5th DIA Clinical Operations and Monitoring Workshop

Clinical Operation Changes Clinical Trial

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KFC Hall | Ryogoku, Tokyo

Novel Action Checklist and Flowchart in Large Scale Disaster

Institution / Sponsor Efficiency Improvement Project (ISEI-PJ)

National Cerebral and Cardiovascular Center

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DIA

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Institution / Sponsor Efficiency Improvement Project (ISEI-PJ)

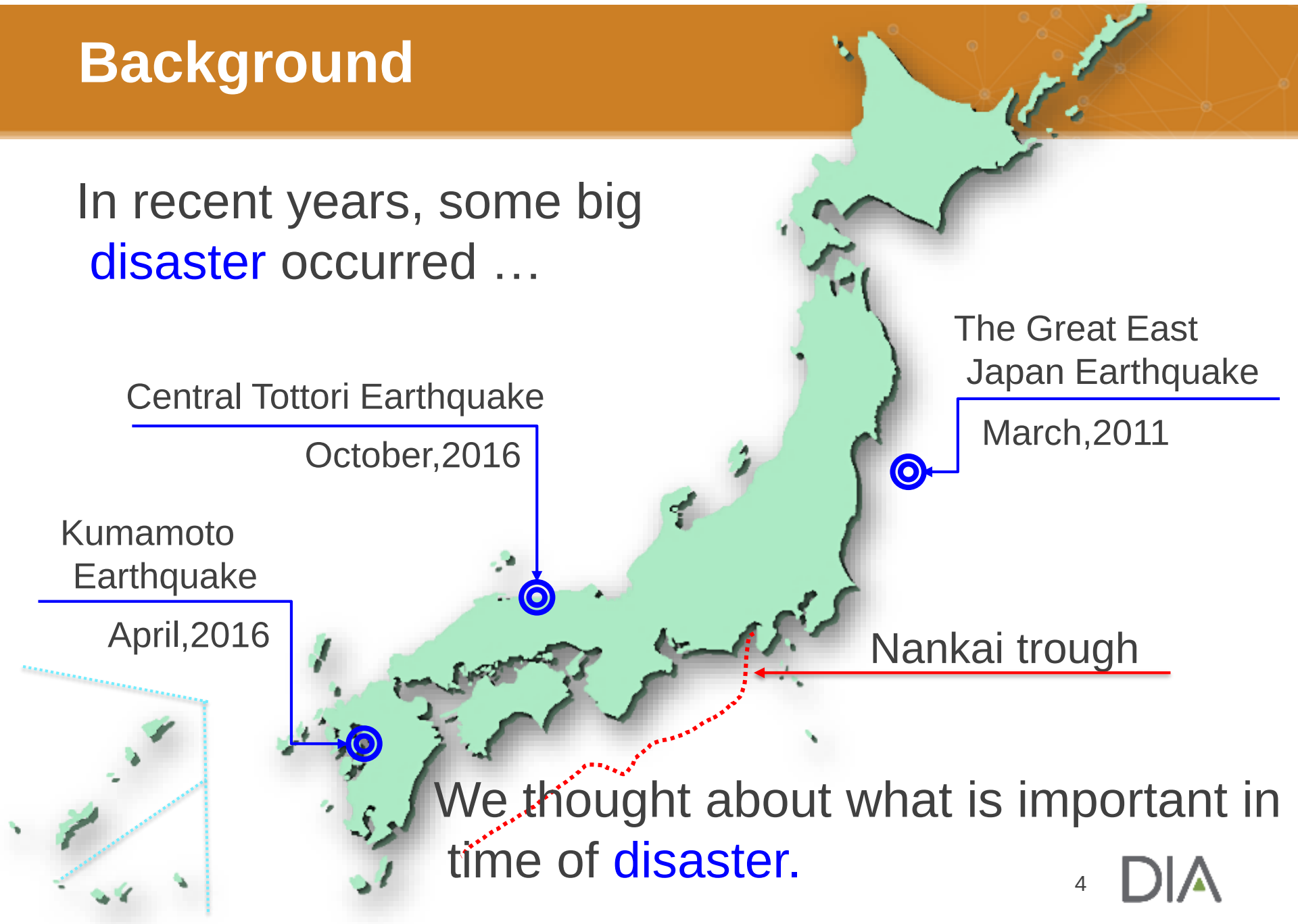
Osaka Clinical Research Collaborative Network

Osaka Pharmaceutical Manufacturers Association

- Fill the perception gap for clinical trial between medical institutions and sponsors
- Contribute to improve the efficiency of clinical trials
- Regular meeting : 2012～ monthly (4hr)

Background

In recent years, some big disaster occurred …



We thought about what is important in time of disaster.

