

## Database for Drug Use-Results Survey

### What is the DURS Database?

The Drug Use-Result Survey is a regulated post-marketing surveillance system unique to Japan to collect information on treatment outcomes in real-world clinical practice. We have integrated data from drug use-results surveys provided by member companies and tried to construct a database that can be used for studies ensuring the safety of drugs. We have evaluated the efficient use of the database in collaboration with public institutions, and have reported the results at academic conferences and in publications.

We hope you can utilize the database for your studies to contribute to drug safety.

### Databases available

“Database for drug use-results survey of antihypertensives”

(21 antihypertensives, 143,509 cases)

“Database for drug use-results survey of oral antibacterial agents”

(7 oral antibacterial agents, 91,797 cases)

### How to use DURS

1. An applicant needs to contact ‘DB management of PE sub-committee’ so that the Terms of Services and the review process for applications can be provided.
2. You are prohibited from printing or copying the database or the results of any trial. Should you search or use the database, please consult with the person in charge of the DB management in the Pharmacoepidemiology study group of the RAD-AR Council to get an explanation of the terms of service.
3. To apply for reference service
4. Download the application form from the website for the steering committee on the RCJ website (only in Japanese). (<http://www.rad-ar.or.jp/member/index.html>)

Refer to the database at the RCJ office.

Software available for use

Access the database with a dedicated computer.

You can try statistical analyses with various statistical software (Microsoft Office 2007 Excel, JMP, R).

Bringing your own computer is allowed to try other statistical software (SAS etc.).

The trial data is now available on CD-ROM.

## Contents of Database for Drug Use-Results Surveys

The data is available in the following data formats for use in various applications.

CSV (.csv), MS-EXCEL (.xls), SAS dataset (V8 format)

Refer to the “*Report for Expansion of Database for Drug Use-Results Surveys of Antihypertensives*” and the “*Final Report for Construction of Database for Drug Use-Results Surveys of Oral Antibacterial Agents*” regarding the construction of the Database ([http://www.rad-ar.or.jp/01/05\\_database/05\\_database.html](http://www.rad-ar.or.jp/01/05_database/05_database.html)) (only in Japanese)

## Feature

- Data with high reliability used for reexamination requests.
- MedDRA/J, the current standard dictionary, is used for adverse reaction terms.
- Survey items are standardized among preparations.
- Causal relationship of collected adverse reactions is evaluated by doctors.
- Integrated data of drug use-results surveys (observational drug utilization studies in medical practice).

## Contents of the trial CD-ROM

- Randomized 1500 sample data items from the “Database for drug use-results survey of antihypertensives”
- Sample data items are the same as “Database for drug use-results survey of antihypertensives” but some of the data elements to identify the subject of the survey, prescribed antihypertensives prior to initiation of the subject and concomitant medications have been deleted.

Data table	Data title	Contents
Patient background	ptbg	Background of patients including age and gender, mechanism of antihypertensives <sup>1)</sup> , condition of administration of the drug
Antihypertensives before survey	p_drug	Code of antihypertensives before survey (upper 3 digits of drug name data file) <sup>2)</sup>
Group data for antihypertensives before survey	pdrug_class	Classification of drug efficacy of antihypertensives before survey
Concomitant disease	dcomp	Code of concomitant disease (upper 3 digits of MEDIS code of disease name) <sup>3)</sup>
Group data of concomitant disease	dis_class	Classification of concomitant disease
Allergy	allgy	With/without allergy (drugs, others)
Concomitant medication	co_drug	Code of concomitant medication (upper 3 digits of drug name data file) <sup>2)</sup> , day of starting/finishing administration
Group data on concomitant medication	co_d_class	Classification of mechanism of concomitant medication
Concomitant therapy	wthtr	With/without combination therapy (diet, exercise, others)
Blood pressure	bp	Day of observation, blood pressure, pulse
Data on routine blood pressure	bp_gp	Classified blood pressure and pulse measured at a certain period (day of starting administration, after 1 month of administration, etc.)

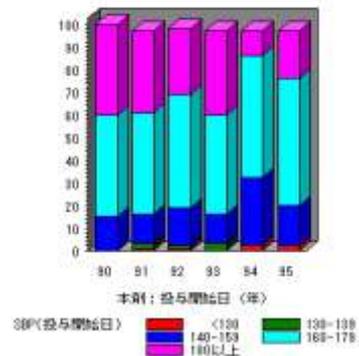
Adverse reaction	adr	Adverse events ( J-ART, MedDRA/J Ver.9.0), day of development, severity, measure, outcome, etc.
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- 1) Cannot classify the mechanism of antihypertensives (e.g. diuretics) with the trial CD-ROM. Cannot identify the survey products with the original database.
- 2) Codes of drugs for antihypertensives before the survey and concomitant medications are based on the drug code that is required by the regulatory authority for ADR reporting. Generic names (upper 7 digits of drug code) are used in the original data, however, it is restricted to classification of drug efficacy (upper 3 digits of drug code) on the trial data CD-ROM.
- 3) Codes of concomitant disease are based on MEDIS codes of disease names.

### Structure of sample data in the CD-ROM



Distribution of SBP (%)



sample data frame

### Publications

- ◆ Fujita, T. and Mayama, T., 2007. A database of anti-hypertensive drugs from Drug Use Investigations and its practical use example. *Journal of the Japan Statistical Society*. Japanese issue, 36 (2) pp.205-217
- ◆ Ishiguro, C., Fujita, T., Omori, T., Fujii, Y., Mayama, T. and Sato, T., 2008. Assessing the Effects of Non-steroidal Anti-inflammatory Drugs on Antihypertensive Drug Therapy Using Post-Marketing Surveillance Database. *Journal of Epidemiology*, 18(3), pp. 119.
- ◆ Fujita, T., Miura, Y. and Mayama, T., 2005. A pilot study to build a database on seven anti-hypertensive drugs. *Pharmacoepidemiology and drug safety*, 14(1), pp. 41-46.
- ◆ Yoshida, M., Matsumoto, T., Suzuki, T., Kitamura, S. and Mayama, T., 2008. Effect of concomitant treatment with a CYP3A4 inhibitor and a calcium channel blocker.

*Pharmacoepidemiology and drug safety*, 17(1), pp. 70-75.

Refer overleaf for details.

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*The RAD-DR (Risk/Benefit Assessment of Drugs-Analysis & Response) Council, Japan was founded in 1989 as a consortium by major R&D-oriented pharmaceutical companies in Japan to evaluate and verify risks and benefits of drugs scientifically. It is a not-for-profit organization promoting appropriate use of drugs and conducting a series of activities to educate and empower patients by showing the results of its studies.*

Member Companies Supporting RAD-AR Activities: 23 companies in alphabetical order

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