

Welcome FDA!



US FDA select FF GPRD to support post marketing pharmacovigilance activities

Following an international procurement exercise, the US Food and Drug Administration has awarded the GPRD Division a five year contract to supply them with access to anonymised longitudinal patient level electronic medical record data via Level 4 access to the Full Feature GPRD.

Commenting on the decision Louise Wood, the Director of the GPRD Division, said *“We are delighted with the FDA’s decision which testifies to the quality and international applicability of GPRD data. The MHRA’s Post Licensing Division has been a licence holder for the last couple of years and other regulators are considering direct access. This recognises that the GPRD is a key resource for pharmacovigilance for use by regulators, the industry and academics who conduct research to inform regulatory decision making on critical drug safety issues.”*

More new users!

The GPRD Division welcomes the latest members to the GPRD family with Boots Healthcare International joining this quarter. Boots are involved quite heavily in the POM to P process for pharmaceutical compounds and the access to the GPRD will allow them to assess the safety profiles of prospective compounds without the need for expensive and extensive clinical trials. Boots have been users of the GPRD through third parties in the past but have now decided that having on-line access offers considerable benefits in both time and money. *“Having access to the GPRD will extend the information we have at our fingertips,”* says Heather Clarke, of Boots Healthcare International. *“The GPRD will enable us to undertake more studies, quicker, and at a lower overall cost”.*

Joining Boots as new users of the online full feature GPRD are BMS and Sanofi-Aventis. Bruce Wong, Vice President of Global Epidemiology at BMS says *“BMS has subscribed to GPRD because of the established validity and track record of this dataset in undertaking healthservices research”* We are also pleased to welcome the Boston Collaborative Drug Surveillance Programme as on-line users of FF-GPRD. The Boston group are very experienced in conducting research on the GPRD, and have many publications in peer reviewed journals (see the GPRD bibliography).

The GPRD International Symposium



We held our first international research Symposium at the British Museum in London on 13 October to celebrate the five year anniversary of the MCA (now MHRA) assuming responsibility for the GPRD. Chaired by Professor Sir Alasdair Breckenridge, the aims of the Symposium were to:

- * illustrate the broad range of research applications of GPRD data, including: clinical epidemiology; drug safety; health outcomes; drug utilisation and pharmaco-economics.

- * provide examples of the use of GPRD-based research in informing drug development, regulatory decision making and the development of policy for the National Health Service.

- * promote awareness and debate the utility of GPRD and other large automated databases in health decision making.

Delegates included researchers and policy makers from academia, the pharmaceutical industry, regulatory authorities and the UK's Department of Health as well as three GPs who have been long standing contributors to GPRD.

In his keynote address, Professor Alec Walker, CEO of Ingenix (above), provided a typically insightful and thought-provoking consideration of the capacity of large automated databases to transform health decision making, using the topical issue of the influenza vaccine crisis in the US to illustrate his point. Professor Samy Suissa (McGill University) highlighted the impact that database research had made on our understanding of asthma. A description of the use of GPRD to study depression and antidepressant therapy from Carlos Martinez (GPRD Division) continued the topical themes.

Professor Steve Chapman (Keele University) provided several practical examples of how his team's research on topics such as trends in prescribing of proton pump inhibitors and antibiotics and modelling of the likely impact of the availability of montelukast informed planning and monitoring by Primary Care Trusts in his region.

Michael Cook (Merck Research Laboratories) presented a study he had conducted on the natural history of cardiovascular disease among patients with ankylosing spondylitis. Gwenda Hughes (GPRD Division) described her recent epidemiologic study of fibromyalgia syndrome and healthcare resource use in the UK. The use of GPRD for outcomes research, using diabetes as an example, was discussed by Professor Ross Lawrenson (University of Surrey) and Tim Williams (GPRD Division) provided an overview of an investigation of the risk of upper respiratory tract infections in obese people.

Last but not least, June Raine, the Director of the MHRA's Post Licensing Division considered the importance of databases such as the GPRD to support pharmacovigilance risk management planning.

