



The current landscape of biosimilar development

Trends in the development of biosimilars

Key analytical techniques used to demonstrate biosimilarity included:



The proportion of preclinical studies performed in the development of biosimilars:



Yes pred	- we conduct clinical studies 65 %	No – we do preclinic 2	n't conduct al studies 6 %	lt depends 9%	
The main challenges faced when developing biosimilars included:			The main challenges of gaining regulatory approval for a biosimilar included:		
Originator's le	gal obstruction	57 %	PK/PD studies		61%
Acquiring lots	of the originator product	57%	Reference product a	analysis	57%
Cost		52 %	Clinical studies	48 %	
Length of dev	elopment time	52 %	Manufacturing proc	cess challenges 48%	
Clinical studie	s 4 3	3%	Immunogenicity stu	udies 43%	
Preclinical stu Availability of	dies 30% critical reagents 26%				Approval

The proportion who follow a one assay versus a two assay approach for PK bioanalytical assays included:



Key documentation followed to characterize bioanalytical similarity for PK assays included:



The proportion who follow a one assay versus a two assay approach for ADA bioanalytical assays included:





Key documentation followed to characterize bioanalytical similarity for **ADA assays included:**

The guidance in the EMA immunogenicity guideline (2017)

The recommendations in the Civoli et al. (2020) White Paper

30%

91%



The future of biosimilar research

The cost of manufacturing biosimilars over the last 5 years has:



In the next 5 years, the percentage of approved biosimilars will:





Demographic of respondents



This infographic has been created as part of a Bioanalysis Zone feature in association with LabCorp.



