Translational Research Informatics Center

Foundation for Biomedical Research and Innovation

http://www.tri-kobe.org/

Translational Research Informatics Center (TRI)
provides comprehensive supports in every phase of clinical studies,
to improve prognoses for intractable human diseases.

TRI was founded by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and Kobe City, as the first academic data center and statistical analysis center for clinical studies in Japan. TRI is available for all medical researchers who conduct clinical studies by providing comprehensive support from research planning to data analysis.

TRI contributes to the improvement of public health through innovation of technology, consolidation of infrastructure, and creation of new science.

TRI history

- Oct. 2002 : Launched as a sister research department of the Institute of Biomedical Research and Innovation, and commissioned by the MEXT to engage in the " TR Infrastructure Construction Program". TRI began its activities in an office of the Kobe Chamber of Commerce and Industry Building.
- Jun. 2003 : Construction of the current TRI Building was completed. Operations were officially launched as TRI's Clinical Trial Operations Department on the building's 4th floor.
- Aug. 2004: Commissioned by MEXT to engage in the "Research Promotion for Innovative Therapies against Cancer".
- Apr. 2005 : The name was changed to the "TRI Research Project".
- Aug. 2007: Commissioned by MEXT to promote the "Coordination, Support and Training Program for Translational Research", and began supporting translational research centers throughout Japan.
- Apr. 2012 : Commissioned by MEXT to engage in the "Translational Research Network Program".
- Jun. 2012 : Adopted by the Ministry of Health, Labor and Welfare (MHLW) a project to develop global clinical research infrastructure in Japan.
- Apr. 2014 : Comissioned to promote the "Project of Translational and Clinical Research Core Centers".

Experts from various fields form a team to

Activity policy

Goal

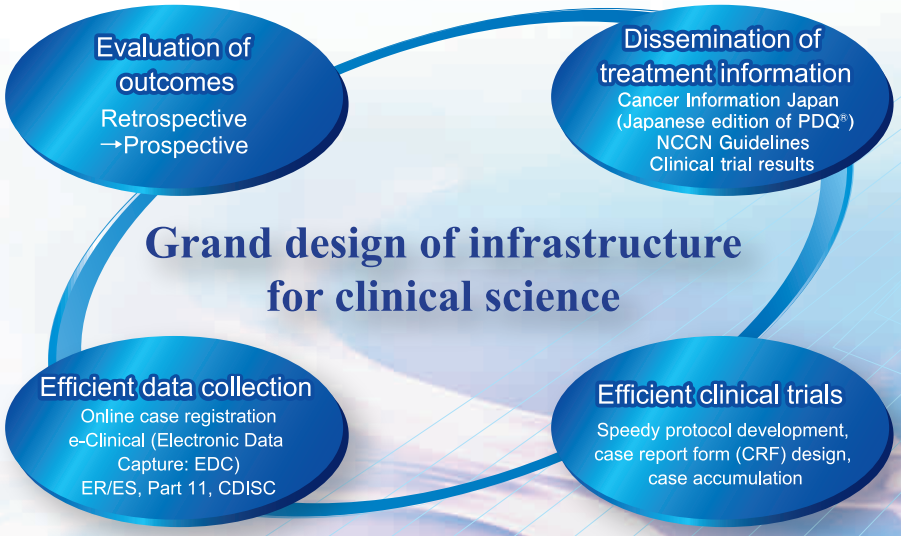
Enhance the therapeutic outcomes and improve the prognosis of intractable diseases such as cancer, heart disease, stroke, and Alzheimer's disease.

Mission

- Innovation in standard treatment
- Development of new diagnostic, therapeutic & preventive strategies

Approach

To reform the current standard treatment methods, Phase III studies will be successively conducted, and Phase I and II studies will be promoted to develop next-generation treatment methods. Concomitantly, systematic and exhaustive investigations of promising translational researches (TRs) will be carefully conducted to determine future potential, and plan and promote corresponding Phase I and II studies.

