

A New Era of Collaboration to Advance Digital Measures

Introducing the DEEP Ecosystem



EU Connect 2021

The Clinical Data
Science Conference

Your hosts for this session

Bert Hartog, ideating scientist

“in theory everything is possible”



Senior Director, Janssen Clinical
Innovation, Janssen Pharmaceutica NV



Kai Langel, pragmatic guy

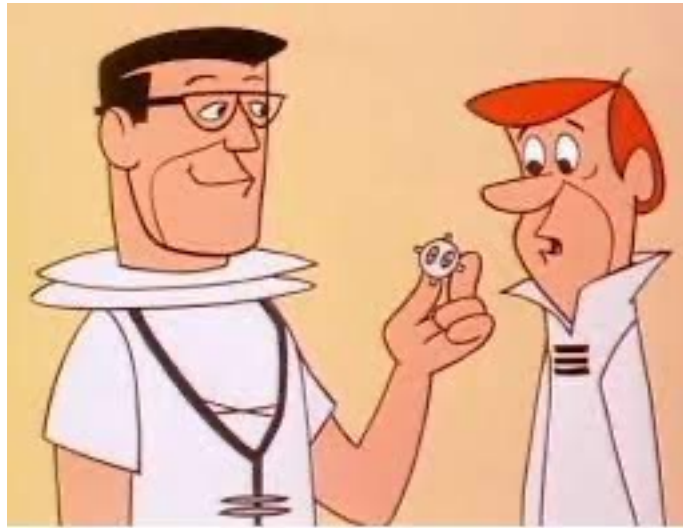
“When nothing goes right... go left”



Senior Director, Janssen Global
Regulatory Policy and Intelligence,
Janssen-Cilag S.A.

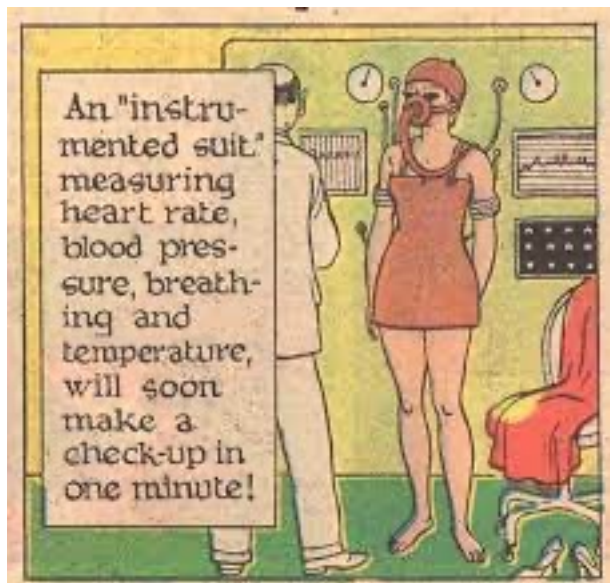


Glimps from the past: the 1960's



Peek-A-Boo
Prober Capsule

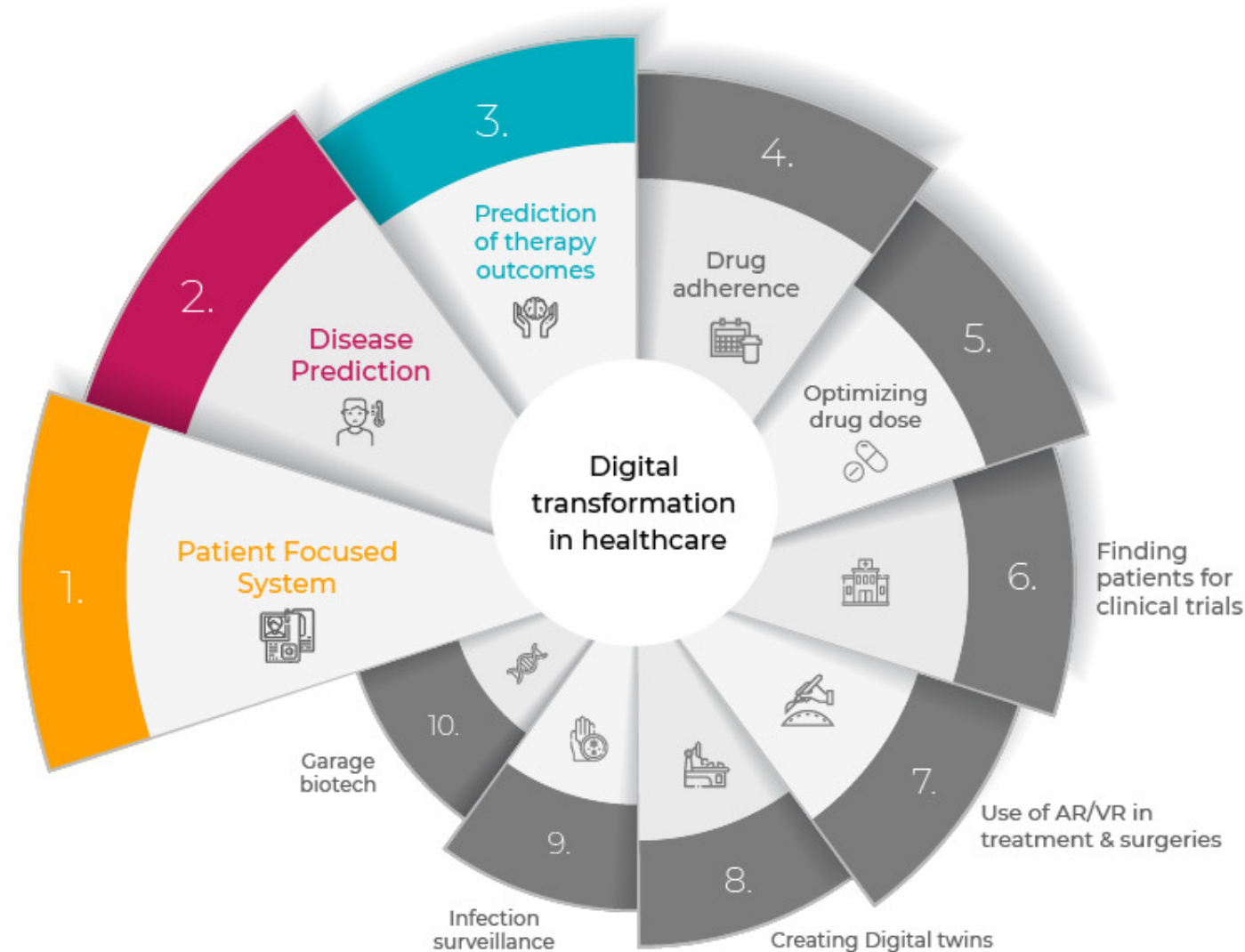
Images from The Jetsons



Images public domain

Instrumented
suit for vitals

Digital transformation in healthcare today



Source image: <https://www.acuitykp.com/blog/digital-transformation-in-healthcare/>

