



Comment from Association of Clinical Research Organizations (ACRO)

This is a Comment on the **Food and Drug Administration (FDA) Notice: [Expansion Cohorts: Use in First-In-Human Clinical Trials To Expedite Development of Oncology Drugs and Biologics; Draft Guidance for Industry; Availability](#)**

For related information, [Open Docket Folder](#) 

ID: FDA-2018-D-2777-0009

Tracking Number: 1k2-95t5-v27y



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Date Posted:

Oct 9, 2018

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Submitter Information

Country:

United States

Submitter's Representative:

ACRO (Association of Clinical Research Organizations)

Category:

Association - D0003

Comment

October 5, 2018

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: ACRO Comment on
FDA Draft Guidance for industry: Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics

Dear Sir or Madam:

ACRO thanks the Agency for the opportunity to provide comment on this "Draft Guidance for industry: Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics."

ACRO has attached its comment here as a PDF document.

Please do not hesitate to contact ACRO if we can answer any questions at all or provide additional details.

Respectfully submitted,

Karen Noonan
Vice President, Global Regulatory Policy, ACRO

ATTACHMENT: ACRO comment (as a PDF document)

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Comment from Pfizer Inc

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Comment from AstraZeneca

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Submitter's Representative:

Caleb Briggs, PharmD

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


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C Comment from Regeneron Pharmaceuticals

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C Comment from IQ Consortium

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C Comment from GlaxoSmithKline (GSK)

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