Pharmaceutical Safety Reporting System on UMIN

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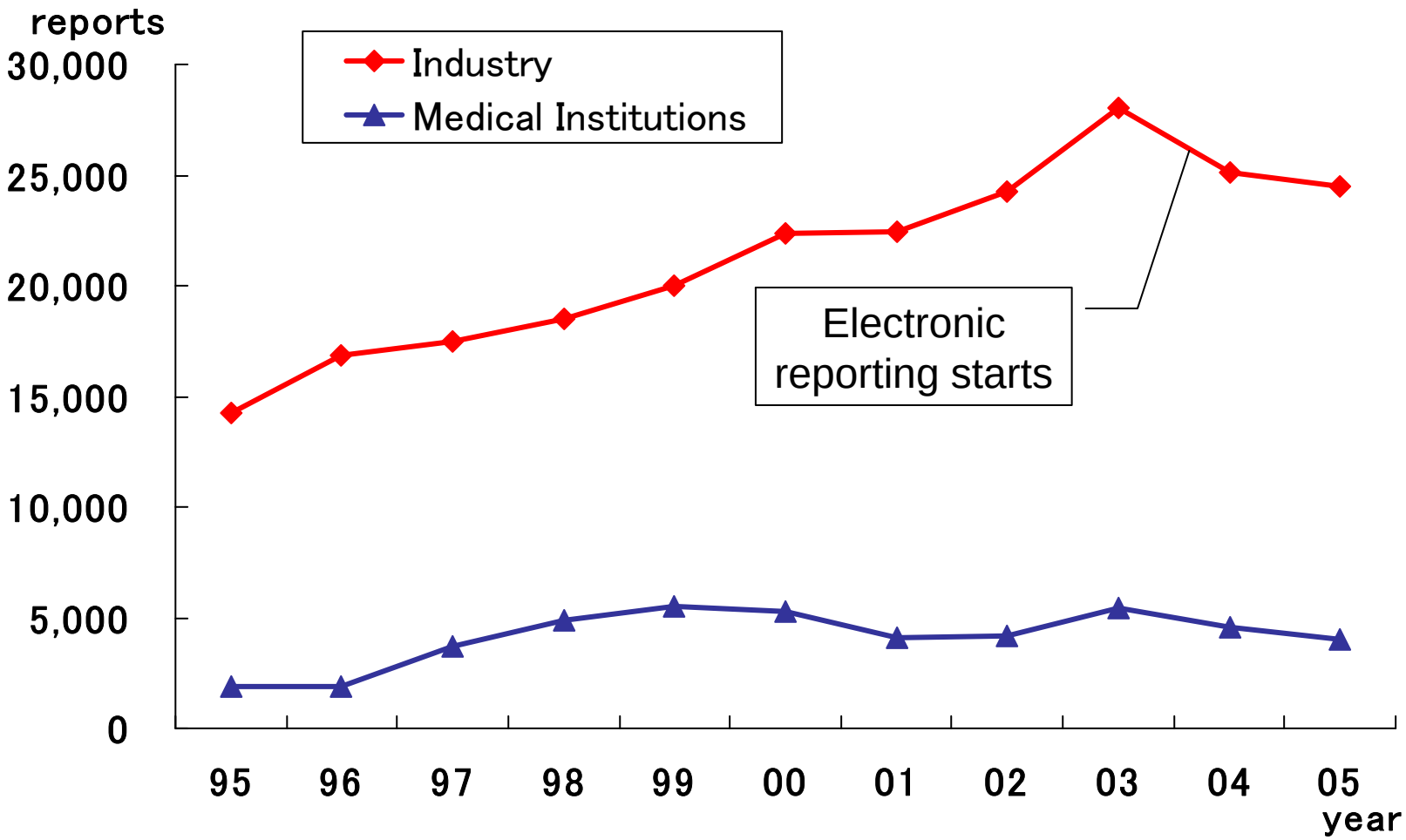
Introduction

- ICSRs of ADRs need to be transmitted nationally and Internationally.
- ICH E2b/M2 guidelines provide standardized data elements for transmission of ICSRs.
- Since Oct. 2003, electronic ICSRs have been accepted for industry by MHLW in Japan.
- However, most medical institutions still need to report ICSRs to the government as paper form.