Momentum is building up quickly

DiMe's Crowdsourced Library of Digital Endpoints



69 Sponsors have collected digital endpoints

69 Sponsors have collected digital endpoints

Primary, Secondary or Label Claim

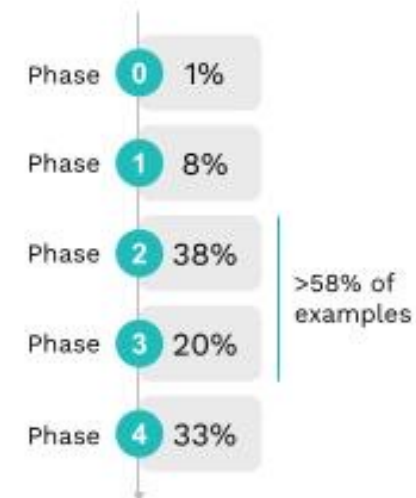


Exploratory Only



Sponsors start digital endpoint development early

Digital Endpoints



*Only drug trials with reported phases are included

Digital endpoints are being used across drug, device, and biologic development

Investigational Product



● Drug	60.2%
● Device	24.7%
● Biologic	9.8%
● Other	5.3%

Pharma trusts digital products, primary/secondary endpoints

Endpoint Positioning

63 Primary endpoints

148 Secondary endpoints

14 Exploratory

225 UNIQUE ENDPOINTS



Is your company's work missing? Submit it to DiMe: <https://bit.ly/DiMe-Endpoints>

Source: <https://www.dimesociety.org/index.php/knowledge-center/library-of-digital-endpoints>

Last updated September 2, 2021

Digital measurements are not fail-proof



In its [response letter](#), the FDA said there was not enough evidence that the criteria evaluated in the assessment were meaningful for patients' lives.

From the response letter:

“For example, it is unclear how the change in the digital signature for finger tapping (as measured by the Verily Study Watch) could be interpreted as representing meaningful change in patient function.”

Looking Beyond COVID

Digital Measures Unlocking Novel Science

- Real-world setting
- Continuous
- Passive
- Faster time-to-signal
- Higher sensitivity
- Objective
- Enabling novel remote care models



And new, complex and ever-evolving!

What should we focus on?

Key challenges for the next 5 years

1. Seeking harmonization:

- Measure definitions & interpretation
- Instrumentation standards

2. Intellectual Property (IP) and collaboration frameworks

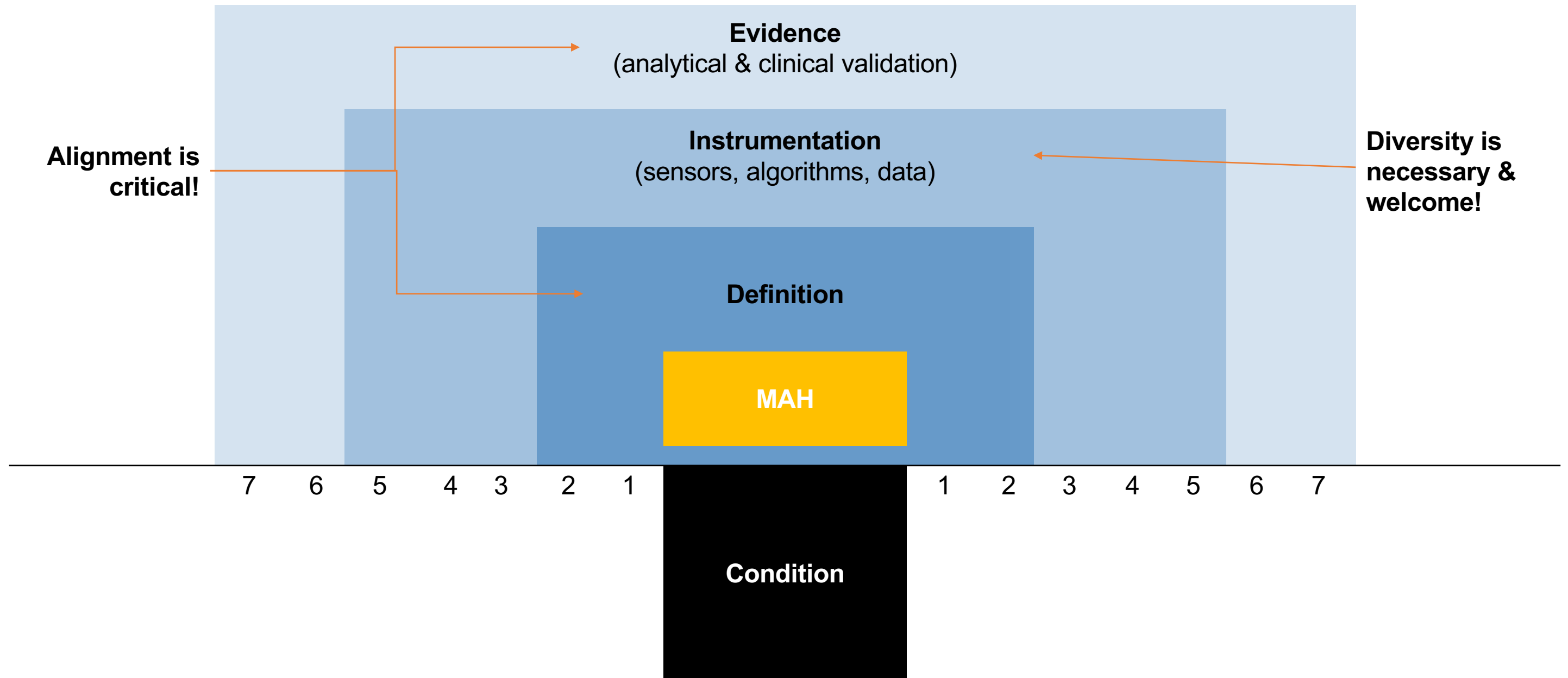
- Enable re-use and re-purpose of components within the ecosystem

