

Standard Time Table from Application to Completion of Clinical Trials

Time table for procedures

Procedure	Gunma Univ.	Shinshu Univ.	Chiba Univ.	Univ. of Tsukuba	Tokyo Medical & Dental Univ.	Univ. of Tokyo	Niigata Univ.	Univ. of Yamanashi
Application - IRB	12	14	15	13	15	15	14	21
IRB - Contract	1	7	1	17	7	0	1	14
Start-up meeting Completion of clinical trial	0	7	0	7	1	2	4	1
Report from PI to a director of hospital	1	7	0	6	1	1	2	1
Notification from a director of hospital to a sponsor	0	21	1	15	1	0	21	1

(days)

Timetable for safety reports

	Gunma Univ.	Shinshu Univ.	Chiba Univ.	Univ. of Tsukuba	Tokyo Medical & Dental Univ.	Univ. of Tokyo	Niigata Univ.	Univ. of Yamanashi
Onset of SAE - IRB	1	14	1	1	1	1	1	1
Issue of official SAE report	1	7	1	2	4	1	1	7

(days)