Streamlining biosimilars development with *in vitro* immunogenicity assays

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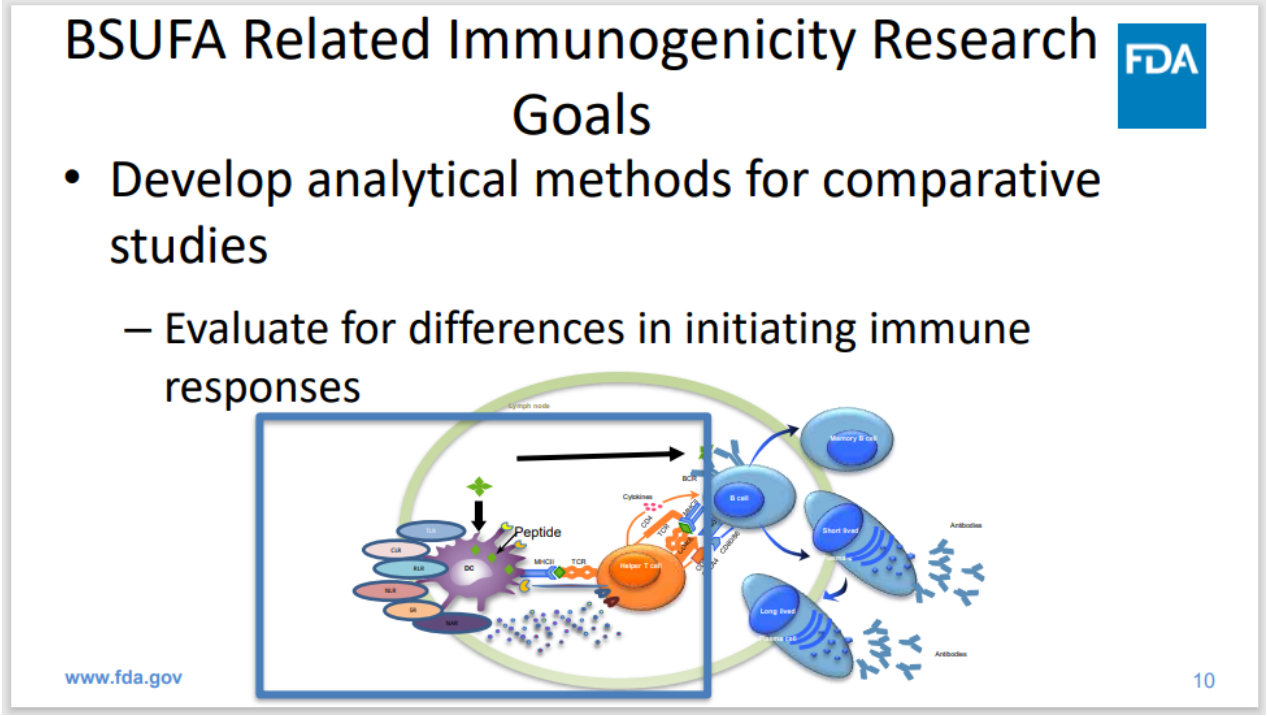
October 22, 2024

Disclaimer

The opinions expressed in this presentation are those of the presenter and not necessarily those of Teva Pharmaceuticals, Inc. or its affiliates (collectively "Teva").

