## TYPES OF BIOLOGICS



Monoclonal antibodies (mAbs)



Fusion proteins



Antibody-drug conjugates (ADCs)

## WORKFLOW OF BIOLOGICS DEVELOPMENT

Target Selection		CLINICAL DEVELOPMENT			
& Identification C	Cell Line Development	PHASE I	PHASE II	PHASE III	PHASE IV
a. Identification	Mark to the date of the other transfer of the	<b>Proof of Concept</b>			
Candidate Selection To	Animal Studies: ocicity, Efficacy, Safety	Safety	Safety	Safety	
3-400-6-20		GMP Production	Efficacy	Efficacy	
8.1	Pharmacokinetic (PK) Pharmacodynamic (PD)	Stability Studies	PK	Full GMP Production	
Early System Biology Studies	Formulation Development	Product Characterization	Scale-up	Quality Assurance	COMMERCIAL
Biomarker Identification	Stability Studies	PK & PD in Healthy Humans	Stability Studies	Quality Control	
Preclinical Testing	Product Characterization	Method Validation	Dose Titration	Stability Studies	
				Product Release Testing	
Cell-Based Assays: Early Toxicity, Efficacy, Safety	Process Characterization	IN	ID	Process Validation & Characterization	

10-12 YEARS

**20-25 YEARS** 

# **Biologics Development**

L Darling-Hammond



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