3. Lifecycle Management

4. Optimizing the regulatory pathways

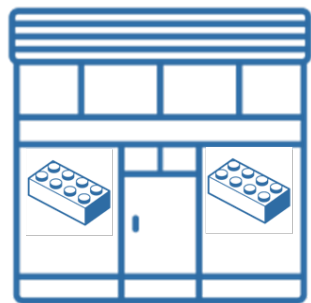
- Additional clarity and guidance
- Best practices
- More efficient collaborative pathways

5. Usability and user acceptance

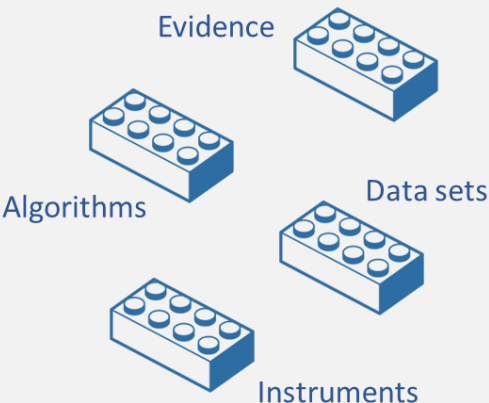


With an agreed definition you can find the right instrumentation to generate required evidence

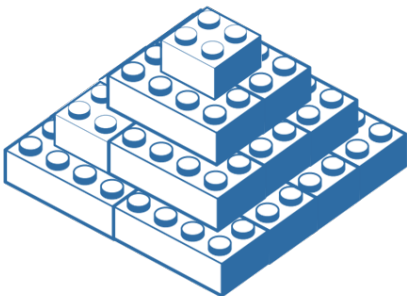
Taking an Ecosystem Perspective



Go to DEEP marketplace



Find assets to build your measurement solution



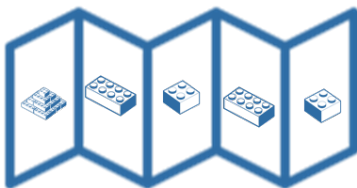
Combine assets into a new measurement stack



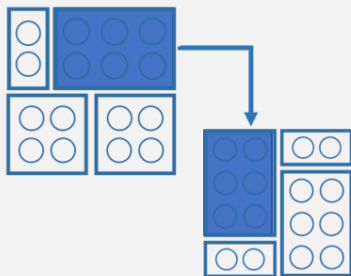
Find complete ready-made measurement solutions



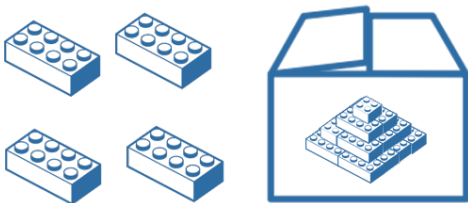
Contact experts to help find what you need



Find blueprints (TSPs) for building new measurement solutions

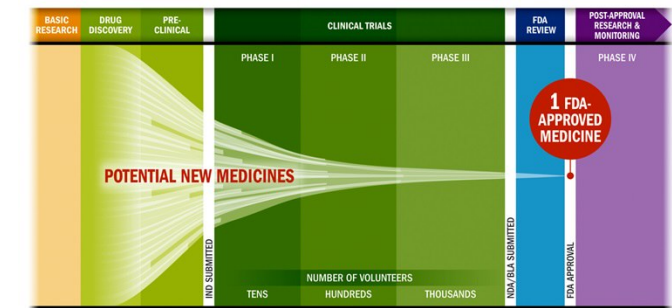
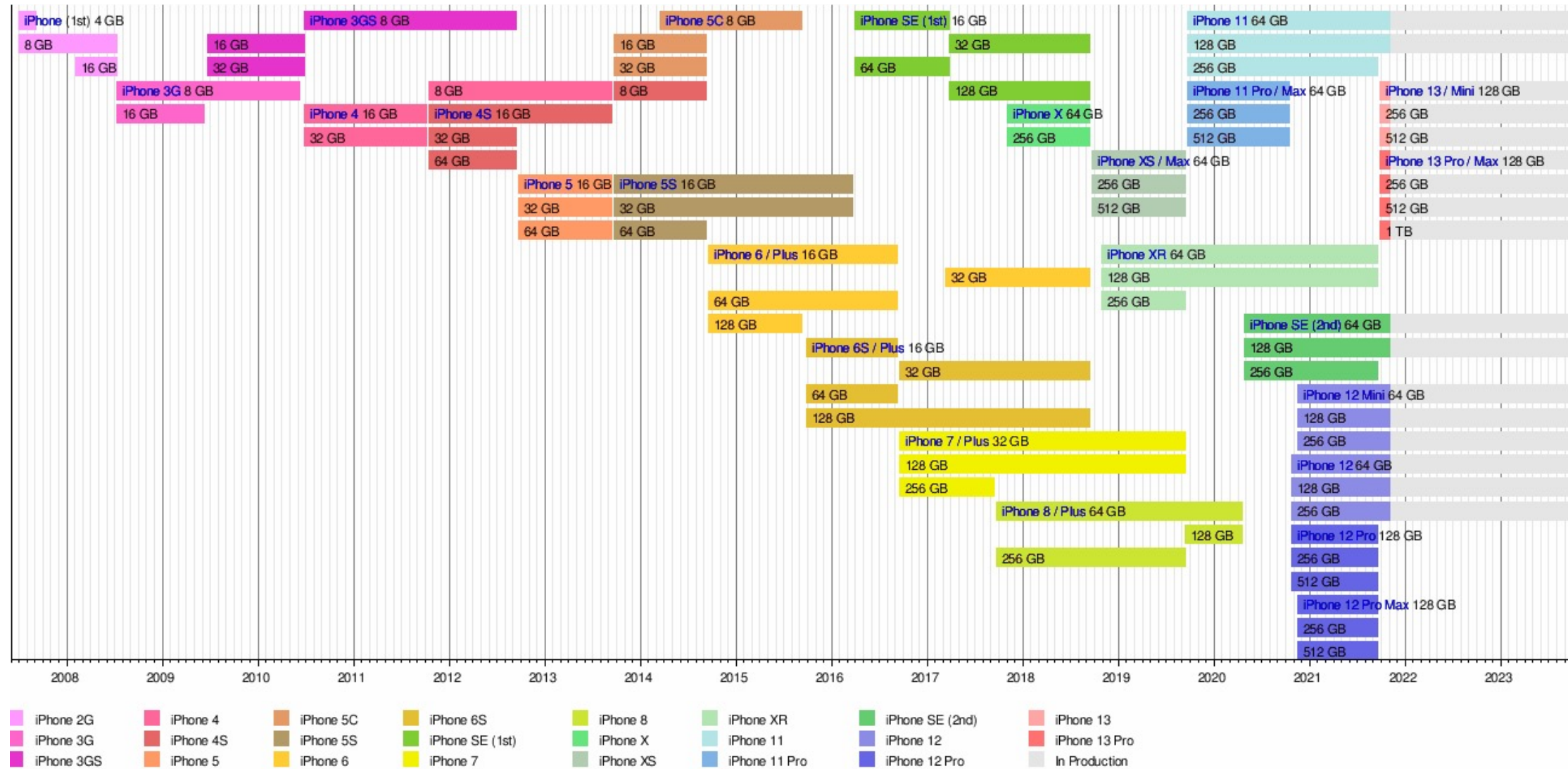