ICSR : Individual Case Safety Report / ADR : Adverse Drug Reaction
ICH : International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

The number of pharmaceutical safety reports to the government in Japan



Purpose

- Facilitate pharmaceutical safety reporting from medical institutions to the government.
- Enhance early detection or prevention of ADRs.

A pharmaceutical safety reporting system should be developed on UMIN

UMIN : University hospital Medical Information Network in Japan

Methods 1 cont.

- Web system based on paper form.
- Each element reflects the ICH E2b/M2 guideline.
- Two-step creation
  - Form 1:minimum data (mandatory)
    - identifiable patient, identifiable reporter, reaction/event, and suspect drug.
  - Form 2:detail data (optional)
    - relevant medical history and concurrent conditions, and results of laboratory tests, etc.

Methods 2

- User class
  - Administrator
    - Representative of a medical institution
  - Responsible user
    - An administrator assigns a responsible user who has right to approve reports to be open or not.
  - Reporter
    - Health professional
- Repository status
  - Temporary saving
  - Waiting for approval

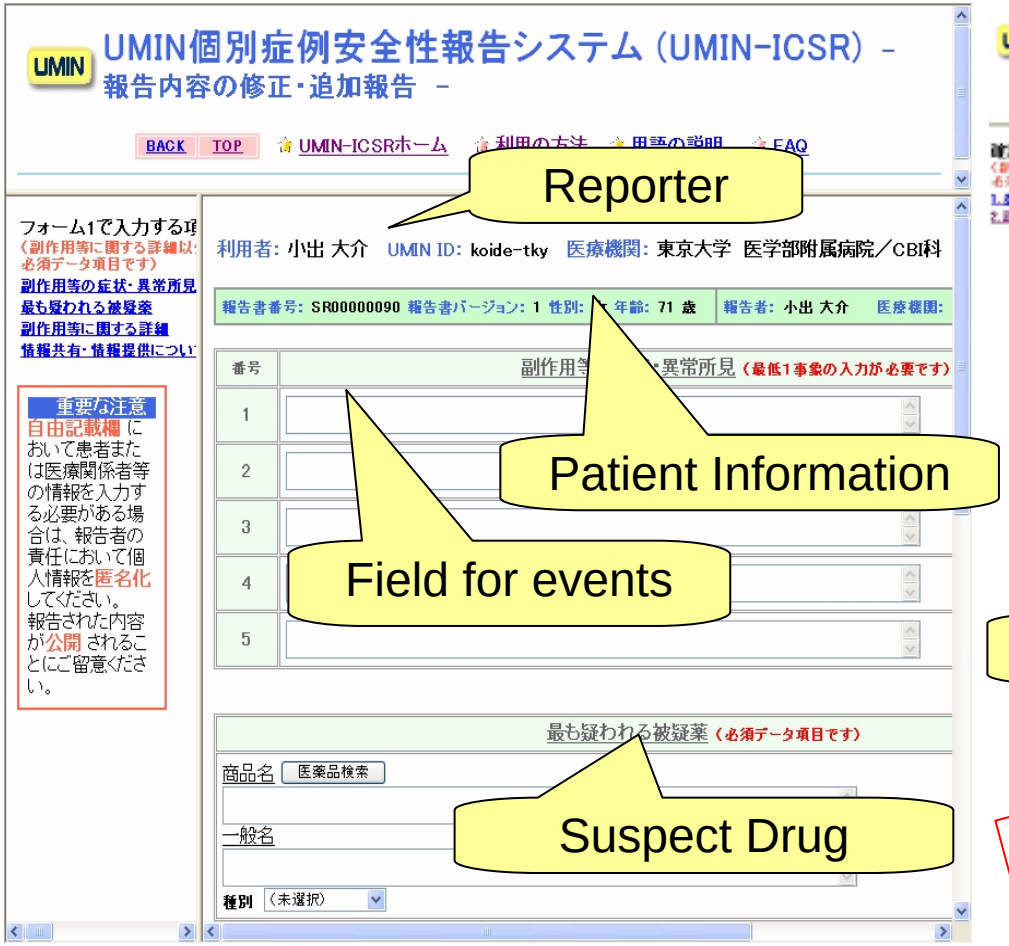
  } Reviewable only within the same institution.
  - Approved report— Open to outside a institution

Results 1 cont.

