

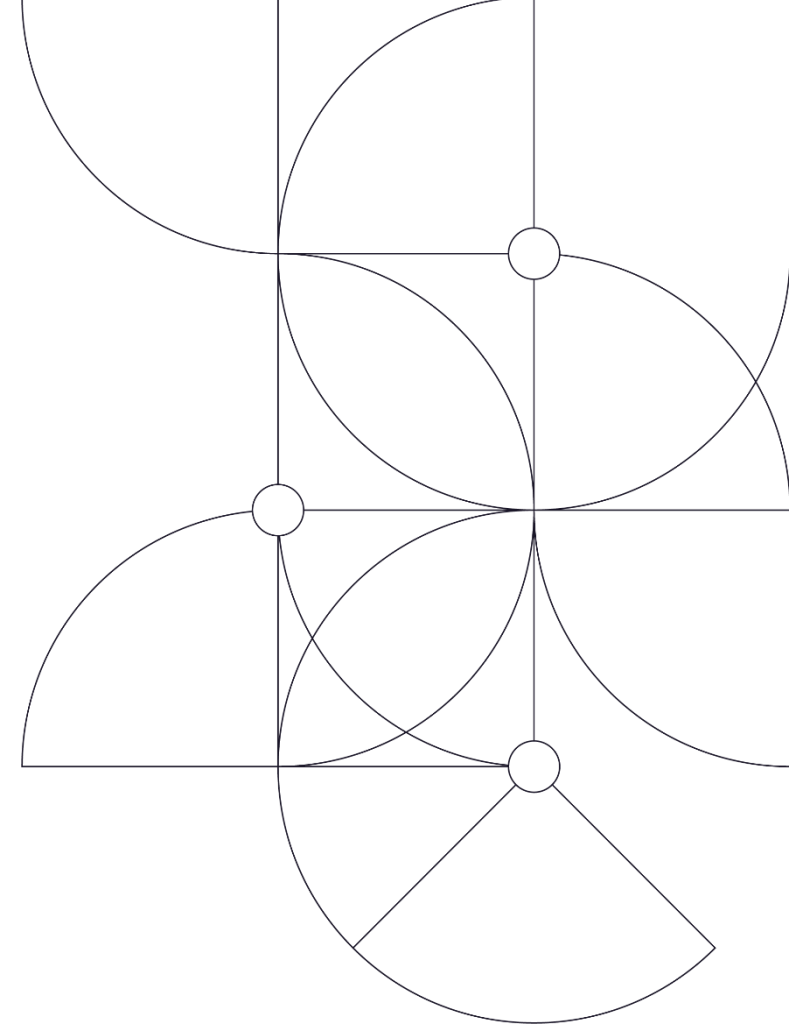


Clinical Trial Annotation and Labelling *ZS Proposal*

Prepared for Amgen
June 7, 2022

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Total cost of the project is estimated to be \$65K for an ~8-week or ~13- week engagement

Scope:

Annotate and label features of interest from clinical trials based on trial eligibility criteria sourced from Cortellis/AACT/Trialtrove

Item	Fees in USD
ZS Professional Fees	\$65K

# of Resources	Estimated timeline
With 1 Associate with 0.25 AC	13 weeks
With 2 Associates with 0.5 AC	7.5 weeks

or

Assumptions:

- Estimate based on **2,851** total industry sponsored trials that started in the last 5 years (1st Jan 2017- 7th June 2022) corresponding to four of Amgen’s prioritized indications (Atopic Dermatitis, Prostate Cancer, Obesity, Colorectal Cancer). We have considered all the trials irrespective of status and trial type (terminated/ suspended/ observation trials). This can be adjusted further based on feedback from Amgen.
- Inclusion and Exclusion criteria details from individual trials will be parsed out as per the template listed in the next slide.

Illustrative format of parsed out clinical trial criteria details

For Atopic Dermatitis:

S. No.	Disease Indication	NCT ID	Sponsor	Trial I.C	Age	Tumor Stage	Combined Gleason score	PSA	Testosterone	DISF-M-II score	FACIT-F score
1	Prostate Cancer	NCT02499497	Dana-Farber Cancer Institute (Non-Amgen)	Age 19 years of age or older	≥19 years						
				Stage pathological tumor-2 (pT2) N0, M0 lesions (If American Joint Committee on Cancer (AJCC) staging is not available in medical records, the investigators will infer the staging based on extensive review of the pathology report)		pT2, N0, M0					
				Combined Gleason score < 7 (3+4)			< 7 (3+4)				
				Preoperative prostate-specific antigen (PSA)<10 ng/ml				Preoperative: <10 ng/ml PSA: <0.1 ng/mL			
				Serum testosterone, measured by Liquid chromatography-tandem mass spectrometry (LC-MS/MS), <300 mg/dL and/or free testosterone by equilibrium dialysis <60 pg/mL.					Serum testosterone: <300 mg/DI Free testosterone: <60 pg/mL		
				Derogatis Index of Sexual Function Male II (DISF-M-II) score ≤20, fatigue (FACIT-F score <30), or physical dysfunction (self-reported difficulty in walking a 1/4 mile or climbing two flights of stairs, short physical performance battery score 4 to 9).						≤20	<30

For Prostate Cancer:

S. No.	Disease Indication	NCT ID	Sponsor	Trial I.C	Age	BMI	AD affecting BSA	EASI score
1	Atopic Dermatitis	NCT00757042	Amgen	Subjects must be aged between 18 and 45 years, inclusive (Part A only)	18-45 years			
				Healthy subjects must have a body mass index (BMI) between 18 to 32 kg/m2		18-32 kg/m2		
				Subject must have active AD affecting ≥10% body surface area; EASI score ≥15, aged between 18 and 60 years, inclusive and BMI between 18 and 35 kg/m2	18-60 years	18-35 kg/m2	≥10% BSA	≥15



Thank you!

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