|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| MINISTRY OF HEALTH  **THE ADMINISTRATION OF SCIENCE, TECHNOLOGY AND TRAINING**    PROCESS OF  **RECEIVING AND HANDLING  SERIOUS ADVERD EVENT REPORT  IN CLINICAL TRIAL IN VIETNAM**  **Code: QT.KHCN.22**  **Revision: 01**  **Date of issuance: 14/02/2019**       |  |  |  |  | | --- | --- | --- | --- | | Responsibility | Prepared by | Reviewed by | Approved by | | Full name | Võ Thị Nhị Hà | Hoàng Hoa Sơn | Nguyễn Ngô Quang | | Position | Official | Vice Head of Division | Deputy Director  in charge | | Signature |  |  |  | | Date of signing | 11/02/2019 | 12/02/2019 | 14/02/2019 | |

**AMENDMENT RECORDS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Required amendment/supplement** | **Relevant Page/Section** | **Description of changes** | **Revision / Amendment No.** | **Date of issuance** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. **PURPOSE**

Describe the steps of the evaluation process registration dossiers clinical trials.

Describe the steps taken and the work related to the handling of serious adverse event reports in clinical trial studies in Vietnam is sent to ASTT.

1. **SCOPE**

Applying for reporting serious adverse events in clinical trials in Vietnam is sent to ASTT.

1. **REFERENCES**

Circular No. 29/2018/TT-BYT dated October 29, 2018 of the Minister of Health Regulations on clinical trial of drugs.

1. **RESPONSIBILITIES OF IMPLEMENTATION**

- Quality leadership, QMS Board is responsible for checking and ensuring that the provisions in this process are implemented and complied with.

- Leaders of units under the Department are responsible for coordinating, inspecting and ensuring that the provisions in this process are implemented and complied with.

1. **DEFINITIONS / TERMS AND ABBREVIATIONS**

**5.1. Define**

The serious adverse event (SAE) is an adverse event that can lead to one of the following situations on clinical trial participants:

a) Death;

b) Threatening life;

c) Must be hospitalized or prolong hospital stay;

d) Disability, permanent or serious disability;

e) Congenital anomalies or malformations for the fetus of the drug test participants;

e) The situation must have appropriate medical intervention to prevent or prevent one of the situations specified in points a, b, c, d, dd or other medical significance situations according to Researchers' comments at the study site.

**5.2. Abbreviation**

- SAE: Serious adverse event.

- ASTT: Administration of Science, Technology and Training - Ministry of Health.

- STM Division: Division of Science Technology Management.

- ADR: National Center for Drug Information and Monitoring of adverse reactions of drugs.

1. **CONTENT**

**6.1. Chart appraisal process product profile**

|  |  |  |  |
| --- | --- | --- | --- |
| Responsibility | **Sequence of implementation** | **Time** | **Reference** |
| Clinical research unit |  | 7 working days1 or 15 working days2 or 10 working days3 | 6.2.1 |
| ASTT | Review SAE report | 5 working days | 6.2.2 |
| Clinical research unit | Complete, re-submit procedure | 10 working days | 6.2.3 |
| ASTT | Check procedure | 5 working days | 6.2.4 |
| NEC | Evaluate SAE report | 20 working days | 6.2.5 |
| Clinical research unit | Complete, re-submit procedure | 10 working days | 6.2.6 |
| NEC | Evaluate re-submitted procedure | 5 working days | 6.2.7 |
| NEC | Check the research site | - | 6.2.8 |
| ASTT | Inspect GCP | - | 6.2.9 |
| ASTT |  | 5 working days | 6.2.10 |

1 For SAE which causes death or life-threatening

2 For SAE which does not cause death or life-threatening

3 For overseas SAE that leads to stop, suspend research, withdrawal of participants from the research or change the research protocol

* 1. **Describe the steps of the implementation process:**
     1. Submitting the procedure

Clinical trial unit will send directly or by post 01 set of procedure for registering clinical trials to Administration of Science, Technology and Training, Ministry of Health (ASTT) in accordance with Form 15.

* + 1. Checking procedures

Within 05 working days after receipt of the procedures, ASTT checks the validity of the procedures.

- In case of invalid procedures, there must be written notices and specific instructions for the unit to supplement the procedures until the procedures are valid.

- In case of valid procedure, ASTT shall send the procedure to NEC for evaluation, if necessary, ASTT can conduct an inspection for GCP compliance of the study.

* + 1. Completing and re-submitting the procedure as required by ASTT

Clinical trials unit are responsible for coordinating with ASTT to complete documents within a maximum of 10 days after receipt of the written notice.

* + 1. Checking the re-submitted procedure

Within 5 working days after receipt of the procedure, ASTT will re-check the validity of the procedure whether the procedure is complete and valid and send the procedure to NEC for evaluation.

* + 1. Evaluating procedures

Within 20 working days after receipt of procedure, NEC shall review, evaluate and if necessary, respond to individual SAE reports and inform of SAE in annual progress reports and overall report on the results of clinical trials and send the evaluation results to ASTT.

- In case the supplement and clarification of information are required, NEC shall notify to the clinical trial unit to complete the procedure.

- In case of necessity, NEC may supervise and inspect the investigator site.

- NEC gives advice to ASTT on timely instructing the clinical trial units, organizations and individuals with IMPs to ensure absolute safety for participants in a clinical trial.

* + 1. Completing and re-submitting the procedures as required by NEC

In case the procedure is satisfactory but needs correction and supplements, the clinical trials unit shall coordinate with NEC to complete the procedure within 10 days after receipt of the written notice.

* + 1. Evaluating re-submitted procedures

Within 05 working days after receipt of procedures, NEC shall evaluate the re-submitted procedure send it to ASTT for review and decision.

* + 1. Checking the investigator site

In case of necessity, NEC may inspect the investigator site.

* + 1. Inspecting GCP

In case of necessity, ASTT can conduct an inspection for GCP compliance of the study.

* + 1. Keeping records as archives

Within 05 working days from the date of final decision on the serious adverse events report, ASTT is responsible for collecting records and keeping records as archives as specified.

1. **DOSSIER**

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Composition profile** | **Place saving** | **Time saving** |
| 1 | Serious adverse events report | Division of Science Technology Management | 10 years |
| 2 | Records of inspection and supervision | Division of Science Technology Management | 01 year |
| 3 | Official letter | Division of Science Technology Management | 01year |

1. **APPENDIX**

1. BM.KHCN.22.01 - Serious adverse events report form.