Session 2: Market Assessment Needs for MPTs
The Human Factor: Applications for Product Development & Early Stage Clinical Trials
Moushira El-Sahn & Jeff Lucas, Routes2Results and Cal Bruns, Matchboxology
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.
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.
Pharma and commercial groups have historically integrated market research into their thinking and throughout their decision-making/product milestones.

1. Understand your market
   *Perception is reality*

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

3. Researching innovation should be a continuous process

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

5. Forecast, forecast and forecast again

6. Track & develop your success
1. Understand your market

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

- Champion
- Adherence/Loyalty
- Trial
- Interest
- Awareness but not convinced
- Unaware
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 investigate 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?
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?
Moushira El-Sahn, Jeff Lucas Routes2Results (R2R) and Cal Bruns, Matchboxology (MBX)
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/

<table>
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<tr>
<th>WHO consultation on PrEP adherence</th>
<th>Adherence to Antiretroviral Medications for HIV PrEP</th>
<th>Adherence to Pre-Exposure Prophylaxis: Current, Emerging, and Anticipated Bases of Evidence</th>
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<td><em>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?).</em></td>
<td><em>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.</em></td>
<td><em>Gaining a more nuanced understanding of factors influencing PrEP should be a behavioral research priority.</em></td>
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http://www.who.int/hiv/pub/prep/Prep-June2014.pdf  
http://cid.oxfordjournals.org/content/59/suppl_1/S5_5.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

**Phase I**
- Ideation and Idea Testing
- Landscaping and Market Orientation
- Desk Research and Literature Reviews
- Stakeholder perception Study
- End-User Research – value proposition
- Journey and Behavioural Research

**Phase II**
- Landscape Analysis & current channels used
- Consumer analysis
- Stakeholder perception Study
- Human/User Centered Design
- Early Stage Concept Test
- Stakeholder Mapping
- Scientific Leader Research

**Phase III**
- Patient/end user Journey
- Customer Segmentation
- Routes to commercialization & sector channels
- Forecasting
- Human/User Centered Design
- Usage testing

**Pre-launch**
- ‘Co-creation’ Concept Testing
- Customer Drivers
- Pre-Launch Attitudes and Usage
- Price Sensitivity
- Concept Testing
- Key Opinion Leader Mapping/Understanding
- Positioning
- Forecasting
- Adherence understanding
- Profile testing

**Post launch**
- Customer Satisfaction
- Post Launch Attitudes and Usage
- Compliance/Adherence Understanding
- Message Recall
- Forecasting
- Monitoring and Evaluation
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...
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?

Thinking point: What research could be done?
THANK YOU

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