Background

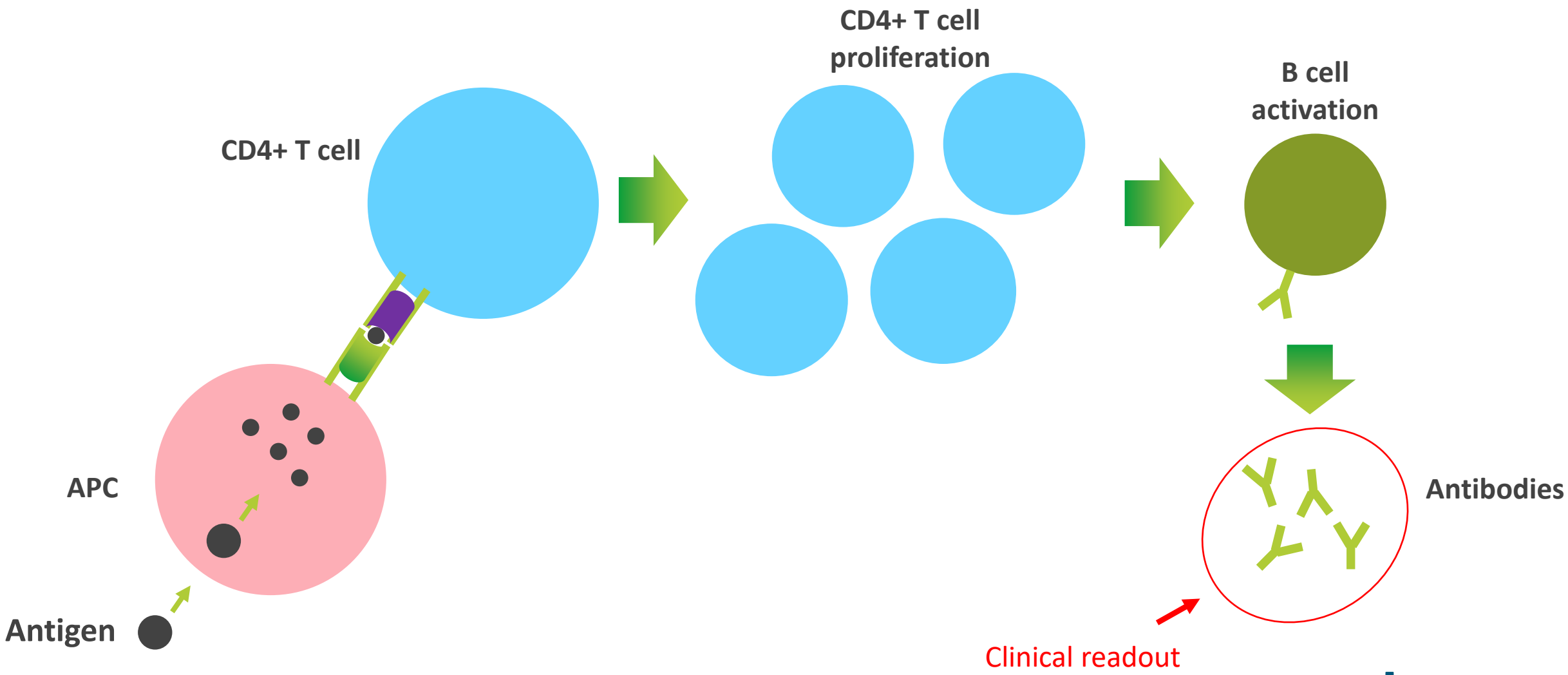
- BsUFA III has a stated goal of reducing the clinical and animal studies requirements for biosimilar approvals by 2027
- One possible approach is increasing reliance on *in vitro* immunogenicity assays
  - Many of these assays are already in use
  - FDA appears to support expansion and standardization
  - Utilizing these assays to support submissions may require additional validation work



