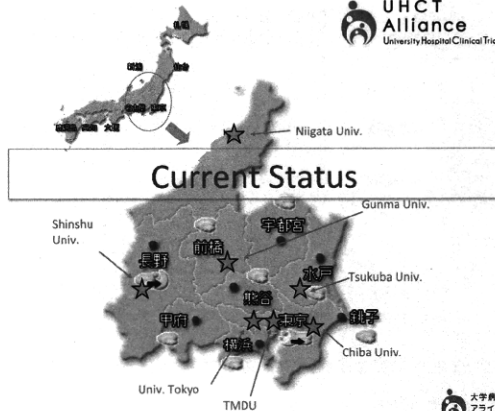
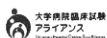
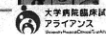
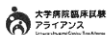
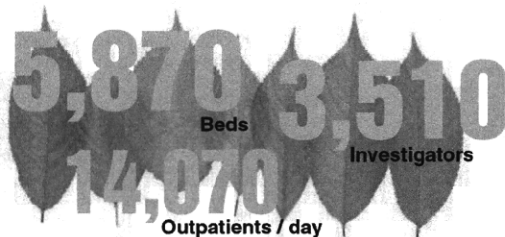


## Activities to improve clinical trial infrastructure in Japan

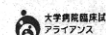
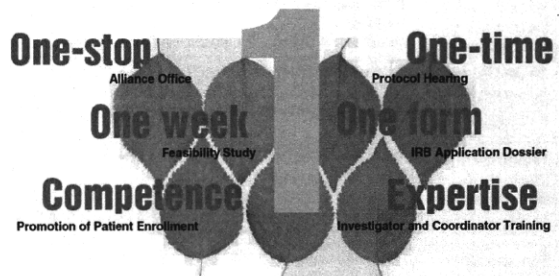


## Outstanding Capacity and Capability of UHCT Alliance

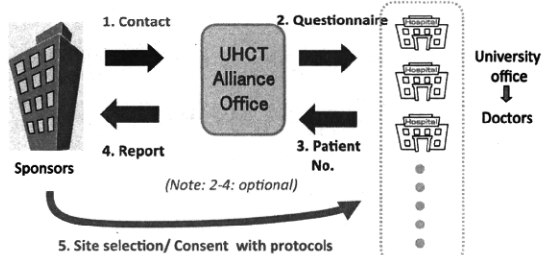
Consists of Seven Excellent National University Hospitals in Japan



## New Japanese Standards from Our Alliance

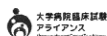


## An Example of Alliance Activities: Inquiry of eligible patients number

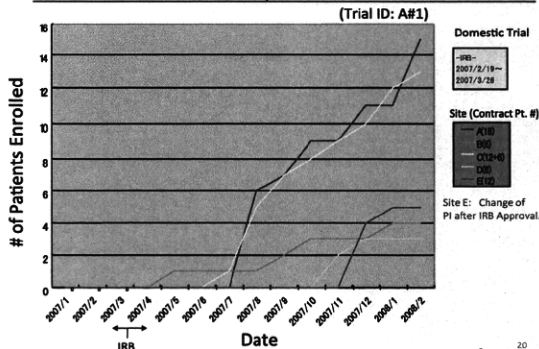


Inquiry of eligible patient numbers can be answered by the Alliance office within 1 week.  
This can be done under masking sponsor's name

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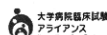


## Patient Enrollment is Monitored by the Alliance Office and discussed in Monthly Video-conference

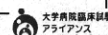


## UHCT Alliance Promotion Project

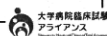
- Supported by MEXT as an inter-university collaboration research project
- FY2009-FY2013
- 7 projects by each UHCT Alliance member
- Secretariat meeting by 7 universities members and office in Tokyo



University & Project Name	Major Tasks
<b>Univ Tokyo</b> (Liaison & Project Management), (Globalization Committee)	Coordinate the following as a hub institution. 1) Administration of the UHCT Alliance Promotion Project 2) Establishment of UHCT Alliance Office 3) Development of the IT system that supports clinical trial implementation 4) International collaboration aiming at becoming a global COE
<b>Tokyo Medical and Dental Univ</b> (Public Relations Committee)	Develop the method for public relations towards globalization 1) Bilingual website and brochure 2) Notifying the all stakeholders about UHCT Alliance activities and performance
<b>Gunma Univ</b> (Investigator Education Committee)	Develop an inter-university education course for investigators 1) Seminars for Investigators 2) OJT course for Investigators 3) Information sharing among universities about investigator's trials



University & Project Name	Major Tasks
<b>Niigata Univ</b> (CRC's Committee for Training and Practical Issues)	Improve CRCs' ability for global communication 1) Seminars and training courses for CRCs through practical issues 2) English training course on technical terms and expression
<b>Chiba Univ</b> (Safety Reporting WG)	Develop an IT system for safety reporting 1) Develop a system for standardized, efficient integration and use of safety information in collaboration with other stakeholders 2) English training course on technical terms and expression
<b>Tsukuba Univ</b> (Quality Assurance Introduction WG)	Plan to introduce QC/QA of the Alliance activities 1) Peer-to-peer monitoring for QC 2) Evaluate the improvement by the external audit 3) Introduce the efficient monitoring method (e.g., sampling monitoring) based on the qualified CRC
<b>Shinshu Univ</b> (Centralized IRB Introduction WG)	Plan to introduce the "Centralized IRB" to the Alliance. Develop standardized and simplified application forms and procedures.



