

# Core 5 Hospitals of Clinical Trials and Research Japan (Core 5 Hospitals CTRJ)

Central Secretariat Office, Web-based Joint IRB and Remote SDV Monitoring Center

One Stop Service ; Prepare SOP and Unify various forms / Establish and make use of joint IRB  
Active management of secretariat office of clinical trial networks

## Virtual Mega-Hospital

Core 5 Hospitals of Clinical Trials and Research Japan  
( Core 5 Hospitals CTRJ )

Faster,  
tougher,  
smarter

## One Stop Service

> Central Secretariat Office  
> Web-based Joint IRB  
> Remote SDV Monitoring Center

Internet  
VPN

Activation

Contract

Performance-based Payment  
Milestone style

NHO Takasaki  
General Medical Center

Maebashi  
Red Cross Hospital

Gunma University  
Hospital (ARO)

Saku General Hospital

Fukaya  
Red Cross Hospital

Future

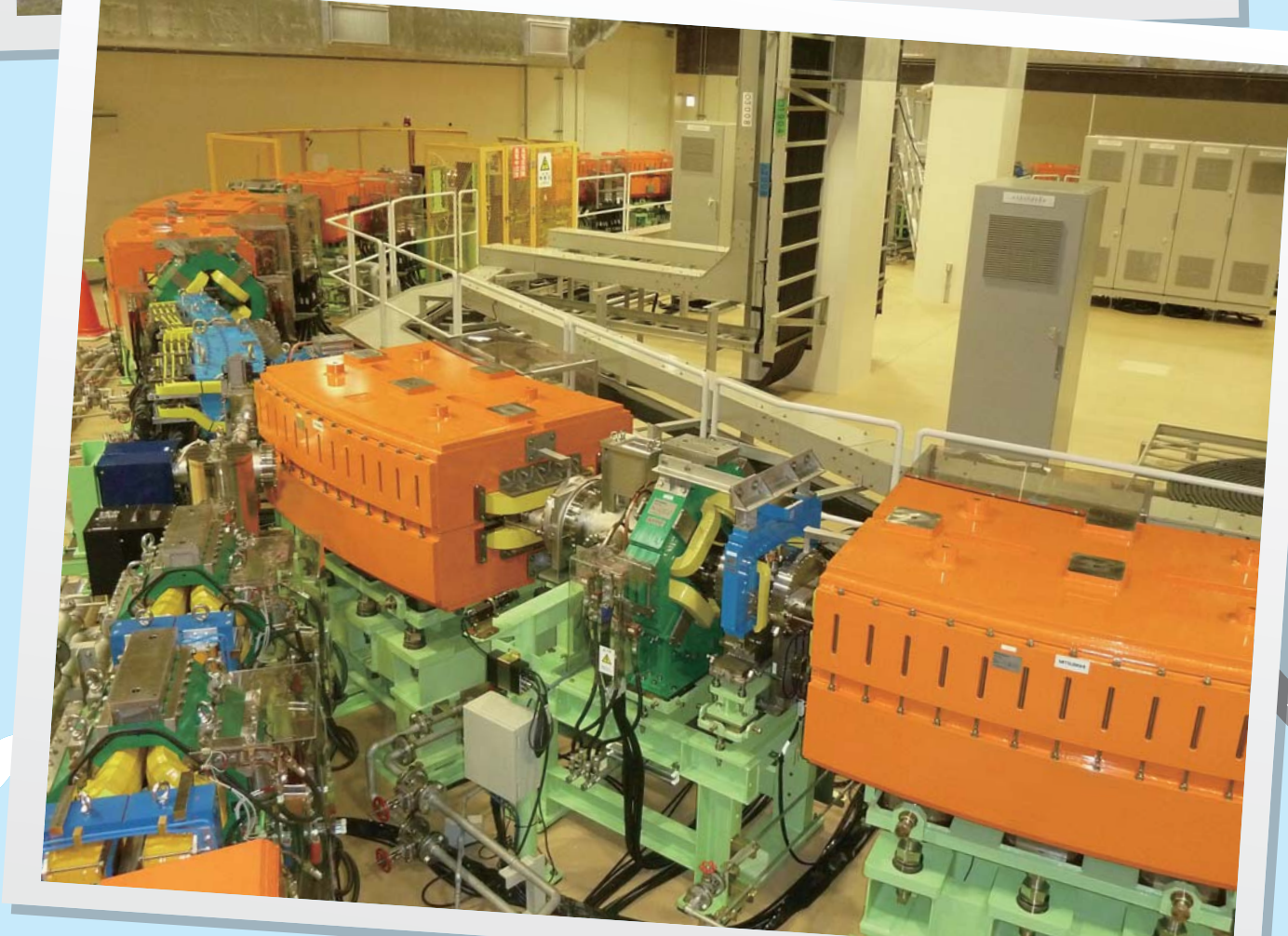
Ethical

Harmony

## Measures by MHLW toward 5-Year Clinical Trials Vitalization Plan 2012

- Measures taken in 2012- Further Leap and Independence of Clinical Trial Sites Based on 9 years' Activation Plans