Repurpose assets for new measurement stacks



Find assets and solutions from aggregators

Lifecycle management



Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

* The average R&D cost required to bring a new, FDA-approved medicine to patients is estimated to be \$2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Source: PhRMA adaptation based on Tufts Center for the Study of Drug Development (CSDD) Briefing: "Cost of Developing a New Drug" Nov. 2014; Tufts CSDD & School of Medicine, and US FDA infographic, "Drug Approval Process," <http://www.fda.gov/downloads/Drugs/Resources/forYou/Consumers/UCM284393.pdf> (accessed Jan. 20, 2015).

Audience Q&A

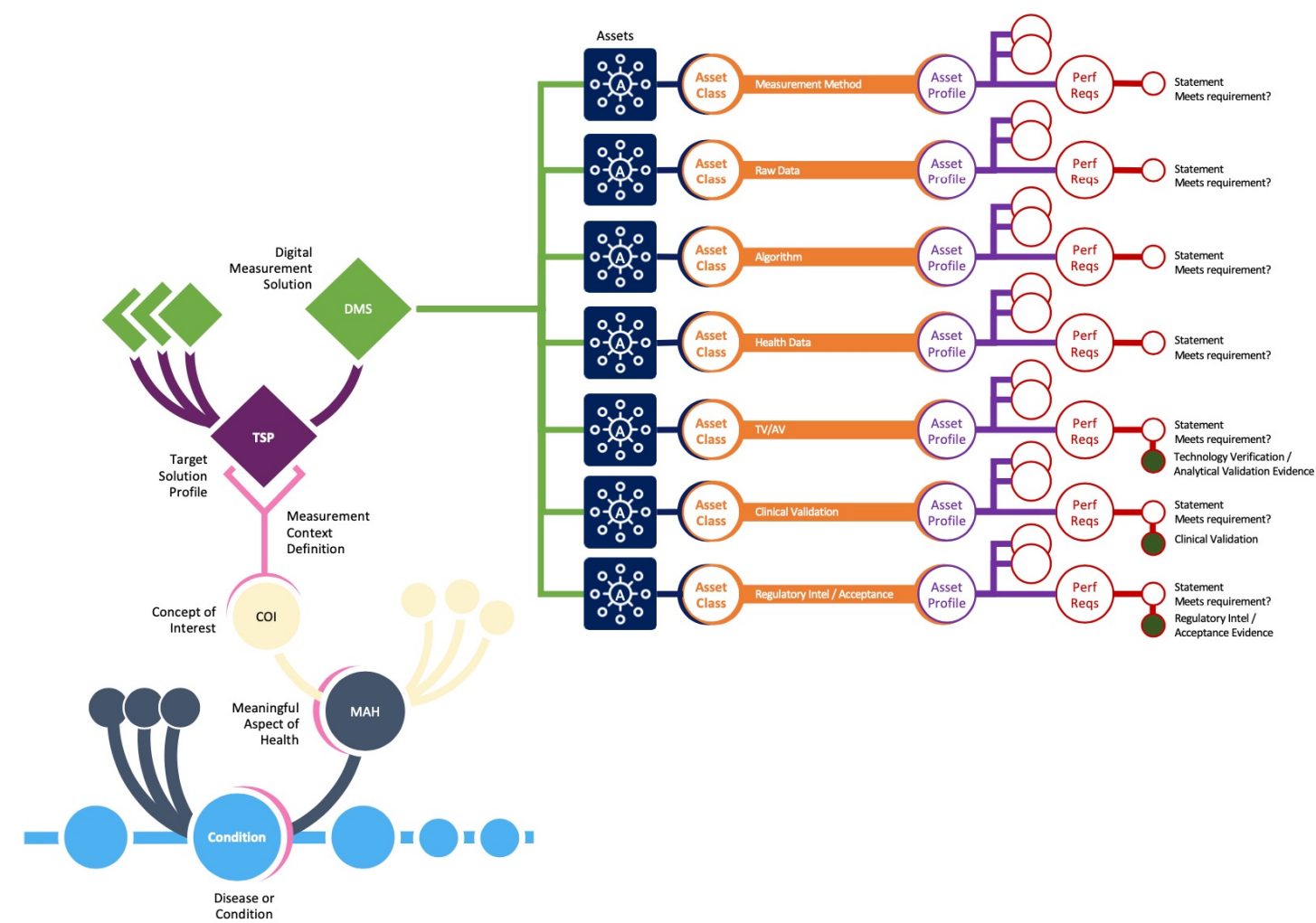
DEEP™

Introducing DEEP™*

Next Generation Framework

Curation Overview

Overview of linked elements within the Curation Software



Catalogue of re-usable components

Disease-specific measurement concepts

* Digital Endpoints Ecosystem and Protocols (DEEP) - Janssen has led the co-creation of the DEEP framework and holds the IP for it. The intent is for the pre-competitive and collaborative framework to serve the broader ecosystem as a whole