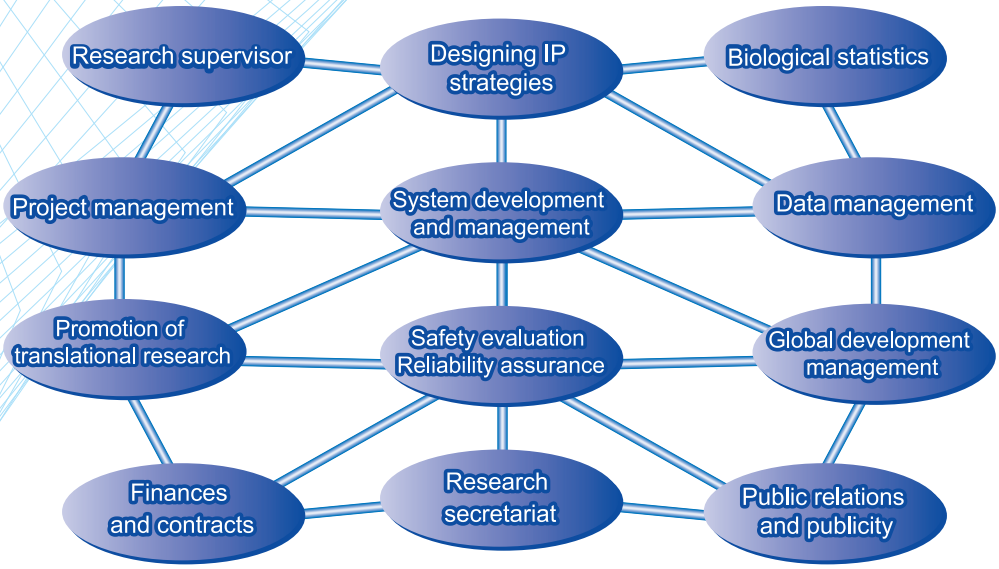


comprehensively assist research.

Operational setup

TRI ensures smooth startup and operation of clinical studies.

TRI has a whole set of professionals, including medical doctores, biostatisticians, project managers, data managers, system engineers, IP specialists, and financial/contract specialists to comprehensively promote and manage TRs and every type of clinical studies.



Expertise and strengths

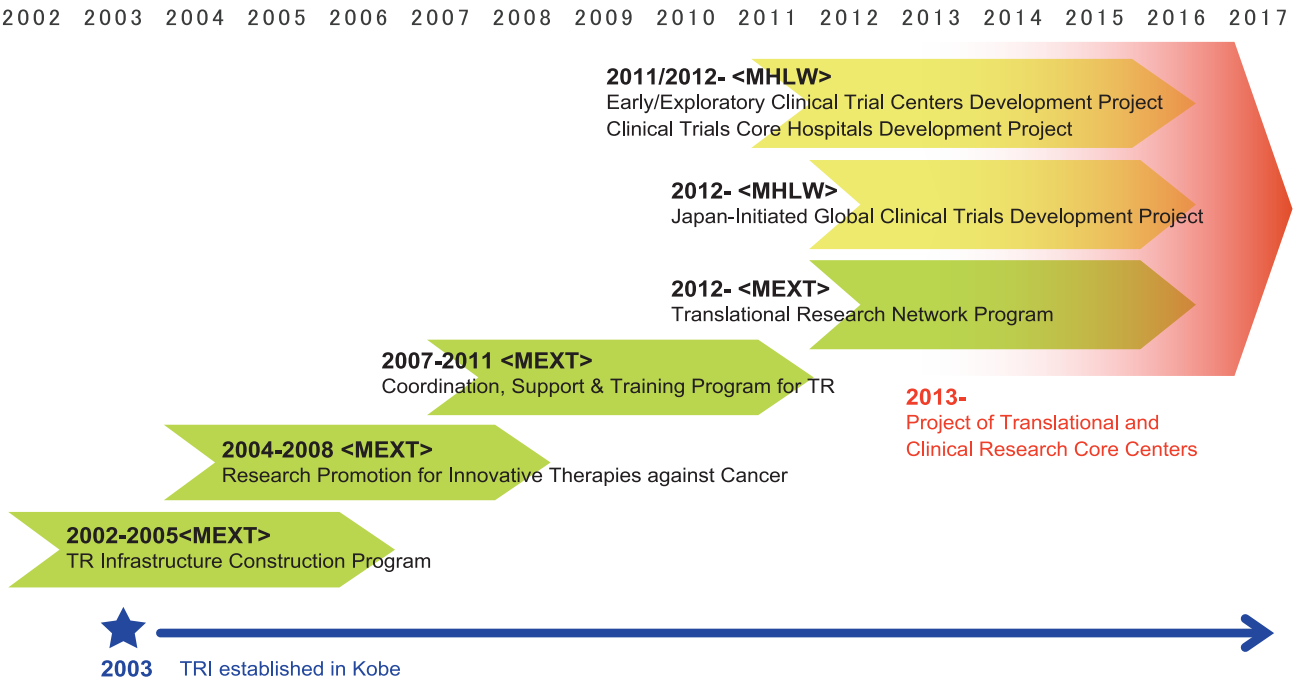
We have a wide range of strengths in supporting clinical study.