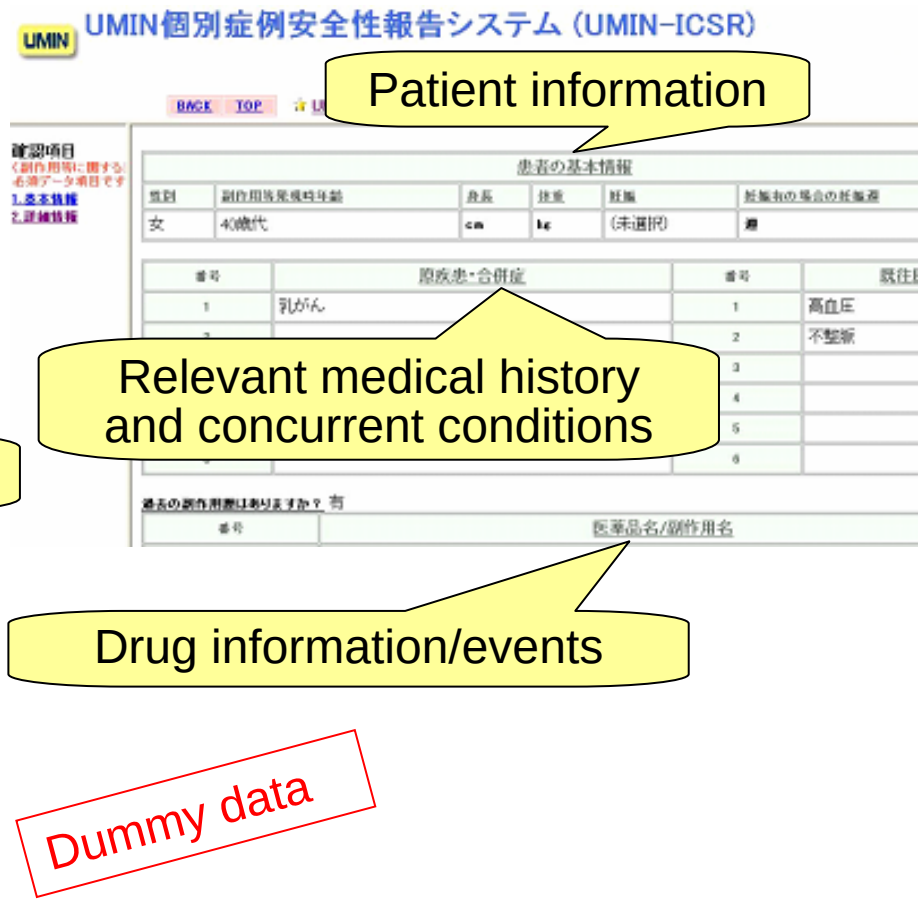
- The system has been developed successfully.
- The right figure is the top page of this system.

Results 2 cont.

