



How can Model-Integrated Evidence Accelerate LAI Generic Availability?

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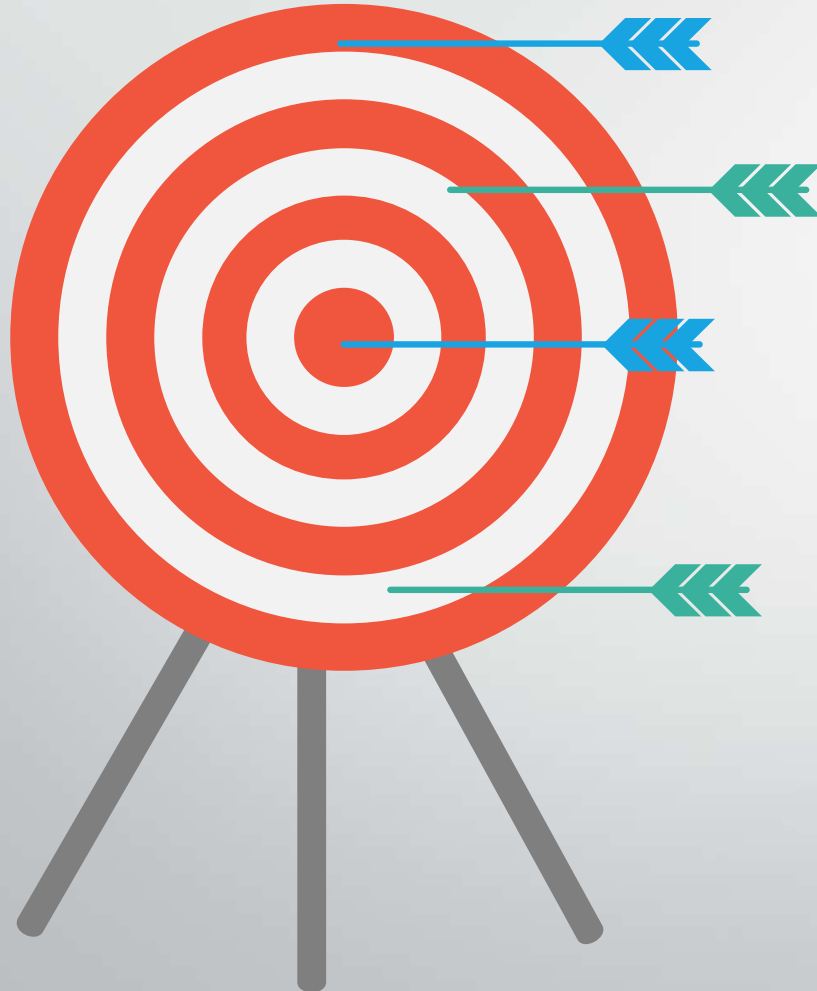
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Conflict of Interest

- Gobburu is a co-founder of Puma-AI Inc., which commercializes Pumas and Lyv software. www.pumas.ai
- Gobburu is a founder is Vivpro Corp., which commercializes R&D Intelligence software (RIA). www.vivpro.ai