1

SCENARIO 1

Measurement Definition

Finding the
right measure that
matters

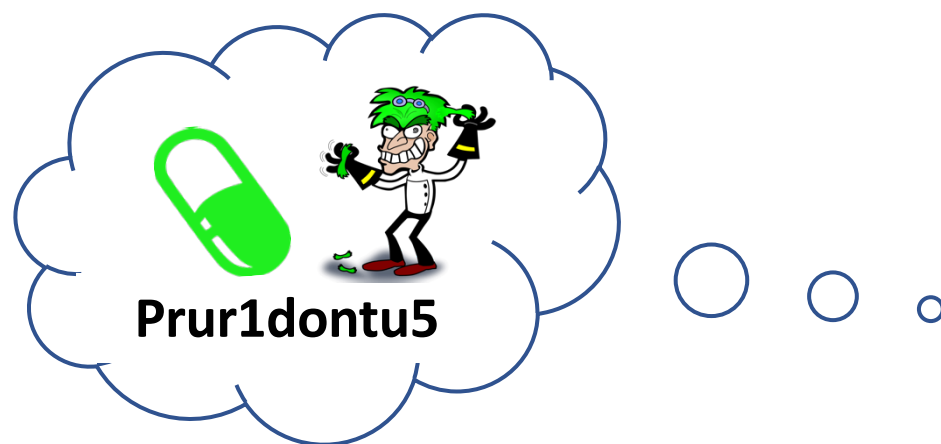


1

Measurement Definition

Introducing our characters

Goodwill Pharmaceuticals



Our new compound can offer long lasting relief from **itchy skin** for people with Atopic Dermatitis. This drug can reduce the impact of **nighttime scratching** on sleep.



What we need to find are **Concepts of Interest** related to itching that matter most to patients.

What are our options?

Search
DEEP
Catalogue



Demo



1

Measurement Definition



I found several useful measures but which one would patients care about the most?



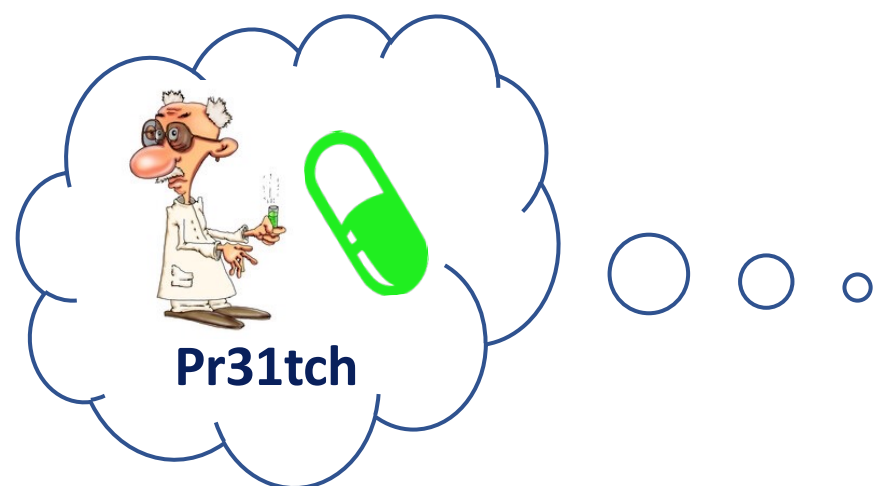
I can't be the only one looking. This is an opportunity for pre-competitive collaboration...

1

Measurement Definition

Introducing our characters

Benevolent Bio-Meds



Our new compound is a **cream** for the topical treatment of **acute Atopic Dermatitis**.



We are looking for **Concepts of Interest** related to itching that matter most to patients.