- Accumulation of expertise and experience with diverse projects commissioned by MEXT and MHLW
- Concentration of information as the support institution for TR centers in the “Translational Research Network Program” of MEXT
- Close collaborations with hospitals and research groups
- Opening of a consultation desk for clinical studies, and provision of relevant information
- Patent surveys and designing IP strategies
- Liaison and licensing with corporations
- Guarantee of independence from individuals/entities conducting clinical research
- Ability to develop protocols independently
- High-quality independently developed EDC system
- Rigorous data management system
- Various research management and promotion systems
- Adaptability of quality control levels
- Specimen storage systems that protect personal information
- Systems for preventing human and electronic invasions

1 R&D of novel medical technologies (TR)

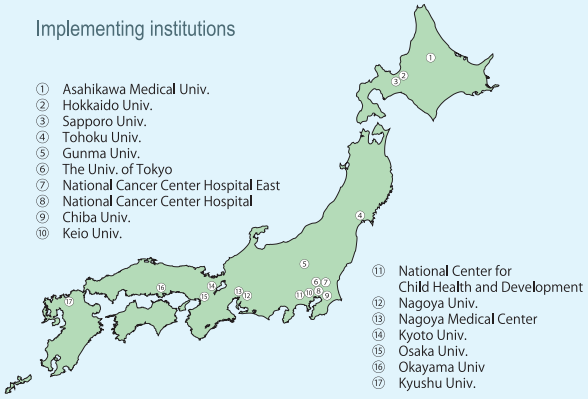
By engaging in multiple projects commissioned by Japanese government, we have been working to establish a foundation for supporting and promoting Japan's Translational Research (TR), with goals of strengthening academic R&D pipelines and forming networks between Academic Research Organizations (AROs).

History of creating medical innovations



2013- AMED "Project of Translational & Clinical Research Core Centers

In 2013, the "Project of Translational and Clinical Research Core Centers" started with integrating several national projects as them above.It aims to establish academic R&D pipelines in our country which continuously creates innovative medical drugs, devices and technology.
According to the launch of Japan Agency for Medical Research and Development (AMED) in 2015, the primary contractor was transferred to AMED, and now we support the participating centers in the project with AMED.
The development of infrastructure as ARO has almost reached perfection with each center's accumulated know-how on development and the established R&D pipelines.
Taking advantage of solid performance and effective network, TRI continues to provide its support to make the Japanese ARO pre-eminent in this evolving world.



Accomplishments of program (March 31, 2016)

IND submission to PMDA (investigator initiated)	102
IND submission to PMDA (sponsor initiated)	18
NDA to PMDA	25
Approved NDA	23
Applied as insurance medicine	12
License out to industry	65
Advanced medicine approval	26
Others	10

2007-2011 MEXT “Coordination, Support & Training Program for TR”

As an institution that supports various TR projects, we constructed a foundation comprising 7 research centers in japan(*), and developed research seeds.
The goal of this program was to cultivate 2 research seeds per center to the clinical trial phase.
We virtually achieved this goal, even more realized that we built facilities for cell processing that comply with GMP standards, and appointed highly specialized staff (CRCs, biostatisticians, data managers, etc.) to setup a center for supporting TR that provides a bridge from academic research to practical applications.

