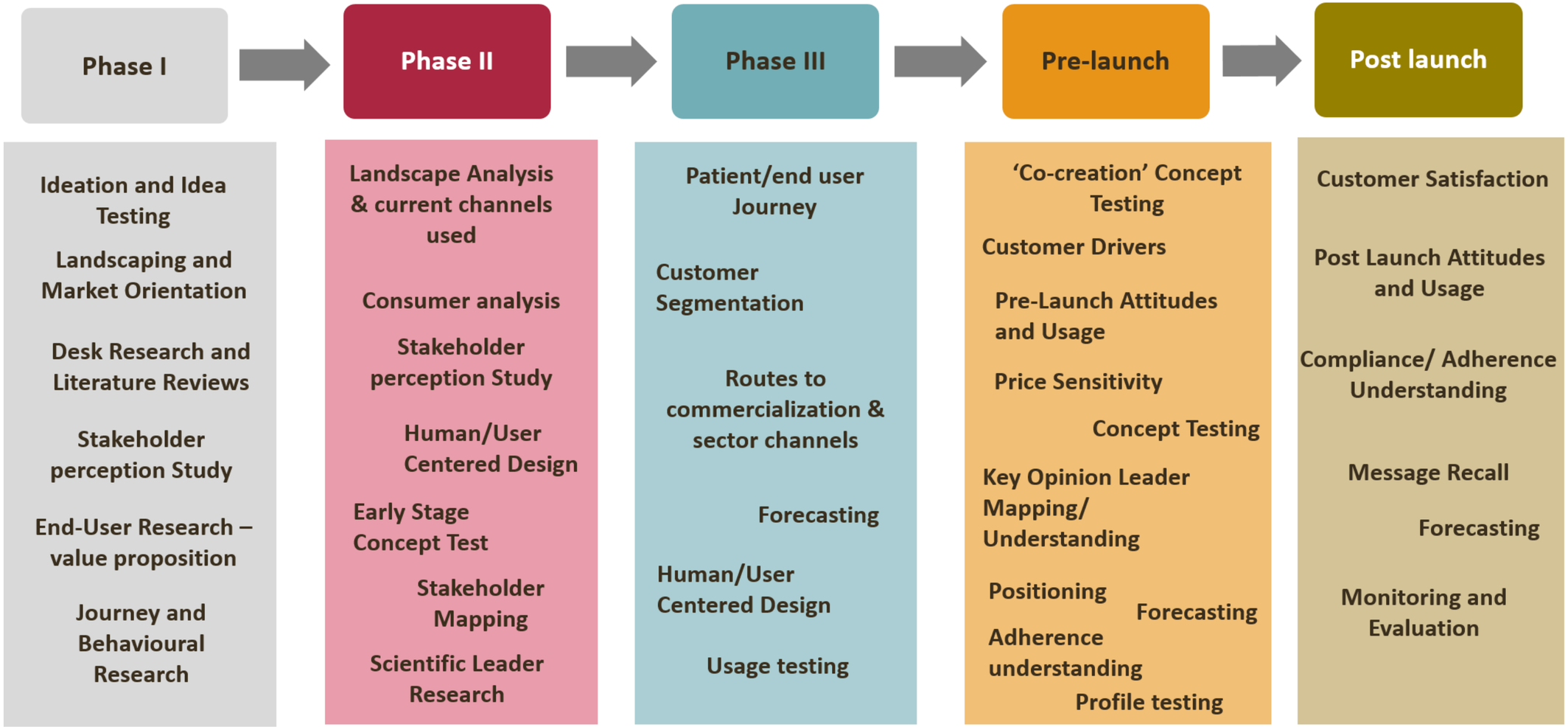
A Systematic Review in 2014 by illustrated the potential interventions to support adherence to HIV PrEP revealed that *"although adherence support strategies have been incorporated into PrEP trials to date, almost all were implemented in such a way that their effect cannot be rigorously evaluated."†*

† http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4107052/

WHO consultation on PrEP adherence	Adherence to Antiretroviral Medications for HIV PrEP	Adherence to Pre-Exposure Prophylaxis: Current, Emerging, and Anticipated Bases of Evidence
In the first month of PrEP use, adherence counseling and provider messages should focus on potential start-up side effects and potential adherence challenges (e.g. What will you do when you have trouble taking it? *How will you get support?).*	*Given the workforce challenges facing primary care and HIV care clinicians, it will be critical to engage nurses, health educators, peer navigators and community health workers, and pharmacists in team approaches to the provision of PrEP-related education, counseling, clinical services, and adherence support.*	*Gaining a more nuanced understanding of factors influencing PrEP should be a behavioral research priority.*
http://www.who.int/hiv/pub/prep/Prep-June2014.pdf	http://www.ajpmonline.org/article/S0749-3797(12)00714-3/abstract	http://cid.oxfordjournals.org/content/59/suppl_1/S55.full

A summary of research, tied to different phases of a product's development cycle

Supporting decision-making from concept to introduction, alongside clinical research



The reality of phase 2 and 3 and fundable activities to support knowledge

Optimising interventions via understanding the ecosystem they will operate in

Marrying acceptability, uptake and implementation

Market research offers techniques to understand the end user and the ecosystem needed to provide the product to the end user

Forecasting and usage – from screening interest to understanding cessation

Tracking patterns, influencing factors/barriers, identifying critical drop-off points and essential supporting interventions

Look and look again...

Thinking point: What research could be done?

Research needs, funding gaps, what do we want to get funded, tangible meaningful funding
Mixing HIV and Contraceptive research.. How, pitfalls, advantages, what do we need to consider?

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