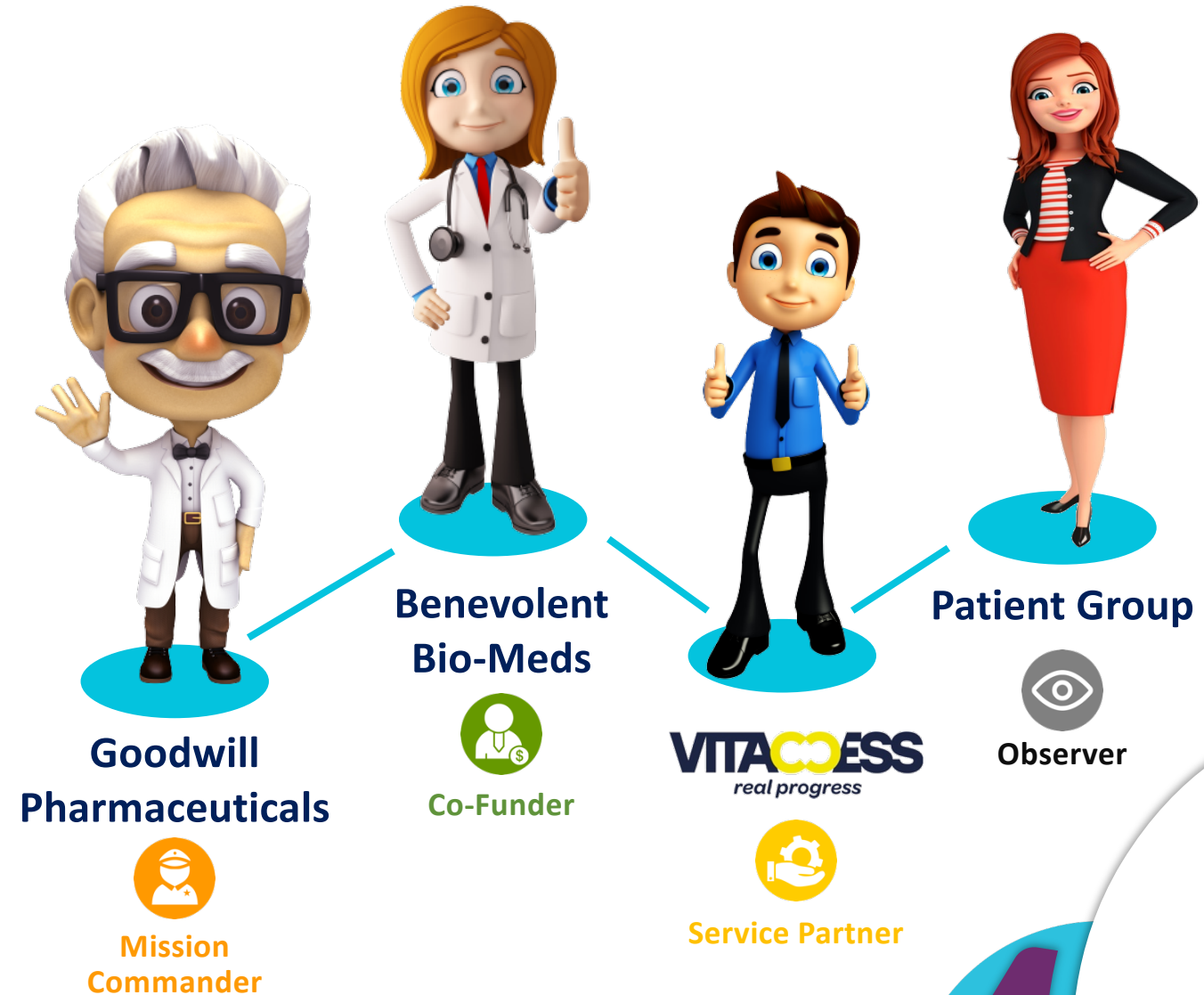
1

Measurement Definition

I will Launch a mission!

The objective will be to define a patient-relevant metric for nocturnal scratching within Atopic Dermatitis

Look, I already have great collaborators for my mission!!



Activate Mission
Launch Sequence
in DEEP



Demo



1

Measurement Definition

Recap

1) Mission Launch

A DEEP mission was launched

The objective was to:

Define a patient-relevant metric for nocturnal scratching within Atopic Dermatitis

2) Mission Operations

A new 'Standard' is born!

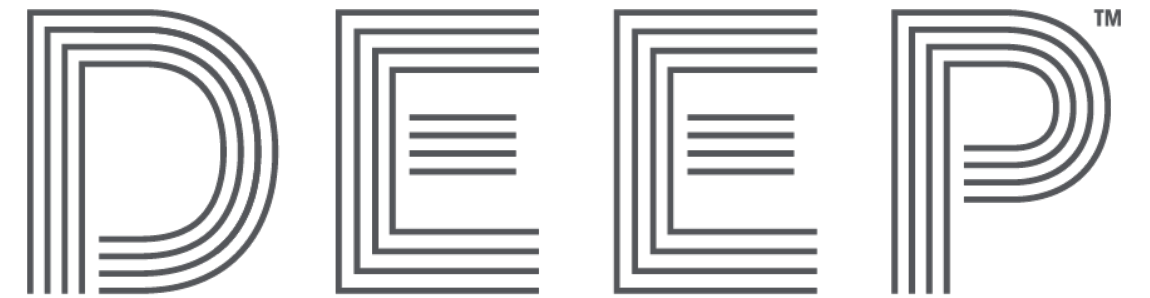
3) Mission Landing
Objective Achieved!