* Hokkaido Organization for Translational Research (Hokkaido University, Sapporo Medical University, and Asahikawa Medical University), Tohoku University, The University of Tokyo, Kyoto University, Osaka University, Foundation for Biomedical Research and Innovation, and Kyushu University

2012- MEXT “TR Network Program”

Following the “Coordination, Support &Training Program for TR”, this project was initiated in 2012.
The program aims to collect 3 new research seeds per center during the 5-year period, and launch over 21 clinical trials at 7 sites in Japan, by utilizing the foundation for supporting TR and R&D pipelines of previous program.
We have fixed the number of personnel and established a foundation for obtaining outside income to make each center enable to operate, by the end of the program, without receiving financial assistance from the government relating to the construction of infrastructures.
From 2013, as the “Project of Translational and Clinical Research Core Centers”, we provide continuous support to form a network and accelerate development of research seeds in the field of drugs and medical devices.

http://www.tr.mext.go.jp/

Track records of holding training sessions

We hold various programs to disseminate our expertise to the world.

Cancer TR Program
Public Debriefing Session

1st: March 2005
2nd: March 2006
3rd: March 2007
4th: March 2008
5th: March 2009

Coordination, Support & Training Program for TR
Public Debriefing Session

1st: March 2008
2nd: March 2009
3rd: March 2010
- Current status of clinical study into regenerative medicine

4th: March 2011
- Current status of seeds of academic origin that have made progress

5th: March 2012
- Life science innovations: The profile of Japanese universities that are being reborn

TR Network Program
Public Debriefing Session

1st: March 2013
- Sending innovations to the market

2nd: February 2014
- Emerging academia-origin medical innovation -Initiation of clinical&translational research center network-

Project of Translational & Clinical Research Core Centers
Public Debriefing Session

1st: March 2015
- Current status & future prospects of the network for creating medical innovations

2nd: March 2016
- To promptly facilitate innovative medical technology to society

Symposium

March 2015
- Consolidated strategic meeting for cancer research

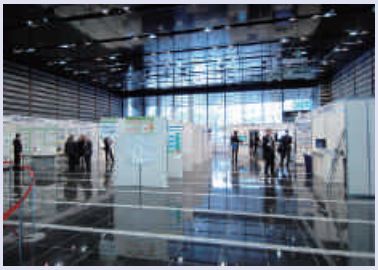
November 2015-February 2016
- Project Cooperation Symposium (Infectious diseases, Intractable diseases, Regenerative medicine, Brain and mind, Cancer, Medical device, Pharmaceutical, Genome)

TR Center Workshop

1st :February 2014
- Management & Acceleration Strategies of TRs

2nd: March 2015
- Success & Challenge of TR Centers in US and Japan -Perspectives for Constructing International Collaboration Framework-

3rd: March 2016
- Life-Science Innovation Infrastructure & Activity in Asia



Contact !

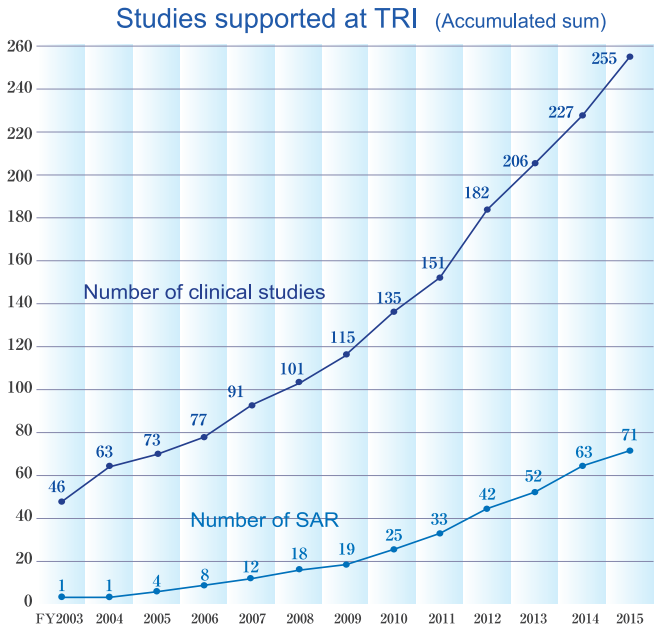
For the information of future educational programs or materials from the past events, please contact the address below.

