Advancing *in vitro* tools to predict bioavailability of biotherapeutics

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CONTROLLED RELEASE SOCIETY
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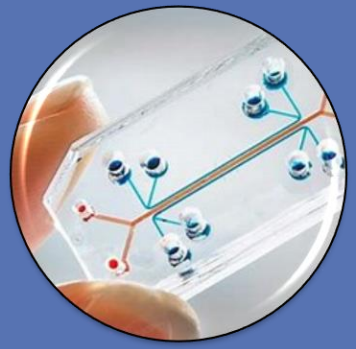
INTEGRATING
Delivery Science
ACROSS DISCIPLINES

The SC *in vitro* tool landscape has progressed significantly in recent years

ARTIFICIAL MODELS

- Gel diffusion & dialysis based systems
- Dissolution apparatus USP 4 & 7
- SCISSor
- ESCAR
- AC SINS
- Osmomat 050
- Aggregation / oligomerisation assays
- Binding assays (protein, FcRN, ECM components)

CELL & TISSUE BASED MODELS



- Microphysiological endothelial models
- WAT tissue on a chip
- Hyposkin®, FlowSkin®
- Perfused porcine limb model
- Catabolism assays

Bioavailability predictions & *in silico* input parameters

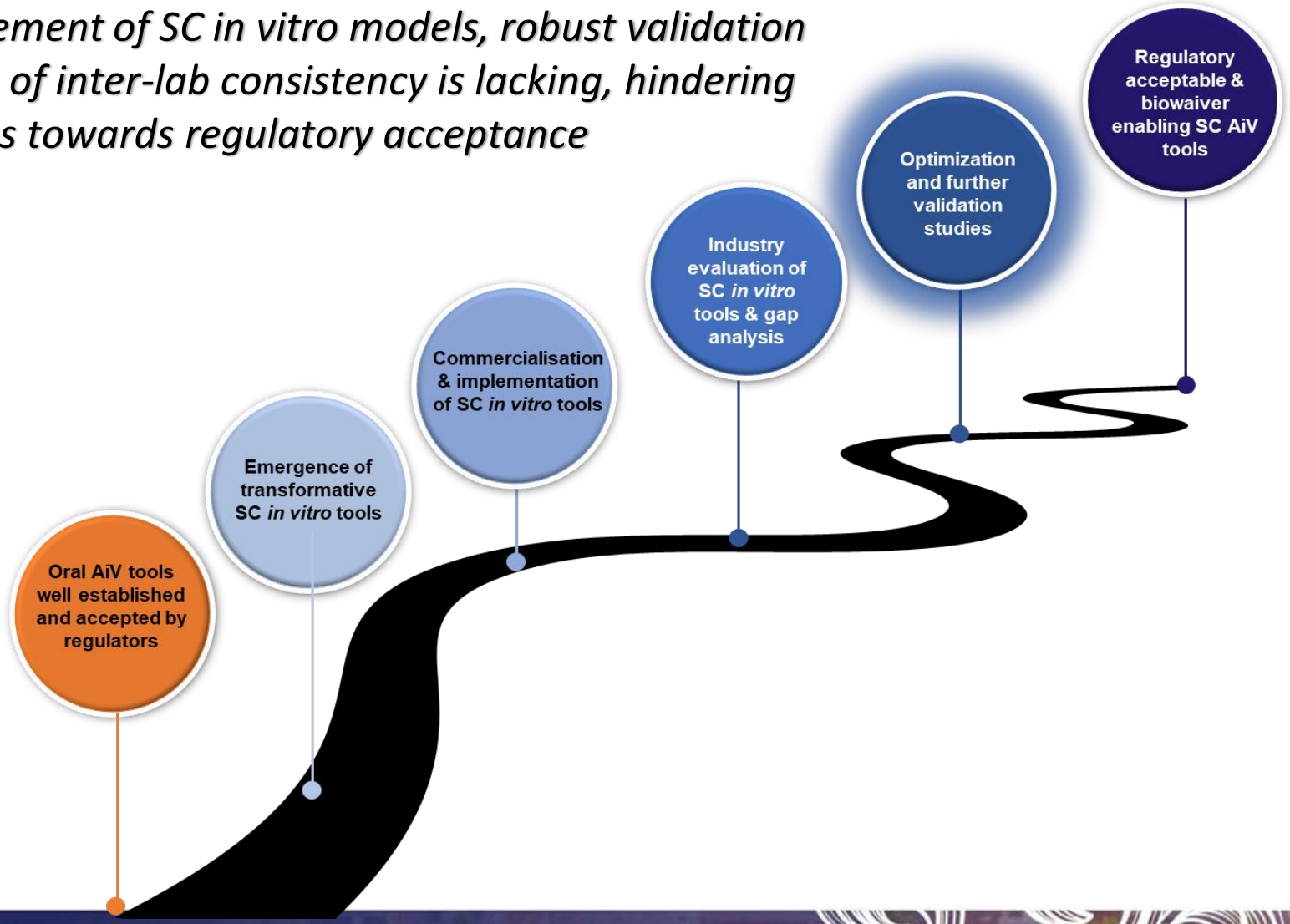
Validation of SC *in vitro* tools remains a key gap