Key Messages



Lack of generic products is a national concern

Patients' lives depend on generic products

Barrier to entry for LAI is high

Conventional methods fail to live to the spirit of Generic Rule

Modern methods can accelerate generic availability

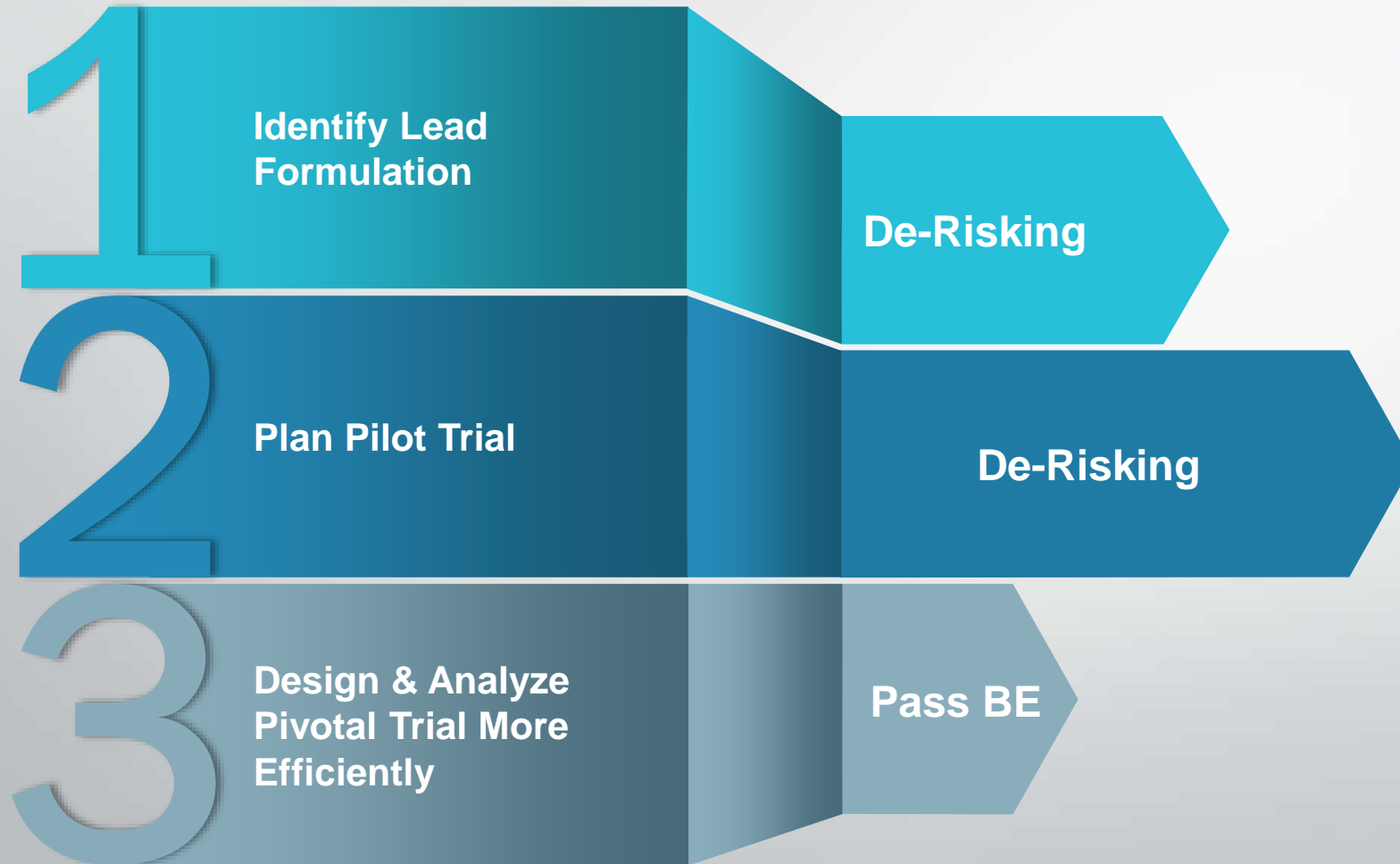
Innovative & advanced methods are available; routinely used in drug development