E-mail: tri-pr@tri-kobe.org

2 Promotion, management, and operation of clinical trials and large-scale cohort studies.

To meet the demand of researchers in Japan, we support various clinical studies to promote the development of novel diagnostic, therapeutic and preventive methodologies leading to the innovation of standard treatments.

Under the TRI's high quality management systems, reliable clinical data are being accumulated.



1. Research Consultation

We are available for a broad range of consultations, from new medical technology and drug development strategies to clinical study.

Consultation fields

Development strategies

1. **Development policies**
   - Marketing research
   - Regulatory classification
   - Development scheme
2. **Patent strategies**
   - Consultation of patents
   - Research for Patent application
3. **Tie-up with joint developer**
4. **Support to organize ARO**

Clinical studies

1. **Protocol development (including first-in-man study)**
2. **Study management**
3. **Data management**
4. **Statistical analyses**
5. **EDC system development**
6. **Support for global clinical trials in planning, launching and operation**
7. **Monitoring**
8. **Audit**

Application for research consultations

For details of the application and further information of research consultation, please access the URL below.

http://www.tri-kobe.org/support/consultation.html

E-mail: sodan@tri-kobe.org

2. Support of clinical studies

We provide comprehensive supports from planning to publication.

Planning

- R&D consultation
- Support for protocol draft
- Support for protocol development
- Preparation of patient registration form and case report form (CRF)
- Support for preparation of informed consent form
- Preparation for adverse events handling manuals
- Development of EDC systems

Operation

- Patient registration
- Protocol management
- Data management
- Quality assurance
- Interim analysis
- Statistical analysis and interpretation
- Storage of clinical samples
- Trial registration to ClinicaTrials.gov
- Support for writing papers

Workflow

Application

Protocol review

Determination of support items and schedule

Protocol refinement and CRF design

Management of EDC system

Study initiation

Monitoring

Interim analysis and handling of committees

Final analysis and reporting

Publication

Application for research support

Consultation by specialists is available. For details of the application and further information of research support, please access from the following URL.

http://www.tri-kobe.org/support/invitation.html

E-mail: ukeire@tri-kobe.org

eClinical Base®

EDC system with an overwhelming ease of use

In 2012, TRI developed and started providing its own EDC system eClinical Base® that made speedy and efficient clinical trial operation possible.

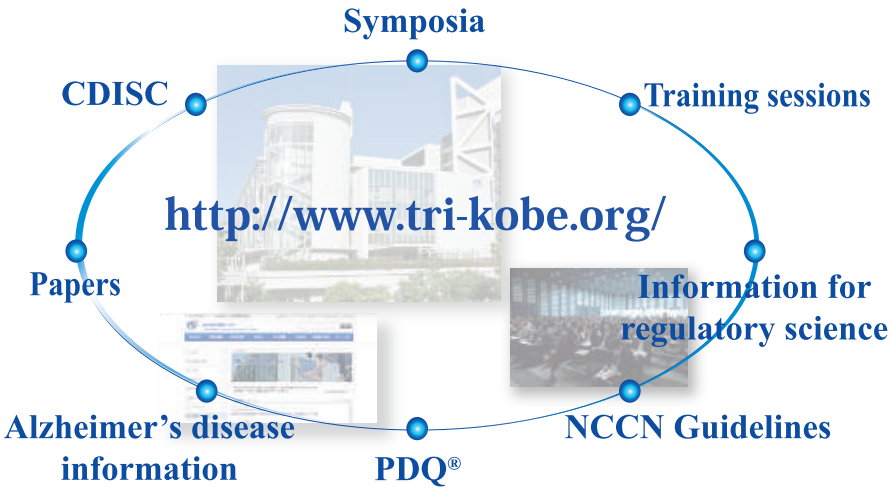
The main feature of eClinical Base is that settings are completed by importing Setting Specifications in Microsoft Excel format, which define all the data collected by CRFs, into the system. This means that you can set up clinical trials or change CRFs in a very simple way. In addition to being equipped with the functions of patient registration, allocation and exporting SAS data set, it is compliant with Part11, GCP, ER/ES Guideline and CDISC standards.