Despite the advancement of SC in vitro models, robust validation and demonstration of inter-lab consistency is lacking, hindering progress towards regulatory acceptance

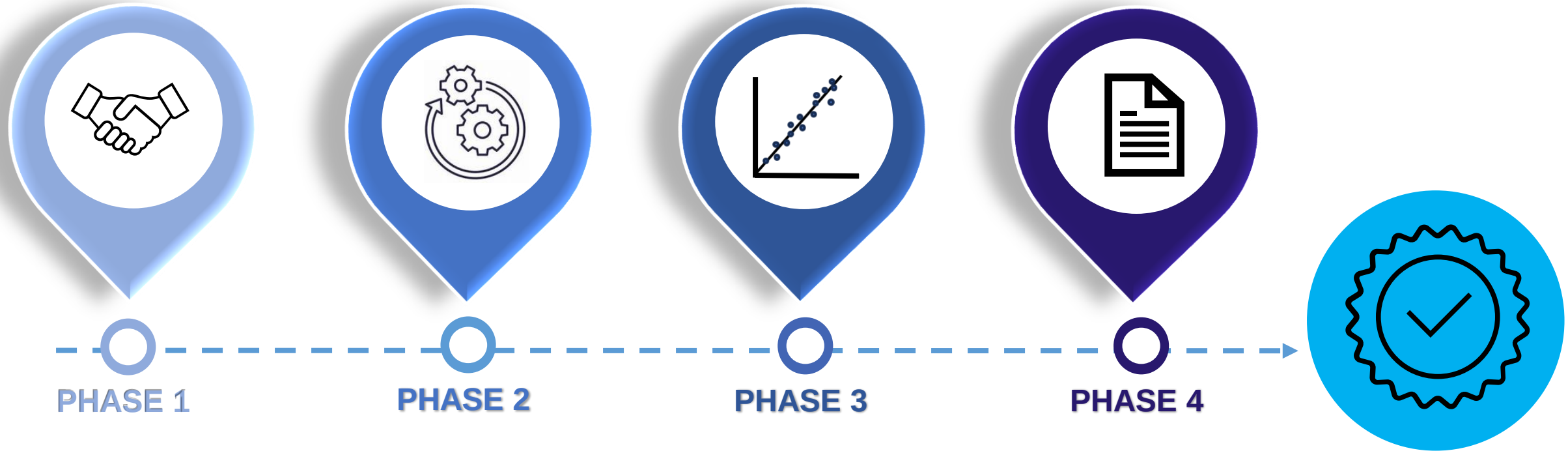
Unaddressed scientific need

- Limited validation dataset
- Un-optimised experimental conditions
- No across-lab validation
- Variability widely observed
- Cost restrictions

Poor BA predictivity, reliant on human studies to aid biotherapeutic drug product development



The SC consortium are actively seeking collaboration with technology companies to validate *in vitro* tools and ensure regulatory acceptability



PHASE 1

Identify priority tools and technology companies

PHASE 2

Method optimisation & evaluation

PHASE 3

Consortia members evaluation

PHASE 4

Regulatory advocacy and publication