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Earthquake !!

What shall we do ?
What can we do?

Preparation is essential !!

Objective

- Primary objective is safety confirmation of all the subjects when a large-scale disaster occurred.
- Voluntary action of medical staffs is required.
- Many medical institutions have prepared own manuals for disaster without considering of clinical trials.

⇒ We developed simply and practical flow chart and checklists involved in clinical trials as the part of the manuals for disaster.

Methods

Acute Phase Checklist (～1Week)

Flow chart for acute phase of disaster

Template for safety confirmation of subjects

Template for report to sponsor

→ Emergency Pack

Subacute Phase Checklist
(2-4Week)

Chronic Phase Checklist
(4Week～)

Normal Time Checklist

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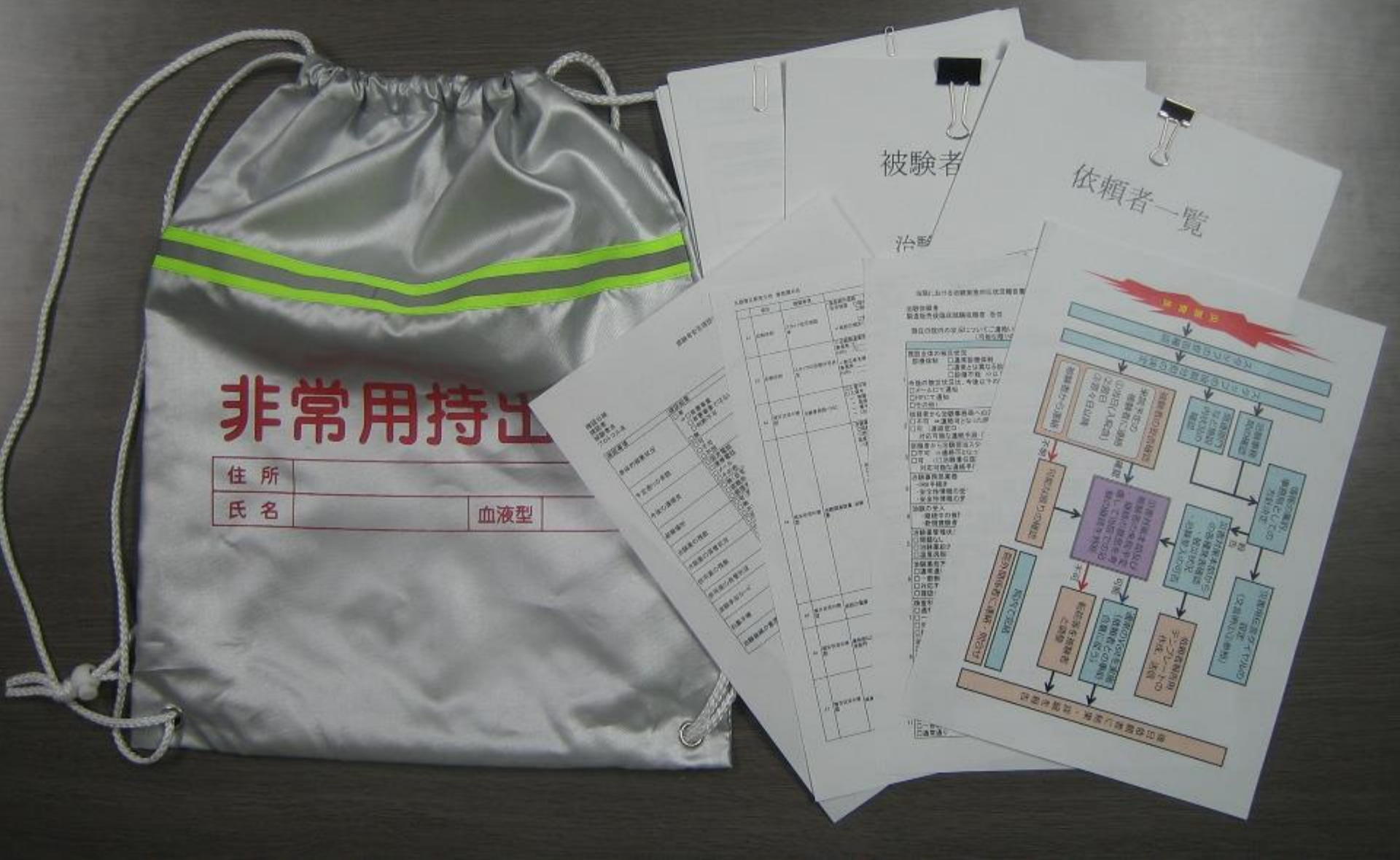
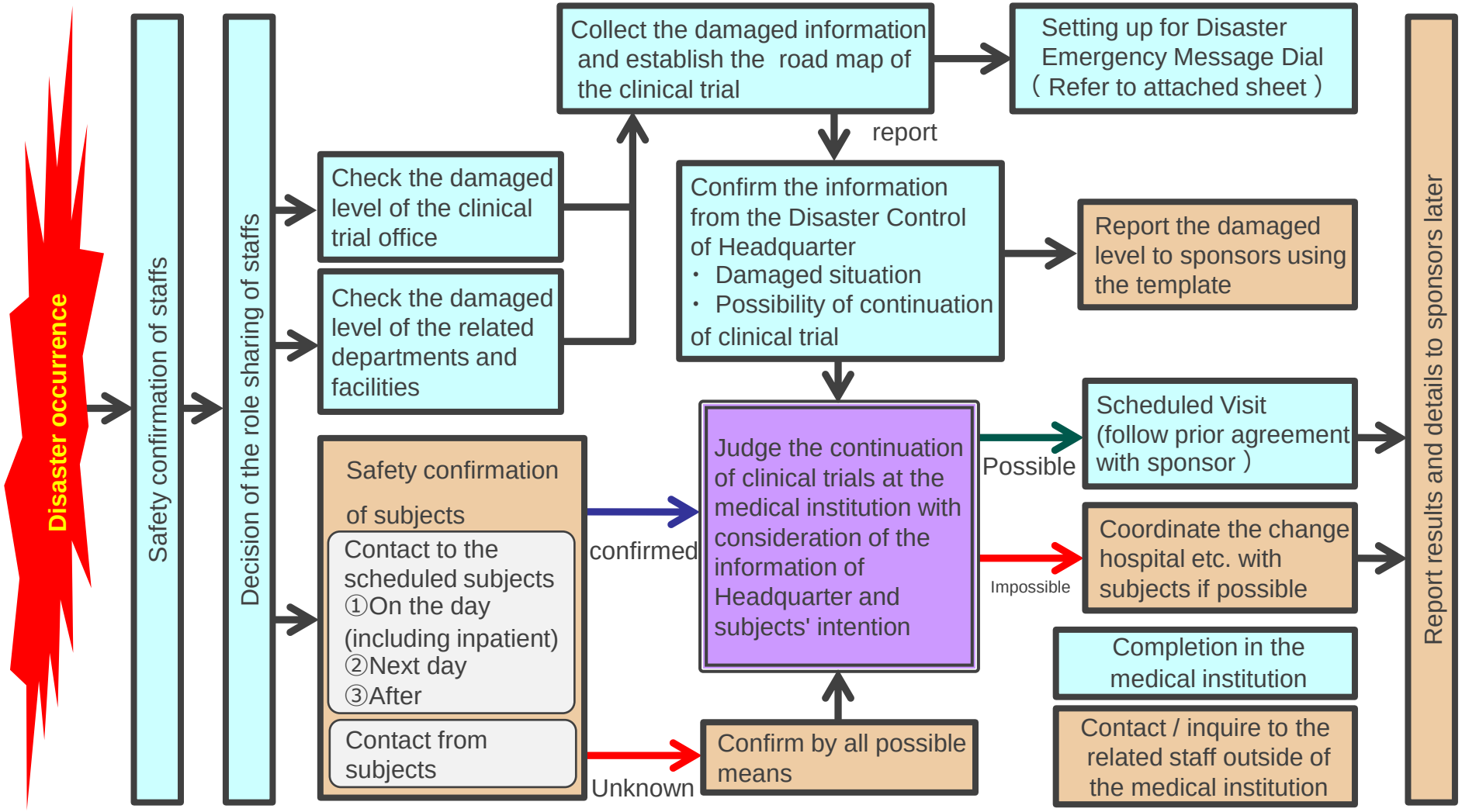
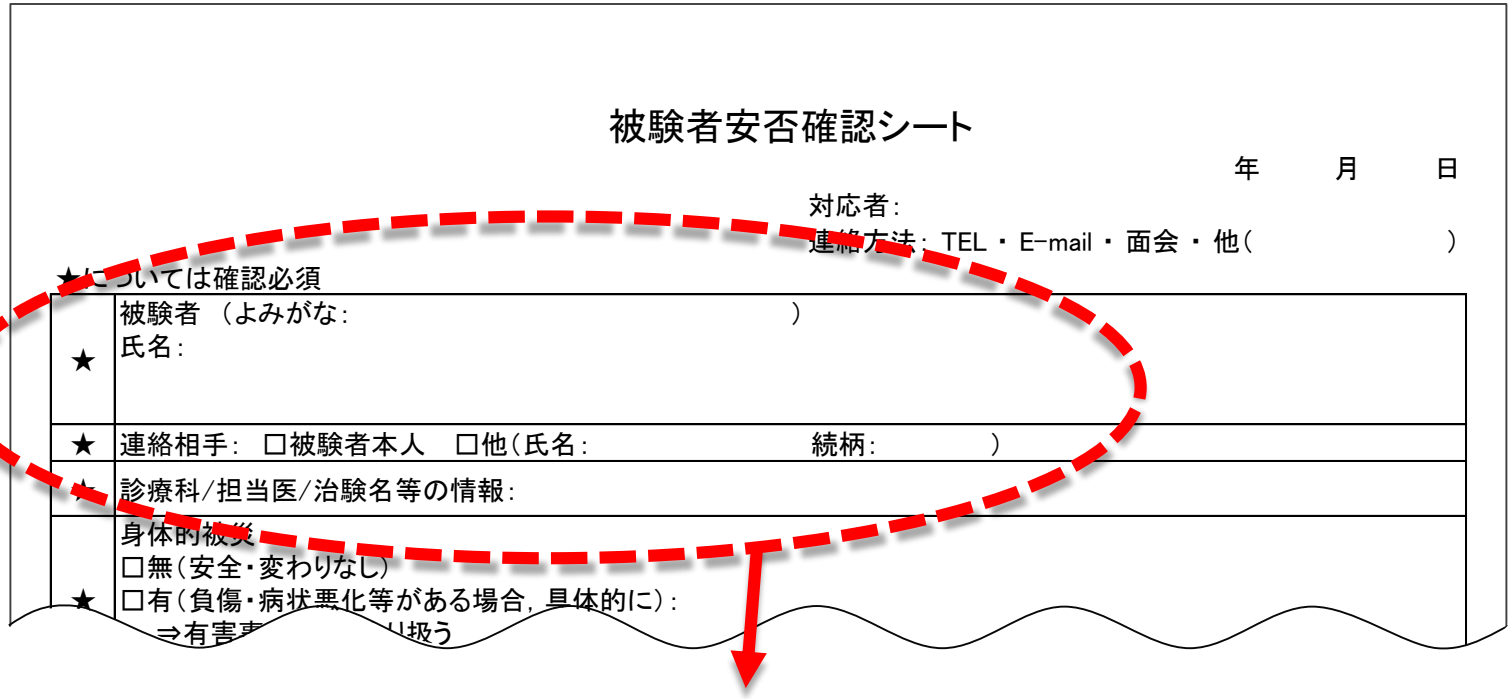
Emergency pack



