Expanded Access Application Quick Guidance for Drugs & Biologics

Does my patient fit EA Criteria?

My patient(s) has a serious **or** immediately life-threatening disease **or** condition with no comparable alternative therapy to diagnose, monitor, or treat disease or condition

No

Yes

Potential patient benefit justifies potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated

No

Yes

Will it interfere with initiation /conduct/ completion of clinical investigations that could support marketing approval of expanded access use or otherwise compromise the potential development of the expanded access use.

Yes

No

Your patient (s) fits Expanded Access Criteria according to FDA regulations

Consultation

Schedule a free one-on-one consultation to get started with your EAP application to FDA today!

EAP mabye not eligible for your circumstances, contact RSO

Expanded Access Programs

What?	Why?	Types?	How?
Expanded Access (EA) is a program in which the FDA allows a qualified physician to access investigational medical products to treat patient(s) who has a serious Or immediate life-threatening disease or condition, have exhausted standard of care therapies and be ineligible for a clinical trial	Required by FDA Regulation 21 CFR 300 *Failure to comply may result in termination of IND/IDE, Warning Letters, Disqualifications/ Restrictions/ Debarments (posted on FDA website), Criminal prosecutions, prison, fines.	Single Patient (Emergency Use IND*)	Contact product manufacture to obtain their agreement to provide product & obtain LOA** → Call FDA to obtain verbal FDA authorization for expanded access use → Obtain informed consent → Administer treatment → Notify IRB (within 5 days of treatment initiation) → Submit written EIND application to FDA (within 15 days) → Close Emergency Use IND with FDA
		Single Patient (Non Emergency Use IND*)	Submit application to FDA (Form 3926, CV, LOA) → Obtain FDA authorization Obtain IND# → Obtain IRB Chair Concurrence Submit FormU1, ICF, Form 3926, IND# → Obtain informed consent → Administer treatment → Submit follow up documents to FDA & IRB (Annual Report, modification) → Close Expanded Access IND with FDA & IRB
		Intermediate-size patient population	Contact Regulatory Support Office Book a one-on-one consultation today! → Prepare EA Application → Submit EA Application to FDA → Submit EA to IRB (Requires Convened IRB Review) → Obtain informed consent after IRB/ FDA approval → Administer treatment to patient(s) → Close IND with FDA & IRB
		Large patient population	

*If this is an emergency situation and there is no time to obtain IRB approval, treat your patient to prevent immediate hazard (i.e. death)

**Letter of Authorization (LOA): Statement from the IND/IDE product's manufacturer for the right of reference to the information contained in their existing IND/IDE application

At a GLANCE

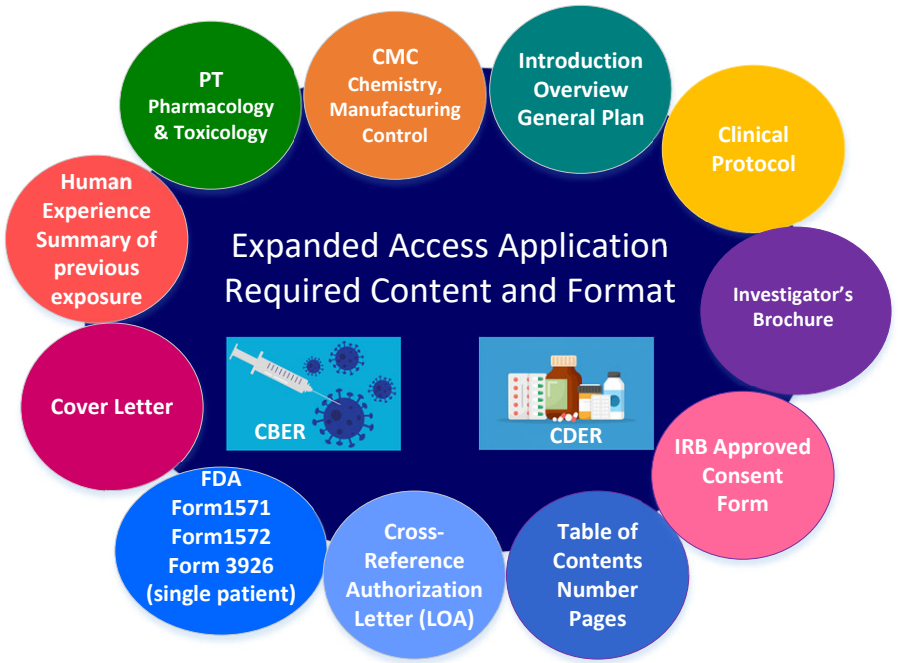
Use EA Application Template

FDA Review Phase
30 days for Response for non-emergency EA

Sponsor will be notified the date FDA receives original application

Possible Responses
Approved
Approved with condition
Staged approval
Disapproved

Sponsor of an existing IND or licensed physician must include following information in the non-emergency EA Application to FDA



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