The day continued with a novel approach to a panel discussion in which the Chairman invited selected speakers and Susana Perez-Gutthann (Pfizer) to pose questions to the audience. The GPs who attended the conference found themselves in the spotlight as the main recipients of the questions.

As a result of the very positive feedback we have received from delegates, we are considering holding the Symposium as an annual event. If you'd like to be added to the mailing list for further information as it becomes available, please contact the GPRD helpdesk on admin@gprd.com.



GPRD: What is new and what does the future hold?



By Louise Wood - Director

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It's just over five years since the Medicines Control Agency (now MHRA - Medicines and Healthcare products Regulatory Agency) assumed management responsibility for the UK's General Practice Research Database (GPRD). Having achieved the initial objectives of reversing the declining contributing GP population, providing secure access to all data on-line via the newly developed Full Feature GPRD and reducing service fees, recent attention has focused on the development of tools to support researchers including

- Matching of cases to controls based on factors such as age, sex, practice, index date
- Daily dose conversion which translates unstructured free text into a numerical value, enabling rapid like-for-like comparisons
- Mapping of the clinical and drugs term used at data entry to hierarchical terminology (MedDRA and ATC/GPRD Drug Dictionary respectively) and of a browser to support the development and use of a code list. implementation of new services, for example
 - Source data verification / Follow Up questionnaires etc. from practices
 - Key word searchers of free text and provision of anonymised free text for selected patients
 - Increasing awareness of the broad usage of applications for the data in addition to pharmacoepidemiology

The GPRD Division of the MHRA is the only source of updated GPRD data. Researchers using the FF-GPRD have been very enthusiastic about the richer, more structured data available from practices using Vision software compared to the historical VAMP Medical software and about recent changes in primary care which have had beneficial impact

on GPRD data. For example, roughly 85% of GPRD practices now receive data electronically from laboratories. This is transferred into the patient record enabling researchers access to quantitative results and laboratory normal ranges as well as the qualitative descriptions available previously.

The new General Medical Services contract, which determines salary for about 75% of General Practitioners will drive further change. The contract's Quality and Outcomes Framework which purports to resource and reward GPs on the basis of how well they care for their patients will act as a major driver for more comprehensive data recording, particularly in the disease areas selected for particular attention: coronary heart disease (including left ventricular dysfunction), stroke and transient ischaemic attacks, hypertension, hypothyroidism, diabetes, mental health, chronic obstructive pulmonary disease, asthma, epilepsy, cancer.

The contract's indicators are designed to encourage more structured care of patients with chronic diseases and practices will be audited annually to determine the extent to which they are complying with framework guidance and the consequent impact on clinical outcomes. For example, in patients with diabetes, practices will receive payment on the basis of: their ability to produce a register of all patients with diabetes mellitus; evidence in the patient record of a recording of BMI, smoking status, HbA1c level, retinal screening, neuropathy testing, blood pressure, serum creatinine, total cholesterol and microalbuminuria testing within the previous 15 months and the percentage of diabetic patients whose last measured HbA1c was 7.4 or less in the last 15 months. Obviously practices need to ensure that they are recording such data in full to ensure they are remunerated appropriately. These data will be recorded in the patient record, extracted for the GPRD and made available for research.

Radical changes in the National Health Service (NHS) in England will be introduced via the Department of Health's National Programme for IT (NPfIT). The Department is investing £6.2 billion (\$11.1 bn; Euro 9.2bn), in what is reported to be the largest IT programme in the world, to implement a modern integrated IT infrastructure for all NHS organisations in England by 2010 with the aim of improving patient care, access to data and choice. The NPfIT deliverable of most importance to epidemiologists is the electronic Care Records Service (CRS) which will provide a cradle-to-grave CRS for each patient across primary and secondary care. Essential information will be held at local level and a summary of care encounters and clinical events will be held in a national data repository.