Flow Chart for Acute Phase of Disaster



Template for Safety Confirmation of Subjects



被験者安否確認シート

年　　月　　日

対応者:

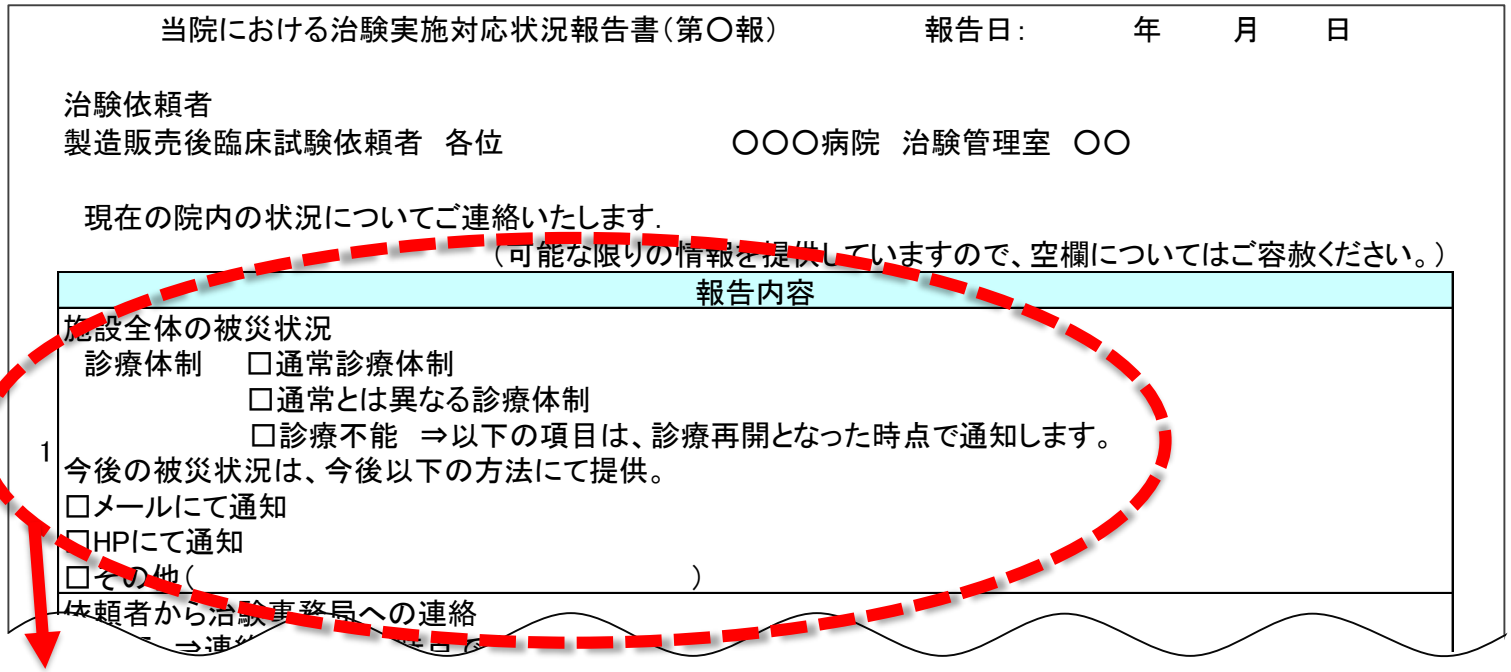
連絡方法: TEL・E-mail・面会・他(　　)

★については確認必須

★	被験者 (よみがな:　　) 氏名:
★	連絡相手: □被験者本人　□他(氏名:　　続柄:　　)
★	診療科/担当医/治験名等の情報:
★	身体的被災 □無(安全・変わりなし) □有(負傷・病状悪化等がある場合, 具体的に): ⇒有害事 い扱う

- Name of Subject (　kana　)
- Contact with ☐Subject　☐Other
- Medical department / Name of Investigator / Name of Clinical trial etc.

Template for Report to Sponsor



当院における治験実施対応状況報告書（第〇報）　　報告日：　　年　　月　　日

治験依頼者
製造販売後臨床試験依頼者　各位　　〇〇〇病院　治験管理室　〇〇

現在の院内の状況についてご連絡いたします.
（可能な限りの情報を提供していますので、空欄についてはご容赦ください。）

	報告内容
1	施設全体の被災状況 診療体制　☐通常診療体制 ☐通常とは異なる診療体制 ☐診療不能　⇒以下の項目は、診療再開となった時点で通知します。 今後の被災状況は、今後以下の方法にて提供。 ☐メールにて通知 ☐HPにて通知 ☐その他（　　）
	依頼者から治験事務局への連絡

Medical care in the medical institution is

☐ providing　　☐ partly providing

☐ not providing ⇒ We will notify when restarted.

