LIVE BIOTHERAPEUTIC PRODUCTS

UNIQUE QUALITY, MANUFACTURING AND NONCLINICAL CONSIDERATIONS FOR CLINICAL TRIAL ENTRY

#DYK
Did you know?

LBPs provide **safe and efficacious interventions** by modulating the human microbiome and its complex host interactions

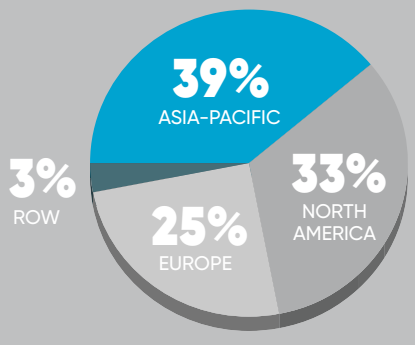
- Given their unique nature, the CMC requirements for LBPs require **strict adherence to regulatory guidelines** to ensure quality and safety
- Key CMC challenges in terms of manufacturing include **process upscaling, batch-to-batch variability** and **differences in the growth yields and strain characteristics**
- Safety evaluation of LBPs requires a **case-by-case approach**, to ensure the microorganism(s) contained within the LBP are adequately characterized

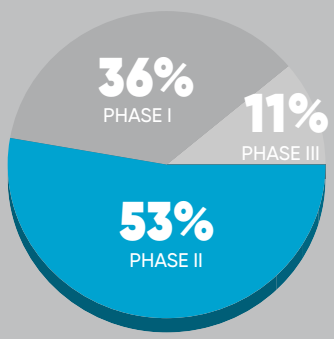
LIVE BIOTHERAPEUTIC PRODUCTS CLINICAL TRIALS

LBPs are **gaining momentum in drug development**, particularly for indications such as recurrent **CDI, inflammatory bowel disease (IBD), and cancer immunotherapy**

The **Asia-Pacific** region, followed by **North America** and **Europe** lead live biotherapeutic clinical trials

The majority of LBPs trials: 53% are in phase II, with 36% phase I, and 11% in phase III.





The **global market** for LBPs and microbiome CDMO is **expanding**

Developing and manufacturing LBPs requires a thorough understanding of **regulatory guidelines**

A **comprehensive nonclinical evaluation** encompassing efficacy and safety is required for success in the clinic