Much of the NPfIT is at a design or an option appraisal stage so it is only possible to make general comments about its possible impact on research and databases such as GPRD. Clearly it offers scope for achieving the 'holy grail' of access to longitudinal integrated primary and secondary care data for large cohorts of individual patients, possibly even the whole population. Successful implementation of NPfIT will require significant technical issues to be overcome, major cultural change in the NHS and agreement on who can access what data for which purposes.

Changes at GPRD

Louise Wood

Louise Wood, Director of the GPRD Division, will be leaving the MHRA at Christmas to become the **Head of R&D Relations with industry** in the Research and Development Directorate in the Department of Health. She joined GPRD in 1999 and has spearheaded the development of the Division when the Agency assumed management responsibility for the database. During her tenure in charge at the GPRD Louise has transformed the database into a widely available resource used regularly by the Pharmaceutical industry, Academia, Regulators and CRO's.

Our thanks and best wishes to her!

Arlene Gallagher and Emma Heeley

We are pleased to welcome two new members to the research services team.

Arlene Gallagher has joined GPRD Division to work as a Statistician/Epidemiologist. She also has a significant role in organising the training for Full Feature GPRD with Sarah Davis, who is on maternity leave.

Following graduation and her MSc, Arlene worked for two years at St. Bartholomew's Hospital, London, where she used the GPRD to research the incidence, prognosis and aetiology of Chronic Fatigue Syndrome (CFS).

Emma Heeley has also joined as an Epidemiologist and is also responsible for the SEAG secretariat.

Following her PhD, and prior to joining the GPRD Division, Emma worked for two years as an epidemiologist in the Pharmacoepidemiology team in the Post Licensing Division of the MHRA, providing data and evaluating data for regulatory decision. Prior to that she worked for two years at the Drug Safety Research Unit in Southampton conducting postmarketing surveillance.

Emma and Arlene's role is to support our clients in providing datasets, to conduct studies and to assist in undertaking feasibility reviews.

Recent Presentations

International Society for Pharmacovigilance - ISPE Communicating our research findings

Several members of the GPRD Division attended the 20th International Conference on Pharmacoepidemiology and Therapeutic Risk Management in Bordeaux in August and enjoyed the opportunity of "putting names to faces" of people with whom they've been working. Oral presentations were made on the use of anonymised free text for the verification of the cause of death and on in-utero exposure to antihistamines and the risk of hypospadias and chryptorchidism.

Posters were presented on:

The incidence of ventricular fibrillation and tachycardia in a primary care population:

The adverse event profile of antidepressants: and

A comparison of the causes of death recorded in GPRD with external sources.

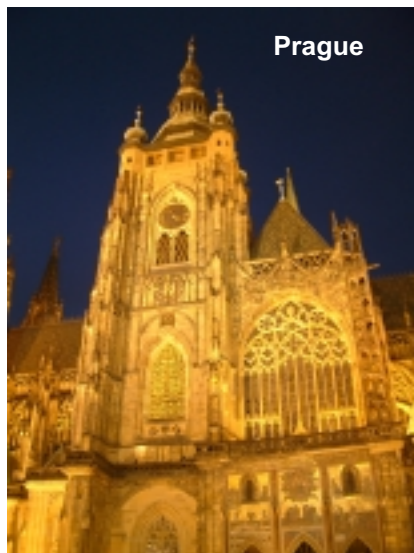


Other meetings

The recording of in-utero drug exposure and the mother-baby link in GPRD were presented at the symposium on European and American data sources for the assessment of human teratogens.

Research we've conducted on trends in the diagnosis of genital chlamydia and pelvic inflammatory disease were presented at the UK Health Protection Agency's Annual Conference and a study on Fibromyalgia syndrome and resource use was presented at the European League Against Rheumatism meeting.

Come and meet us



We routinely have stands at the following meetings: ISPE, Drug Information Association and the International Society for Pharmacoconomics and Outcomes Research. These provide a useful opportunity to meet with existing clients and those who are interested in exploring the use of GPRD. Please feel free to make an appointment for a dedicated meeting with us during these conferences by contacting Martin Fagan on martin.fagan@gprd.com.