Next time, we will contact by

☐ e-mail　　☐ Internet website　　☐ others

Acute Phase Checklist 1

Confirmation of damaged situation (Excerpt)

Power supply in the institution	・Power supply outage ☐yes ☐no (emergency power supply ☐yes ☐no) ・The issue which may be affected by the disaster in clinical trials ☐Electronic medical chart system ☐EDC ☐other( )
Management section of investigational drug (ex. pharmacy)	・Response to clinical studies ☐ as usual ☐ some limits ( ) ☐ Impossible/Power supply outage ☐yes ☐no ・Preparation /dispensing / inventory of pharmaceutical products →☐yes ☐some limits ☐no ・Limits on prescription and/or period of presctiption ☐yes ( ) ☐no

How to fill, notes and concerns are included with every item.

Acute Phase Checklist 2

Total *14* items

- System of Initial response (2 items)
- Confirmation of damaged situation (5 items)
- Safety confirmation of subjects (4 items)
- Information service (3 items)

Normal Time Checklist 1

Total *24* items

- In-hospital response system (10 items)
- Information management (3 items)
- Confirmation with sponsor (6 items)
- Communication system (3 items)
- IRB (2 items)

Normal Time Checklist 2

IRB(Excerpt)

Description in the SOP on the selection and contract with the external IRB	【Selection of the external IRB】 ◆The following items must be listed in the SOP. ・The director of the hospital (institution) may select appropriate IRB to commit the investigation and deliberation. →☐ yes ☐ no ・In case of request to 'the external IRB', the director shall confirm the latest documents of committee for proper judgement. →☐ yes → ☐IRB-SOP ☐ List of committee menbers ☐ Other necessary information ☐ no ・The documents requested to submmit for the deliberation in the selected external IRB ☐ The outline of medical institution ☐ Curriculum vitae of investigators ☐ Informed consent form ☐ The implementation status of the clinical trial (The documents submitted to annual continued investigation) ☐ Copy of the IRB minutes and the documents of the past deliberation (if possible) ☐ Results of the consultation to PMDA, and so on (if possible) 【Contract with the external IRB】 ◆The following item must be listed in the SOP In case of request to 'the external IRB', the director shall make a contract with the manager of selected external IRB according to 'the contract involving the request of investigation and deliberation in IRB' beforehand. →☐ yes ☐ no

How to fill, notes and concerns are included with every item.

Message Dial / Message Board

For Safety confirmation of subject

(example)
(limited in 100 letters in Japanese)

This is (Name), from(Hospital Name). I'd like to ask you about your current situation and to know how many clinical trial medicine you have. Please make a contact to us if you can.
Our telephone number is (Number). Available time is between (time) and (time).

Disaster
Emergency
Message Dial

Results

- We developed some documents which could be disaster manuals specialized in clinical trials.
  - Checklists by stage (Acute/Subacute/Chronic/Normal time)
  - Flow Chart for Acute phase of Disaster
  - Template for safety confirmation of subjects
  - Template for report to sponsor

- Useful in case of a Disaster in a medical institution.
- Useful as educational-training and self-check tools for all staffs who participate in clinical trials.

Discussion 1

To use these tools more effectively

- Customization
  - modify the content suitable for own institution

- Training
  - announce to every related staff,
    and train staffs continuously
- Maintenance
  - make appropriate update rules,
    and keep them available

Discussion 2

Future Investigation:

- Collaboration between sponsors and a medical institutions
- Security of personal information

  → ex.) Subjects, Staffs etc.
- Frequency of information update
- Information delivery system

  → ex.) Emergency Message Dial

How to get familiar with System

Conclusions

- It’s required to prepare disaster manuals specialized in clinical trials, but still not enough.
- We developed several tools specialized in clinical trials that can be disaster manuals.
- We reconfirmed the importance to make the preparation in normal time.
- We can utilize tools (Checklist, Flowchart etc.) effectively in time of disaster by appropriate Customization, Training and Maintenance.

Thank you for your attention!

http://www.dy-net.or.jp/chiken/

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Ask