## CRC Conference/Staff Meeting

Hold training courses of CRCs in collaboration with the industry for rapid change in global operation and EDC.

- First and Second CRC Conference (2007.2.16, 2008.2.22, at Tokyo Univ. Hosp)
- Staff Meeting: Summer Seminar- (Collaboration w/ EFPIA) 「Towards Global Studies」 (2007.7.11, video-conference, 50 CRCs+EFPIA 9 Monitors)
- Staff Meeting: Winter Seminar- (Collaboration w/ EFPIA) (2007.12.14, Face-to face meeting, in Tokyo Univ...)



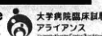
Second CRC Conference



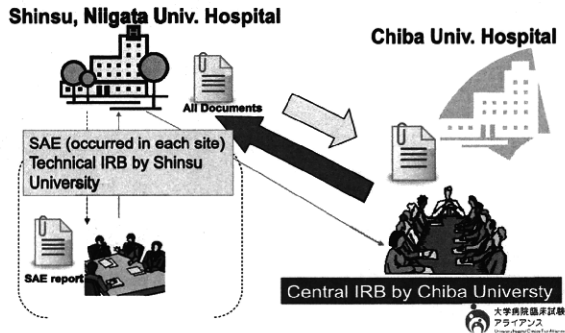
Summer Seminar



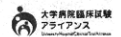
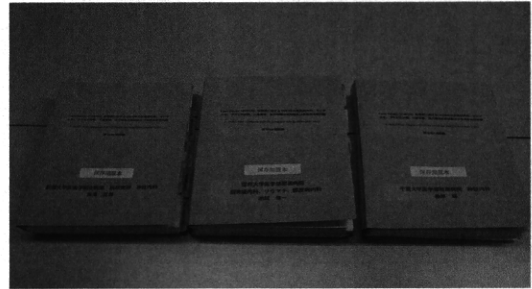
Winter



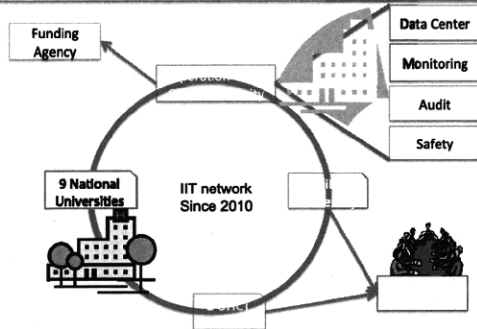
## Central IRB by 3 Univesities Chiba, Shinsu and Niigata challenge since July, 2010



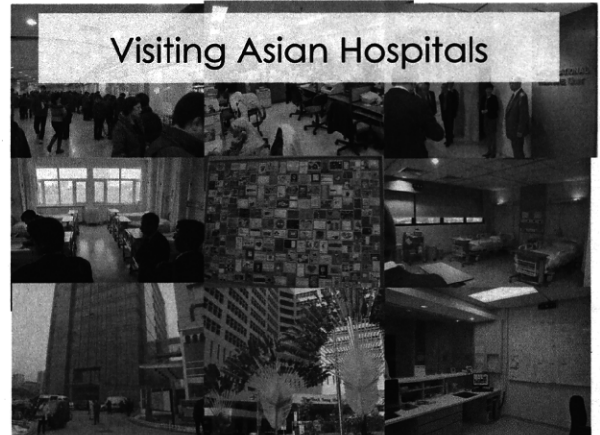
## Protocol of three site applied to central IRB, Chiba University



## Organization of investigator initiated clinical trial

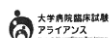


## Visiting Asian Hospitals



## The prospects for the UHCT Alliance next year

- The synergy of strategic alliance will promote our activities in clinical trials.
- Excellent PI with excellent Project teams will be able to construct excellent partner of PIs from other countries and leading pharmaceutical companies
- We would like to start Asian trail.



## Some Results in UHCT Alliance

- We introduced innovative methods for site selection by helping match sponsors and university hospitals.
- We introduced common application forms (including common IC forms) and joint protocol hearing using a video-conference system.
- We introduced a centralized IRB as a trial among 3 universities.
- We are monitoring patients enrollment.

- We hope to increase the number of multi-national clinical trials in Japan by demonstrating our achievement.
- We are continuing the activities to improve the clinical trial environment.