Scientific and regulatory consensus is needed

FDA is in a unique position to lead policy innovation

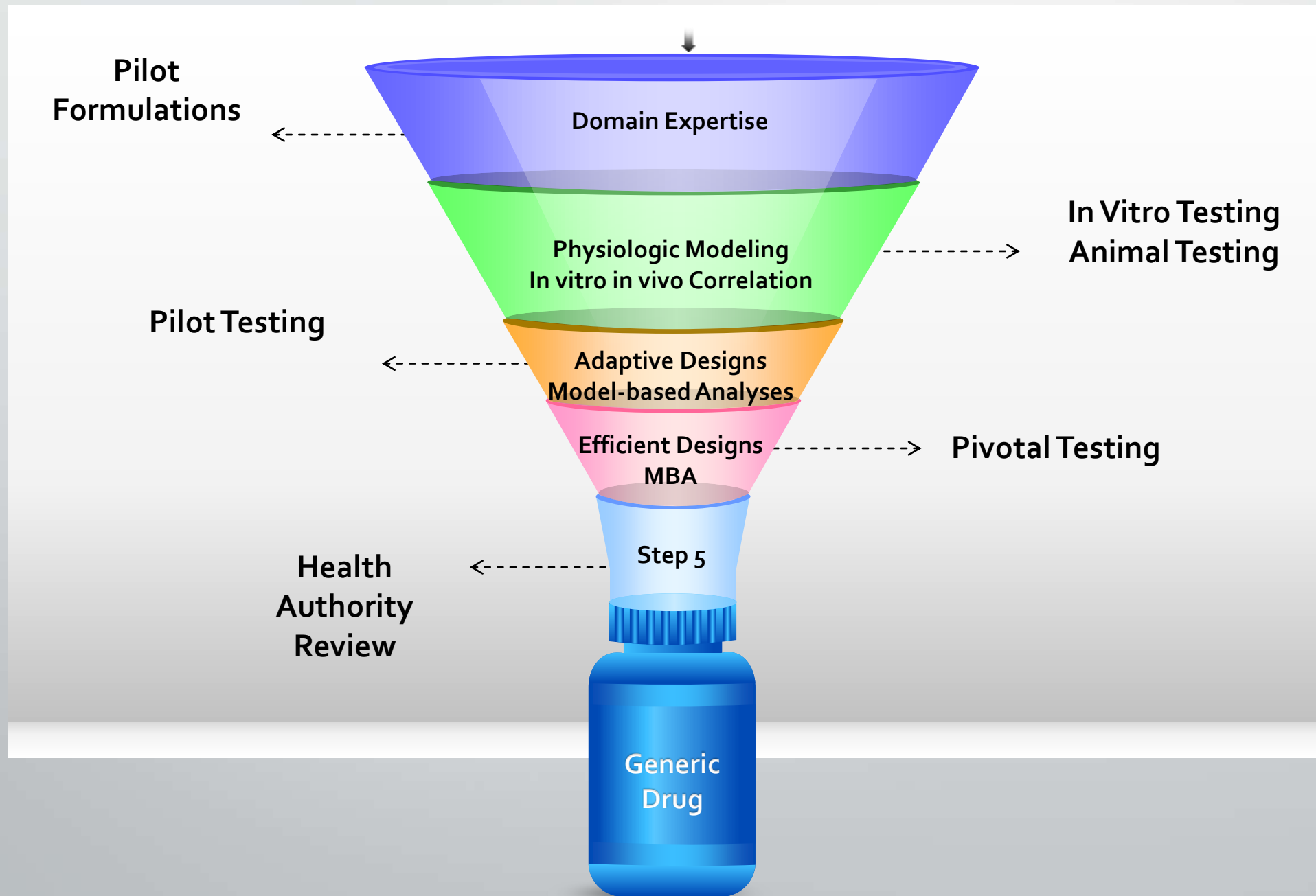


Modern methods can accelerate generic approvals





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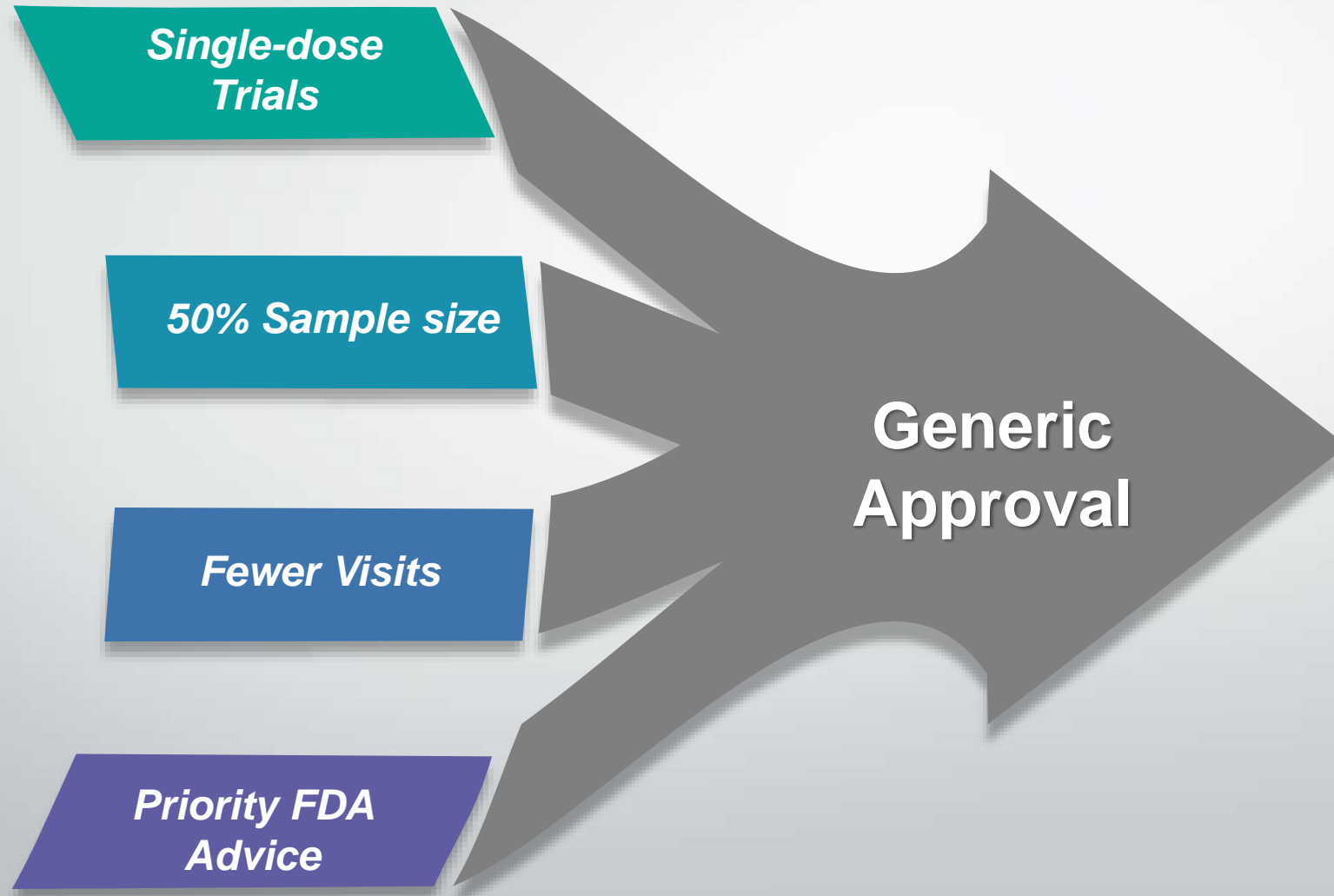
Generating Model Integrated Evidence for Generic Drug Development and Assessment