Definition

Evidence of
meaningfulness

**What's
next?**

Audience Q&A



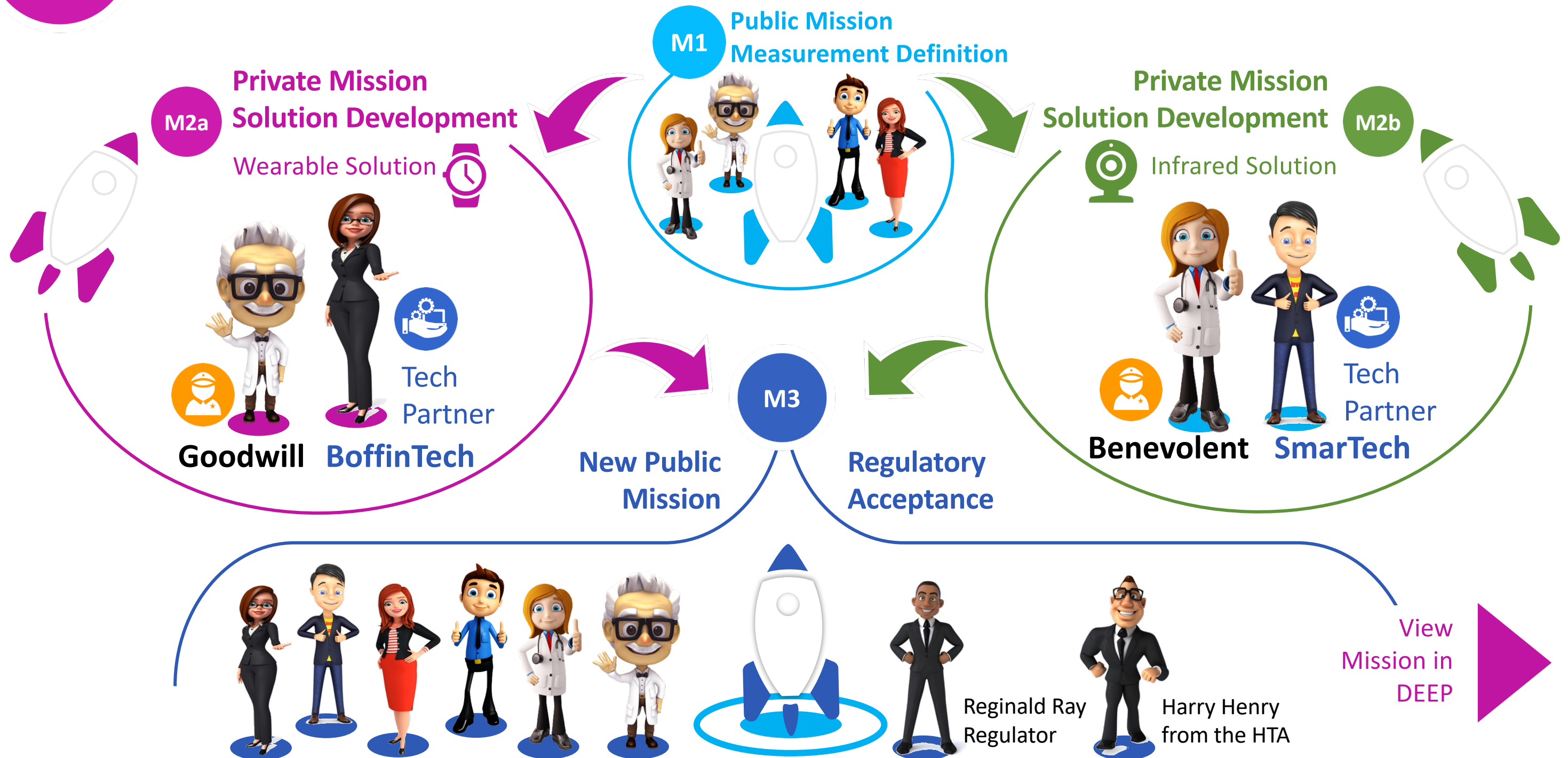
SCENARIO 2

- **Solution Development**
- **Regulatory Acceptance**



2

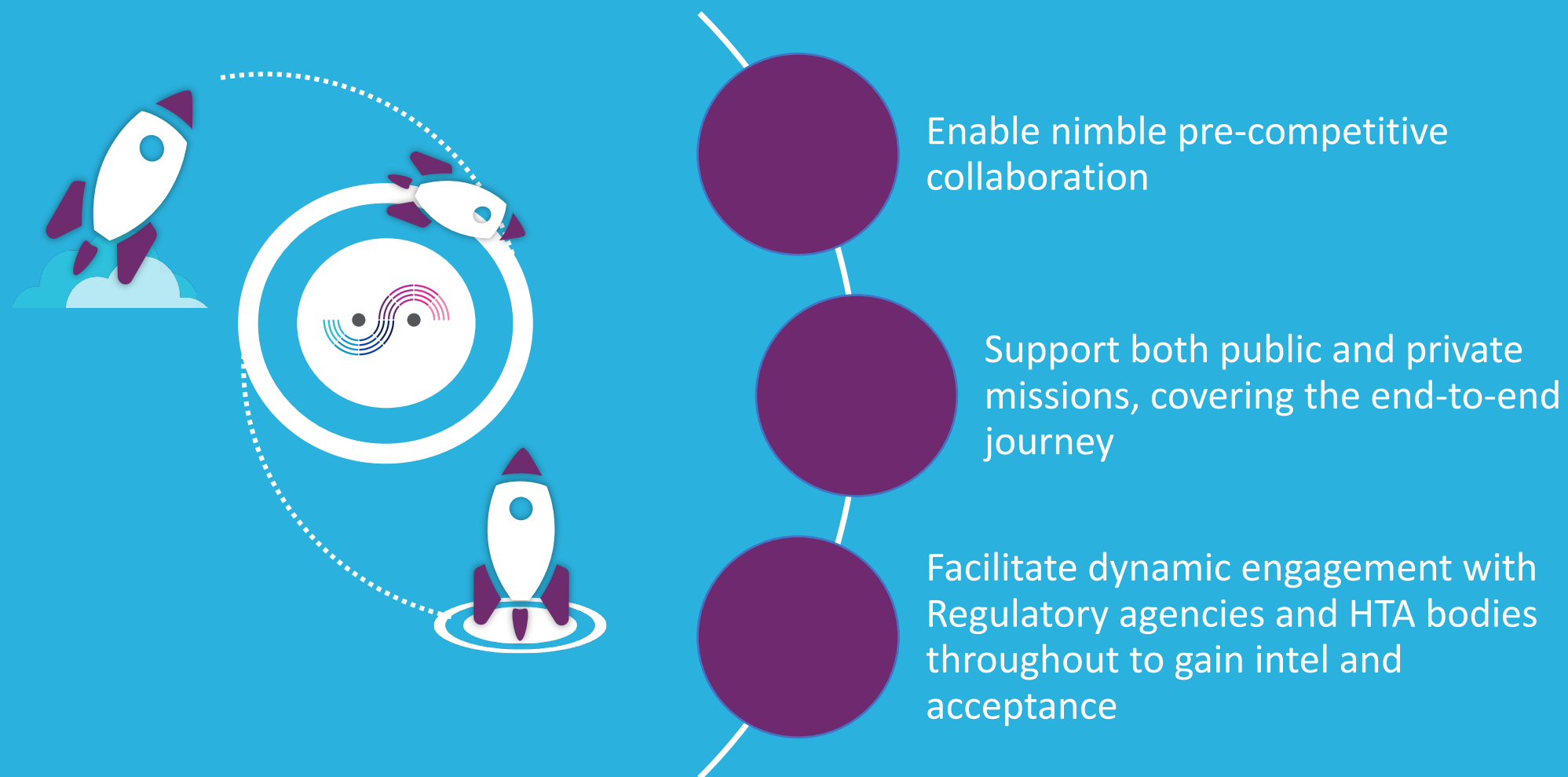
Scenario 2 – Solution Development



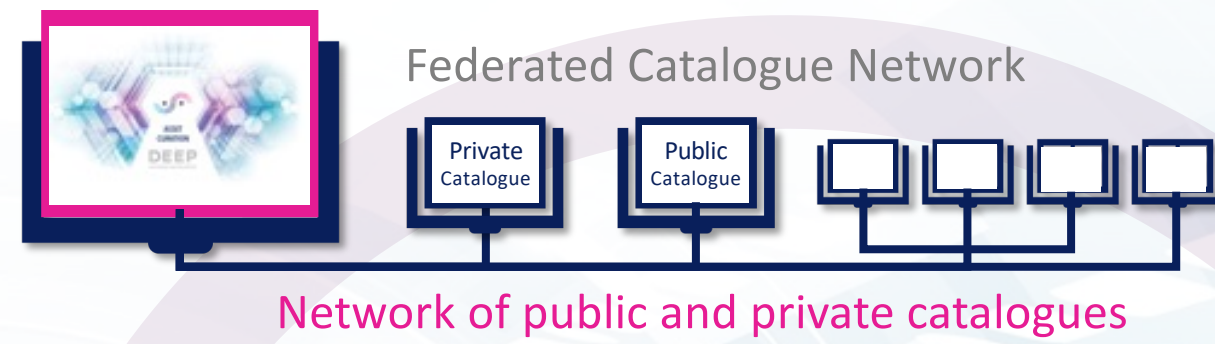
Demo



DEEP Enabled Missions and Partnerships



Asset Catalogues

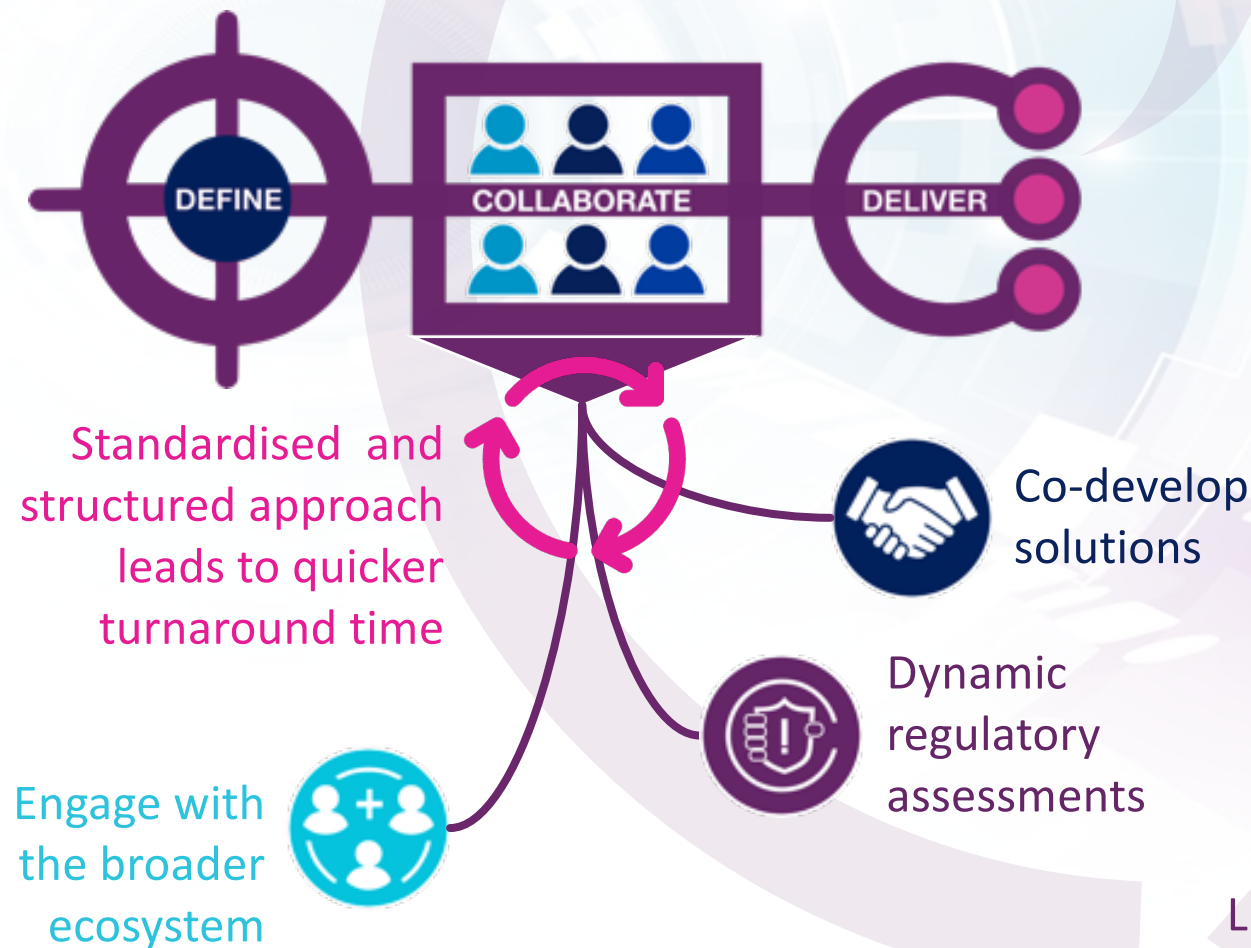


Services Eco-System

DEEP Services

- Asset Discovery
- Asset Curation
- Profiling & Standards
- Facilitation
- DEEP Insights

Mission Collaboration Platform



Partner Services

DEEP Asset Search	Measurement Definition	Prototyping
Analytical Validation	Profiling	Qualification Protocols (QP)
Clinical Validation	Evidence Dossier	Asset Leverage

