

Bridging Studies

Dr Fukase recognised with the publication, in the mid-90s, of the ICH E5 guidance pertaining to 'Ethnic Factors in the Acceptability of Foreign Clinical Data', the importance of the 'Bridging Study'.

Dr Fukase was the first investigator in Japan to perform a bridging study with White/Caucasian subjects and since that first study in the mid-90s, he has performed well over 40 bridging studies involving more than 650 White/Caucasian subjects. It is fair to say that he is one of the most if not the most experienced investigator in Japan in this area.

Tokyo Hospital: Recent Studies with White Subjects

Indication	Route	Phase	No of Cohorts	Race	No of vol	Gender	Genotyping	Year	
Renal Cell Carcinoma	Oral	1	1	White	n=4	Female	Yes	2020	
Endometriosis	Oral	1	2	White	n=16	Male	No	2021	
Pulmonary Arterial Hypertension	Inhalation	1	1	White	n=12	Male	No	2021	
RSV	Oral	1	1	White	n=11	Male	No	2023	
Deep mycoses	Oral	1	1	White	n=12	Male	No	2023	
Underactive Bladder	Oral	1	1	White	n=8	Male	No	2024	
Rheumatoid Arthritis	IV Infusion	1	1	White	n=8	Male	No	2025	Pending

Recruitment

Volunteer recruitment is mainly through **word-of-mouth**. New volunteers are introduced to Tokyo Hospital by current volunteers. An English-speaking member of staff will then contact the potential volunteer to arrange an interview. After a successful interview the volunteer's information is added to the Caucasian volunteer database and mailing list

Currently there are around **300 to 400 active healthy Caucasian male volunteers** listed in the database and around **50 healthy Caucasian females**.

In cases where the numbers of volunteers are not sufficient to cover the needs of a particular study advertising on various Social Media is an option.