

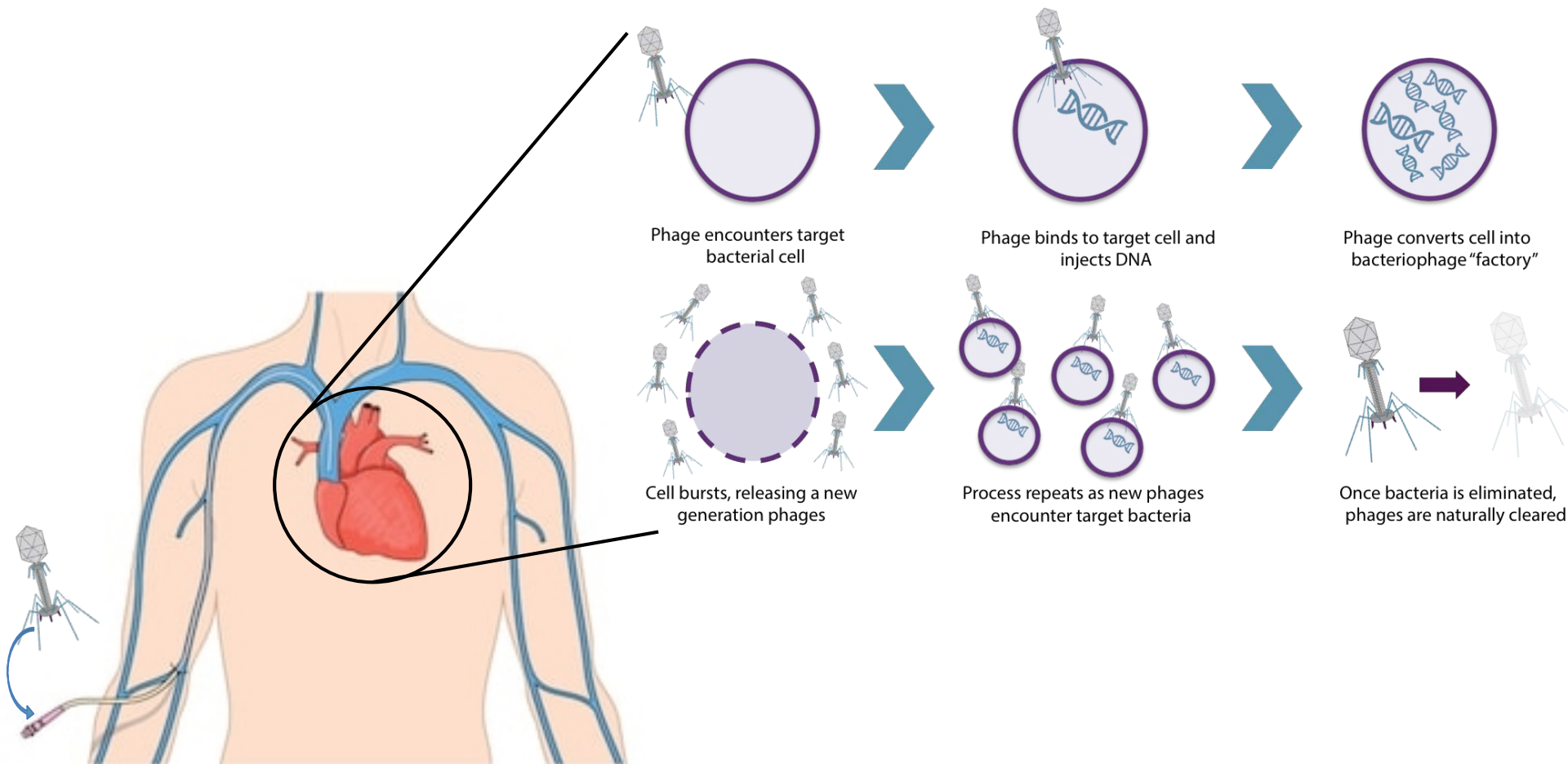


**Unique Challenges  
Transitioning from  
Preclinical to Clinical  
Development with  
Self-replicating  
Antibacterials**

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# Bacteriophages: Antibacterial Agent that Replicates at Site of Infection



# Unique Challenges for Drug Development

## Dosing

- Administered dose is different from actual dose
- Persistence in uninfected animals unrelated to persistence in presence of infection

## PK/PD

- As long as sufficient dose reaches site of infection and initiates replication, serum concentration is not predictive of pharmacologic effect

## Preclinical Toxicology

- Studies in uninfected animals may assess manufactured product but do not reflect phage exposure in infected animals

# What Does This Look Like?

		Small Molecules	Bacteriophages
In vitro	Sensitivity Testing	Yes	Yes (not MIC)
	PK/PD Models	Yes	Under investigation
In vivo	Proof-of-Concept Animal Models	Yes	Yes
	PK/PD Animal Models	Yes	Under investigation
	Toxicology	Yes	Limited
Clinical	Clinical Experience	Yes	Lots of single patients Few RCT