Lifecycle Management

Conclusions & Next Steps



Senior Director, Janssen
Clinical Innovation,
Janssen Pharmaceutica
NV

Connect to your EFPIA representatives, further dialogue in the different WGs and subgroups

EFPIA Steering Group includes:

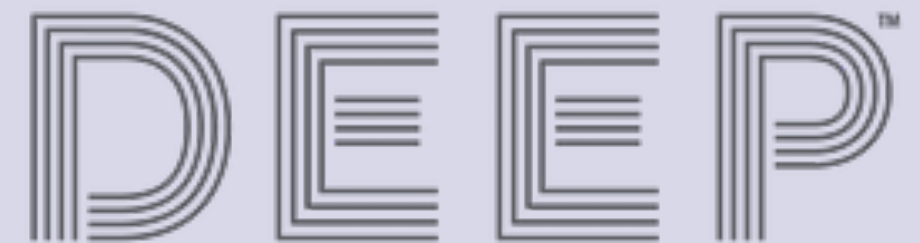
- Bayer – Joachim Luithle, Upinder Grewal, Jaya Pal
- Roche – Lada Leyens
- IMI Office – Colm Carroll
- EFPIA Office – Magda Chlebus (Science Policy & Regulatory Affairs)

Interested to see and learn more and get involved?

Join us on Friday 19th November, 08:45 -10:45 BST

Hands-on workshop

New era of collaboration – towards the adoption of digital measures – DEEP initiative



DIGITAL ENDPOINTS ECOSYSTEM & PROTOCOLS

Audience Q&A