For inquiries pertaining to eClinical Base®, please e-mail to sodan@tri-kobe.org

3 Dissemination of medical and clinical research information

We constantly continue informing doctors and researchers to conduct translational researches. In order to make the accumulated information available to researchers and other individuals, we disseminate it using websites and educational events.

Through these activities, the future direction on TR promotion has been becoming more established.



1. Clinical study-related information services

Since 2002, we have been disseminating information about TRs and clinical trials to doctors and researchers conducting TR through our website:
http://www.tri-kobe.org/

By establishing and promoting the infrastructure of clinical research, we facilitate a project to spread the CDISC Standards as the international data exchange standards. We opened a website and released their Japanese translations as a part of this project.

Website for promoting CDISC Standards project

http://www.tri-kobe.org/cdisc/

Request for donations and support

Our clinical information websites are operated by your donation.
We ask for your generous support.
http://cancerinfo.tri-kobe.org/about/support.html

Contact for donations and support.
E-mail: CANCER-INFO@tri-kobe.org

2. Clinical Information Services

In order to improve prognoses of intractable diseases, the prevalence of standard treatment and achieving the state of the art are essential. TRI chooses most reliable, up-to-date and comprehensive therapeutic information globally, translate it into Japanese and disseminate on the web. Each such web content has received expert' s supervision.

Cancer Information Japan / PDQ® in Japanese

Physician Data Query (PDQ®) by US National Cancer Institute, an umbrella organization of NIH. The original information is weekly updated.

http://www.cancer.gov/cancertopics/pdq/

http://cancerinfo.tri-kobe.org/

NCCN Clinical Practice Guidelines in Oncology® Japanese

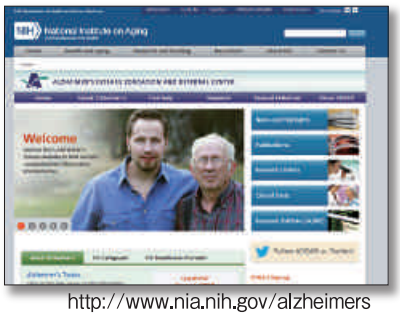
NCCN Guidelines® by National Comprehensive Cancer Network, a not-for-profit alliance of 23 of the US leading cancer centers who formulates clinical practice guidelines.

http://www.nccn.org/index.asp

http://www.tri-kobe.org/nccn/

Alzheimer's Disease Information / ADEAR in Japanese

Alzheimer' s disease information by US National Institute on Aging, an umbrella organization of NIH.



http://www.nia.nih.gov/alzheimers

http://adinfo.tri-kobe.org/

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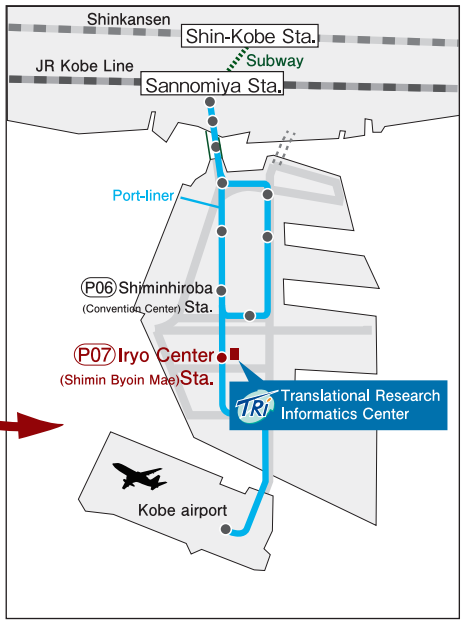

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