Liang Zhao¹, Myong-Jin Kim¹, Lei Zhang² and Robert Lionberger²

Quantitative methods and modeling (QMM) covers a broad spectrum of tool sets, of which physiologically based models and quantitative clinical pharmacology are most critical for generic drugs. QMM has been increasingly applied by the US Food and Drug Administration (FDA) to facilitating generic drug development and review, and has played a critical role in the modernization of bioequivalence (BE) assessment, especially for locally acting drug products, complex products of other types, and modified-release solid oral dosage forms. QMM has aided the development of novel BE methods, *in vitro*-only BE approaches, and risk-based evaluations. The future of QMM is model integrated evidence or virtual BE studies that can potentially provide pivotal information for generic drug approval. In summary, QMM is indispensable in modernizing generic drug development, BE assessment, and regulatory decision makings. Regulatory examples demonstrate how QMM can be used in modernizing generic drug development, addressing challenges in BE assessment, and supporting regulatory decision making.

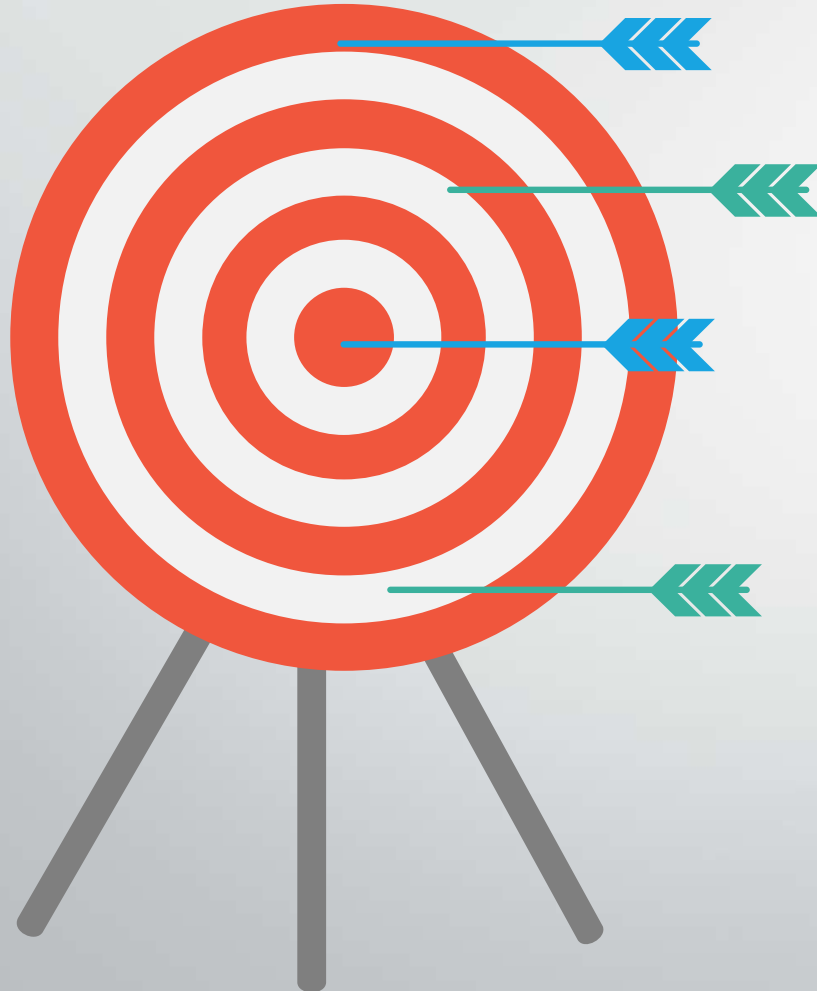


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