- Speed up enrolment of trial subjects \*  
> Promotion of clinical trial networks by utilizing joint IRB, strengthening function of network secretariat office
  - Streamline administrative procedures for clinical trials \*  
> Full enforcement of measures in "Report on More Efficient Clinical Trials"  
> Full utilization of uniform forms
  - Develop and secure human resources such as investigators \*\*  
> Continuous training for CRCs and IRB members  
> Foster investigators and health care professionals familiar with clinical trials
  - Raise people's / patients' awareness of clinical trials \*\*  
> Raise awareness of significance of clinical trials
  - Rationalize cost \*  
> Thorough enforcement of fee-for-service system and investigation of rationalizing clinical trial costs
  - Make better use of IT etc. \*\*  
> Application of IT to IRB procedures, etc.
- \* mainly trials led by companies      \*\* common to clinical trials and researches







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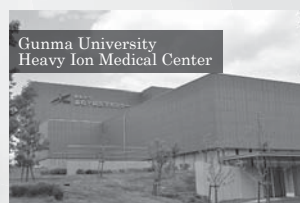
## Our Aim of the business

Gunma University Hospital was honored to be selected as one of the 10 Clinical Trial Hospitals by Ministry of Health, Labour and Welfare in FY2013. Gunma University Hospital is the only university hospital which is equipped with a heavy ion therapy device for cancer treatment. In a history of 10 years and more, we accumulated the successful medical achievements, such as the heavy ion micro-beam technology and the medical Compton camera with radioisotope-based cancer diagnosis, both of which led to the establishment of Heavy Ion Medical Center. We started Clinical Investigation and Research Unit in Gunma University Hospital in April 2001 for the first time in national university hospital in Japan. Since then, we have built a long history of adopting a policy of GCP for all clinical trials and research for both investigator- and company-initiated. We have not separated or distinguished clinical trials and research, depending upon investigator- or sponsor-based in IRB consideration and data-management.

We have already introduced and performed the procedure to conduct all the clinical trials and research according to ICH-GCP as

a daily practice for more than 12 years. This discipline took roots deeply in all the medical stuffs and colleagues in our hospital. We were able to start the heavy-ion therapy safely and steadily in June 2010 as one of the newest cancer medical treatment. The leadership of the president promoted the initiatives of strategy, enforcement, reliability and guarantee for the system of clinical trials for this great brilliant success.

Measures by Ministry of Health, Labour and Welfare toward 5-year clinical trial vitalization plan 2012 is completely precise and exactly timely. Gunma University Hospital strongly wish to contribute to this plan and push forward its discipline into the concrete framework.



## Virtual Mega-Hospital Core 5 Hospitals of Clinical Trials and Research Japan (Core 5 Hospitals CTRJ)

We established Core 5 Hospitals of Clinical Trials and Research Japan (Core 5 Hospitals CTRJ) in the area of central Japan, including Maebashi, Takasaki, Saku and Fukaya cities. Japan Core 5 Hospitals CTRJ consists of Gunma University Hospital, Maebashi Red Cross Hospital, NHO Takasaki General Medical Center, JA Nagano Saku General Hospital and Fukaya Red Cross Hospital for intensive patient's recruitment in clinical trials. The most important significance of Japan Core 5 Hospitals CTRJ is a function as a virtual mega-hospital. A total number of in-hospital beds is over 3,000. One-stop service is a key operational initiative. We set up web-based joint IRB, central trial secretariat office and remote SDV monitoring center for this innovative virtual hospital. In a central trial secretariat office, the most recommended contract is performance-based payment of milestone style. In addition, both web-based joint IRB and a remote SDV monitoring center, utilizing a strong Information Technology support, can cut tremendous redundant procedures, accelerating important clinical trials based

on brand-new life-science technology. Gunma University Hospital plays a vital role as Academic Research Organization (ARO) in this virtual mega-hospital. In addition, we positioned residence clinical research fellows in foreign AROs and will construct the global ARO network, which we have already built in a heavy ion cancer therapy and a large-scale clinical trial. Finally, we insist that our ultimate goal should be a contribution for all the people, as well as for severely ill patients and new-born next generation.



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