Standard Review Process for Clinical Trial (IND) Applications

(45 calendar days)

Hospital, Sponsor, CRO

TFDA

Integrated Medicinal Products Review Office (iMPRO)

Administrative Section	Technical Section				
	CMC	Pharm/Tox	PK/PD	Clinical	Statistics

Assessment Report

IRB

Consult with AC experts if needed

Ethnic concern, Complex trial design, etc.

Advisory Committee

TFDA decision

Hospital, Sponsor, CRO

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食 品 藥 物 管 理 署
FDA Food and Drug Administration