

Bridging studies

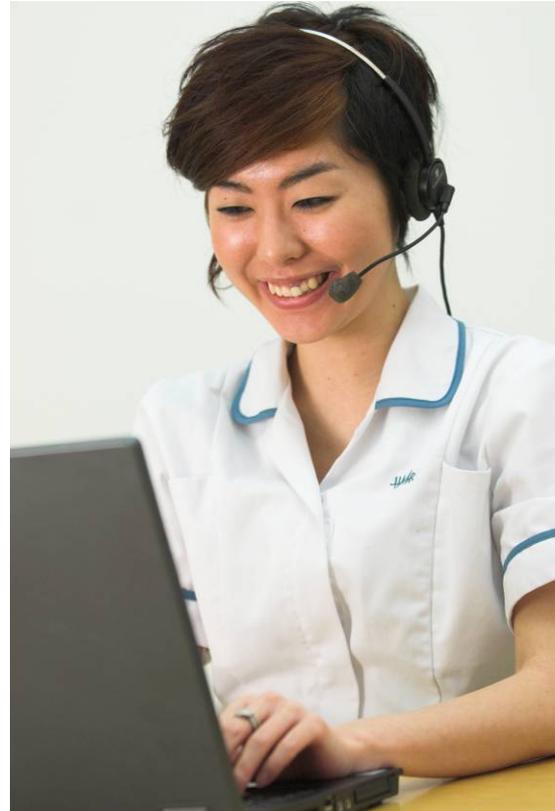
Since 1993, we've done many studies in healthy Caucasians for Japanese companies, large and small. Since 2002, we've also done 'bridging' studies in healthy Japanese subjects, to compare results with those from Caucasians. We've even done a study to compare Caucasians, Japanese, Koreans and Chinese.

About 40,000 Japanese people live in the UK. That's enough to enable us to do bridging studies in a timely manner. The largest Japanese community in London is close to HMR. Our volunteers have Japanese parents and grandparents, and have lived outside Japan for less than 5 years.

Our dedicated team of bilingual Japanese nurses and support staff have substantial experience of bridging studies. They recruit suitable subjects, translate trial documents and help do the studies. We've done:

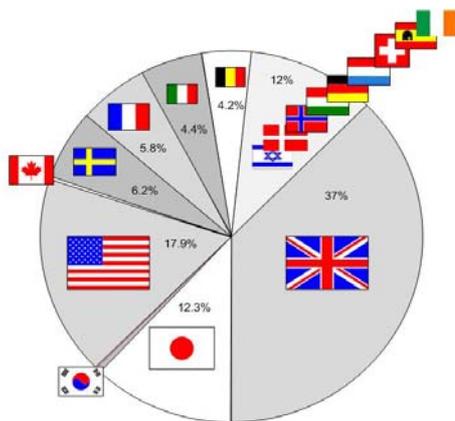
- bioequivalence studies of new products not yet marketed in Japan;
- studies that can't be done in Japan, such as a study of an opioid; and
- studies with 'add-on' cohorts of Japanese subjects for large, complex, first-in-man single- and repeat-dose trials in Caucasians.

Those studies have helped sponsors satisfy Japanese regulatory authority requirements.



Central monitoring and ECG telemetry on all beds

We have spacious new premises with 100 beds, 24-h resuscitation team, CAP-accredited laboratory, GMP pharmacy and radiopharmacy, and MHRA Supplementary Accreditation. There are separate facilities with TV room, computer games, DVDs, comics and books for Japanese bridging studies. And, our kitchen can prepare Japanese meals. Japanese subjects tell us they like doing studies at HMR!



The percentage share by country of our 530 phase 1 trials since 1993

To discuss your needs, please contact:

Steve Warrington, Medical Director
swarrington@hmrlondon.com

or

Malcolm Boyce, Managing and Clinical Director
mboyce@hmrlondon.com

020 8961 4130

Hammersmith Medicines Research
Cumberland Avenue
London NW10 7EW UK



References

1. ICH 5. Guideline on ethnic factors in acceptance of foreign data. 1997
2. Kodama Y, Saito K, Ono S *et al.* Human pharmacology studies with biomarkers for new drug applications in Japan. *Drugs R D* 2005; 6: 21–34.
3. Chow S, Shao J, Hu O. Assessing sensitivity and similarity in bridging studies. *J Biopharmaceutical Statistics* 2002; 12: 385-400.
4. Lister N, Warrington S, Boyce M *et al.* The pharmacokinetics, safety and tolerability of ascending doses of sublingual fentanyl (KW-2246) in Japanese subjects, with and without naltrexone. *J Clin Pharm* (submitted)
5. Small D *et al.* Pharmacokinetics and pharmacodynamics of prasugrel in healthy Japanese, Chinese, Korean and Caucasian subjects. *Eur J Clin Pharmacol* 2009 (in press)