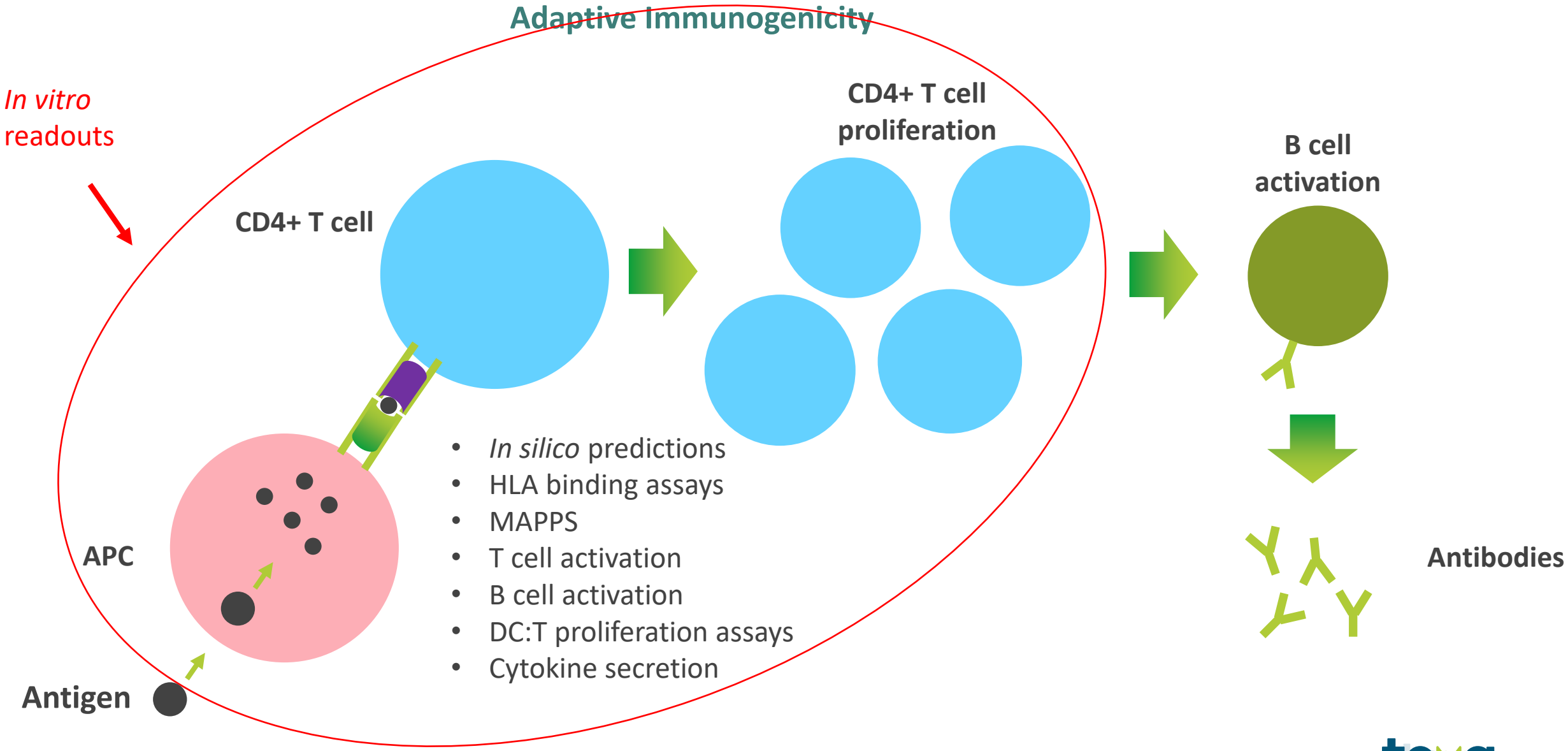
Slide presented by
Susan Kirshner, Director, FDA
October 2023

