General Workflow for Processing Application for Clinical Trial Certificate

Application for a Clinical Trial Certificate

- Is the trial medicine registered in Hong Kong?
  - Yes
  - Type B
    - The application will be discussed at the Registration Committee
    - Request the applicant to provide revised / outstanding document(s)
    - Are the documents found to be complete?
      - Yes
        - Issue the Clinical Trial Certificate (Listed Scheme)
      - No
        - Issue the Clinical Trial Certificate (Standard Scheme)
    - No
      - Type A
        - Process the application through the Listed Scheme
        - Documents to be submitted by applicant:
          1. Duly completed application form;
          2. Protocol;
          3. Sample of the patient consent form;
          4. Approval from the Ethics Committee;
          5. Other relevant documents if any.
  - No
    - Type C
      - Process the application through full document evaluation
      - Documents to be submitted by applicant:
        1. Duly completed application form;
        2. Protocol;
        3. Sample of the patient consent form;
        4. Approval from the Ethics Committee;
        5. Investigator's brochure;
        6. Letter of intent & curriculum vitae of principal investigator;
        7. Relevant GMP certificate;
        8. Certificate of analysis; and
        9. Other relevant documents if any.
  - No
    - Is there any extensive data or clinical evidence for the trial medicine?
      - Yes
        - Type A
          - Process the application through the Listed Scheme
          - Documents to be submitted by applicant:
            1. Duly completed application form;
            2. Protocol;
            3. Sample of the patient consent form;
            4. Approval from the Ethics Committee; and
            5. Other relevant documents if any.
      - No
        - Type C
          - Process the application through full document evaluation
          - Documents to be submitted by applicant:
            1. Duly completed application form;
            2. Protocol;
            3. Sample of the patient consent form;
            4. Approval from the Ethics Committee;
            5. Investigator's brochure;
            6. Letter of intent & curriculum vitae of principal investigator;
            7. Relevant GMP certificate;
            8. Certificate of analysis; and
            9. Other relevant documents if any.
  - Yes
    - Is the trial commercially sponsored?
      - No
        - Type C
          - Process the application through full document evaluation
          - Documents to be submitted by applicant:
            1. Duly completed application form;
            2. Protocol;
            3. Sample of the patient consent form;
            4. Approval from the Ethics Committee;
            5. Investigator's brochure;
            6. Letter of intent & curriculum vitae of principal investigator;
            7. Relevant GMP certificate;
            8. Certificate of analysis; and
            9. Other relevant documents if any.
      - Yes
        - Does the Committee take the view that the application should be processed as Type A?
          - Yes
            - Type A
              - Process the application through the Listed Scheme
              - Documents to be submitted by applicant:
                1. Duly completed application form;
                2. Protocol;
                3. Sample of the patient consent form;
                4. Approval from the Ethics Committee; and
                5. Other relevant documents if any.
          - No
            - Type B
              - The application will be discussed at the Registration Committee
              - Request the applicant to provide revised / outstanding document(s)
              - Are the documents found to be complete?
                - Yes
                  - Issue the Clinical Trial Certificate (Standard Scheme)
                - No
                  - Request the applicant to provide revised / outstanding document(s)
                    - Are the documents found to be complete?
                      - Yes
                        - Issue the Clinical Trial Certificate (Listed Scheme)
                      - No
                        - Request the applicant to provide revised / outstanding document(s)