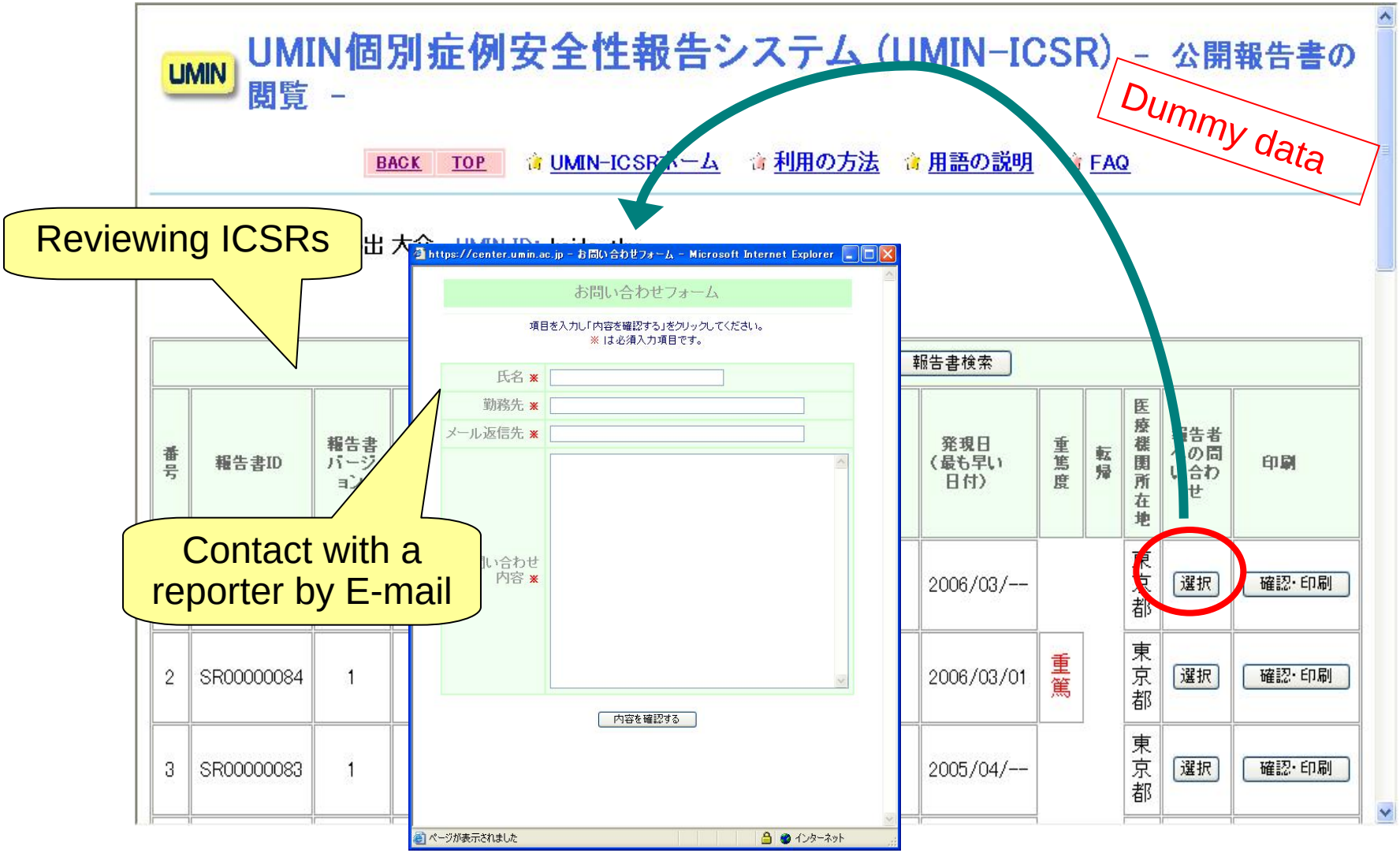
Form1



Form2



Results 3


UMIN個別症例安全性報告システム（UMIN-ICSR） － 公開報告書の閲覧 －
Dummy data
BACK TOP UMIN-ICSRホーム 利用の方法 用語の説明 FAQ
Reviewing ICSRs
Contact with a reporter by E-mail
https://center.umin.ac.jp - お問い合わせフォーム - Microsoft Internet Explorer
お問い合わせフォーム
項目を入力し「内容を確認する」をクリックしてください。
※ は必須入力項目です。
氏名 ※
勤務先 ※
メール返信先 ※
内容を確認する
報告書検索
番号
報告書ID
発現日（最も早い日付）
重篤度
転帰
医療機関所在地
印刷
2006/03/--
2006/03/01
2005/04/--
東京都
選択
確認・印刷
重篤
SR00000084
SR00000083

Discussion

- The two-step data entering prioritizes the information according to its importance.
  - This contributes user-friendly interface.
- Archiving reports by three statuses helps to count how many ADRs occurred inside/outside the institution.
  - The system enables easy management of reports.
- If lots of reports are stored, data mining can be applicable to detect signals of ADRs.

Conclusion

- The pharmaceutical safety reporting system has been developed successfully on UMIN.
- The major benefits of this system are;
  - user-friendly interface,
  - easy management of reports,
  - immediate sharing information on suspect ADRs among medical institutions.
- The feasibility test is necessary.

Ref., Ack & Contact details

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  - Kubota K, Koide D, Hirai T: Comparison of data mining methodologies using Japanese spontaneous reports. Pharmacoepidemiol Drug Saf. 13(6):387-94.2004.
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