Overview of Immunogenicity Assays

Adaptive Immunogenicity



Overview of Immunogenicity Assays



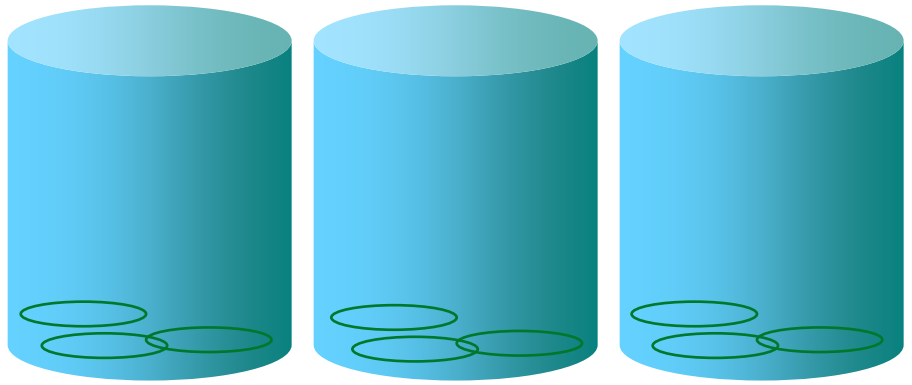
Overview of Immunogenicity Assays

Innate Immunogenicity

Biosim

Add reference product, biosimilar, or controls to THP-1 Blue or RAW Blue cells

Ref



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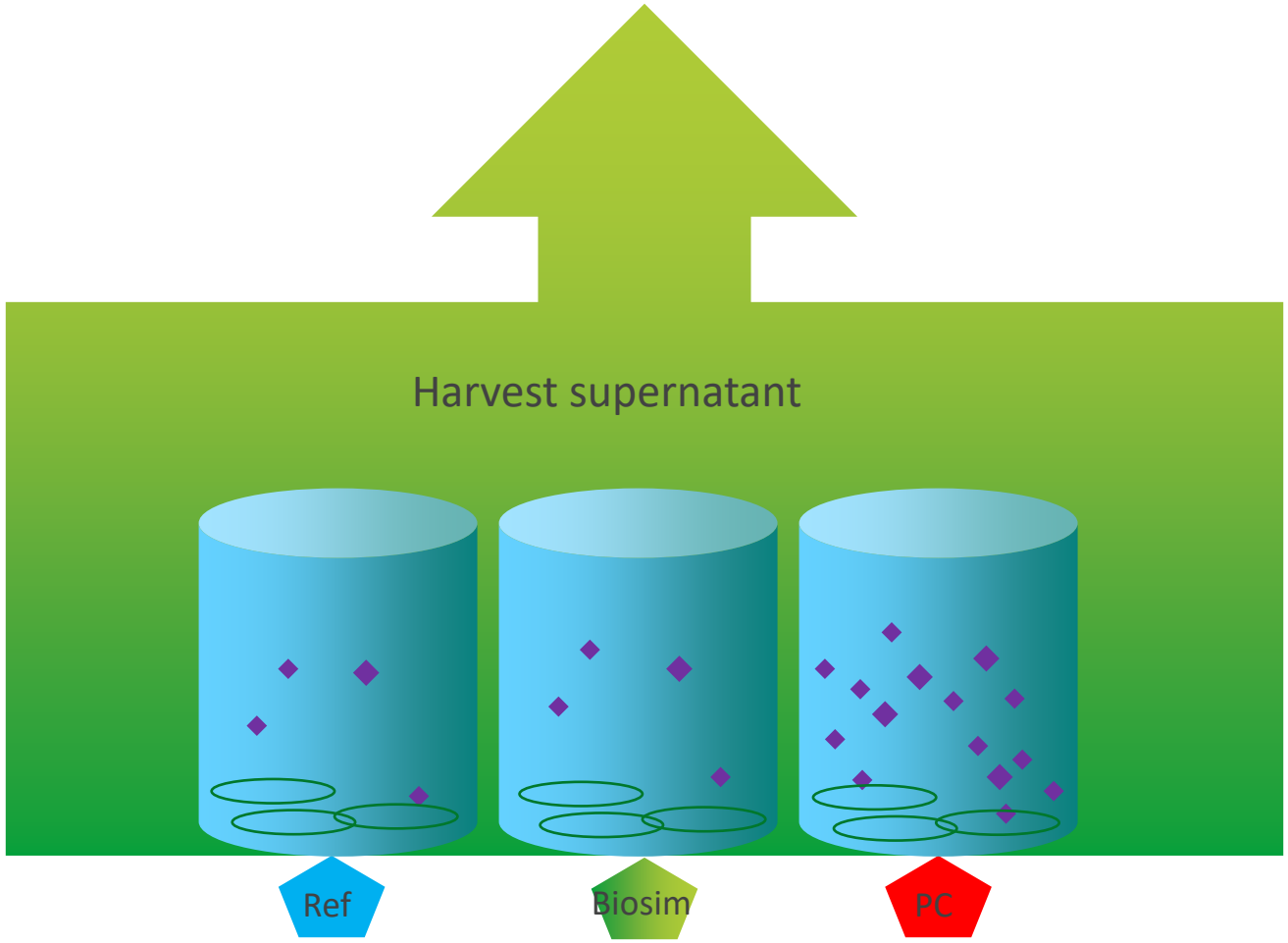
Overview of Immunogenicity Assays

Innate Immunogenicity

- Cell line activation
- Cytokine secretion
- DC activation
- MAT assay



Summary and Parting Thoughts

Immunogenicity assays are a key component in the development of biologics and biosimilars.

Employing orthogonal assays for product evaluations can, in the view of the FDA, contribute to the totality of evidence used to assess the potential immunogenicity risk. These assays have already been successful in supporting submission packages for FDA approval of complex generic peptides through the 505(j) pathway.

We suggest here that these assays can be utilized to generate supporting data that reduces the need and scope of clinical studies for biosimilars. To accomplish this, these assays:

- Must be developed, optimized, and validated for use with biosimilars candidates
- Be properly controlled throughout the evaluation period with comparisons to the reference product
- Apply appropriate statistical analysis based on planned outcomes rather than reactions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