

Approval Document of the Ethics Review Committee

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Approval No.: KY-2024-9-140-2

Item	Content
Official Title	Venetoclax-Azacitidine in Combination With Chidamide and CAG Versus Daunorubicin and Cytarabine in Fit Older Patients With Acute Myeloid Leukaemia: A Multicenter, Randomized, Controlled, Phase 3 Trial
Sponsor	The Fifth Medical Center of the Chinese PLA General Hospital
Research Department	Department of Hematology
Investigator	Dou Liping
Submitted Review Materials	1. Reexamination Application Form3. Case Report Form (Version No.: 1.1, Version Date: September 11, 2024)
Review Basis	The composition and working procedures of this Ethics Review Committee are in line with the GCP principles and relevant national regulations of China
Review Method	Expedited Review
Review Date	November 6, 2024
Voting Result	2 in favor, 0 in favor with necessary revisions, 0 against

Opinions of the Ethics Review Committee

After review, the Ethics Review Committee deems that the above-mentioned materials meet the requirements of GCP and ethical norms, and approves the conduct of this research in the Department of Hematology. The valid period of this approval document is 12 months.

Supplementary Requirements

1. All SAEs and SUSARs occurring in our hospital, as well as the safety update reports during the research period, shall be submitted to this Ethics Review Committee in a timely manner.
2. If there is a change of the principal investigator or any modification to the research protocol, informed consent form, recruitment materials and other documents during the research process, the revised content can only be implemented after being reviewed and approved by this Ethics Review Committee.
3. Submit the annual/regular follow-up review report in a timely manner in accordance with the valid period of the approval document approved in the initial review.
4. Submit the non-compliance and protocol deviation report in a timely manner when a protocol deviation occurs.
5. Submit the research suspension or early termination report in a timely manner if the research needs to be suspended or terminated in advance.
6. Submit the research conclusion report upon the completion of the research.

Date of the document: 2024.11.18