

Rapporteur's Main Points

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Pharmacogenetics is here to stay!

EXAMPLES INCLUDE:

- **Drug discovery**
- **Drug development**
- **Regulatory decisions**
- **Marketing decisions**
- **Clinical practice**
- **Patient knowledge and demand**
- **Policy**
- **Politics**

Achievements today

- Maximising drug response, minimising side effects
- Reducing attrition rate
- Increasing the tools available for evidence-based healthcare
- Reducing size and duration of clinical trials

Economics and Public Health: Herceptin®

Trial Design	With HER2 neu	Without
# of patients	470	2200
Response rate	50%	10%
Years of follow-up	1.6	10

- Savings in clinical trial costs ~ \$35 million
- Income from 8 year acceleration of product ~ \$2.5 billion
- Access to drug from acceleration ~ 120,000 patients

Pharmacogenetics is not an exception

- It is one of many tools to be used in innovation and healthcare.
 - It interfaces evidence-based medicine with regulation, public policy and community health.
- It is an application – the first - of genomics
 - From pgx we can learn how to address and apply other areas of genomics

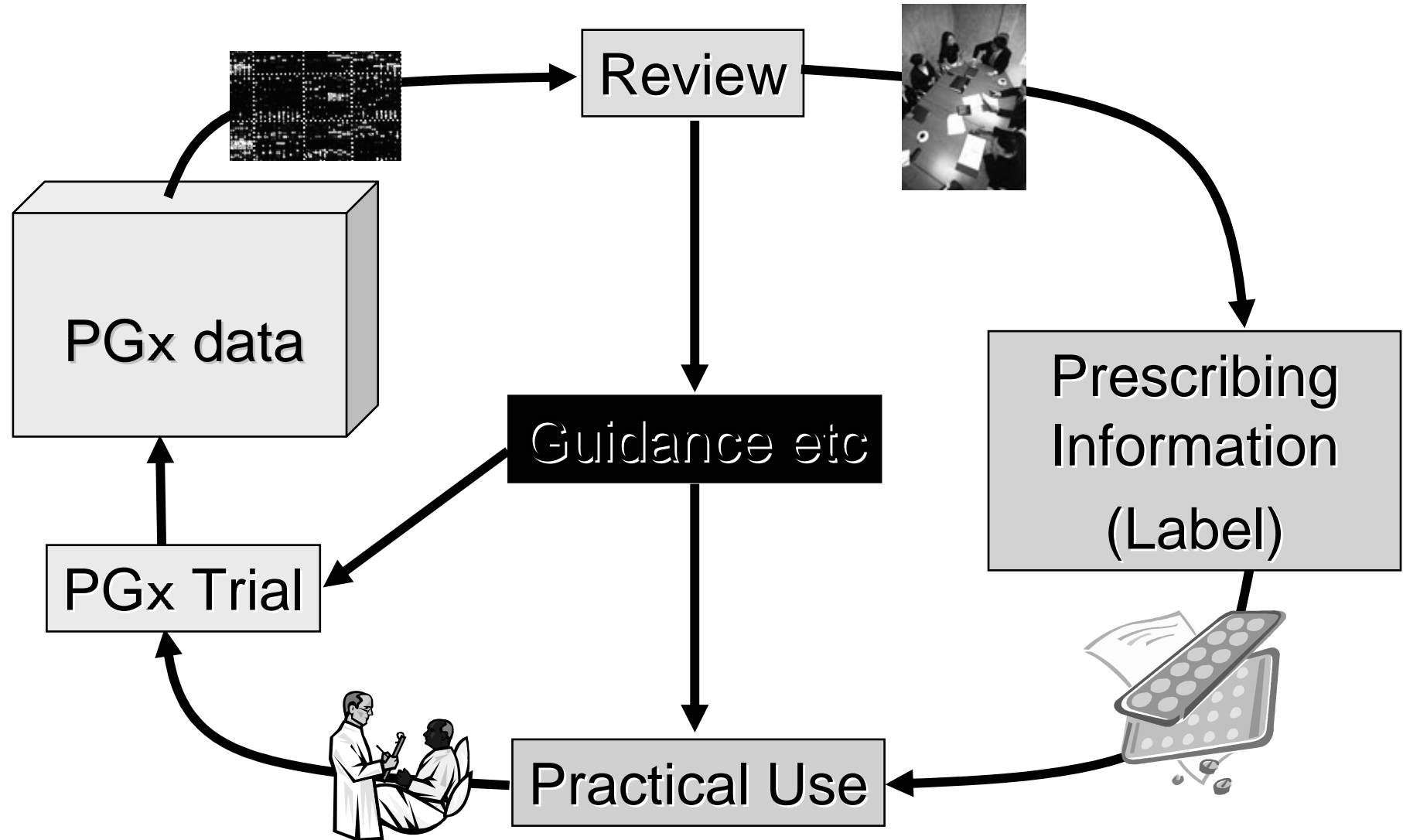
It is beginning to change models and ways of working

- Delivery of human genome data to treat and prevent rare and common diseases
- Recognition by many areas that there is a need for changed models and ways of working
- Evolutionary or revolutionary?
- Frameshift – to preventative medicine?
– to risk management?

Leading the way

- Regulators: new interactive models
- Pharma: readdressing business and innovation models
- Patients: informed, and driving agenda
- Research community: engaged
- Oncology: first sustainable model

Steps for PGx-based medicine



Not keeping pace

- Demonstration of clinical utility
- Reimbursement mechanisms
- Healthcare systems
- Physicians and clinical practice
- Incentives for diagnostic industry
- Ethics and public policy
- Sample collection
- Interoperability

Not only about science

- Pharmacogenetics involves dialogue and communication across many fields
- Legal, sociological and economic issues will delay progress if they are not engaged
- National issues, ethnic and patient issues will delay progress if they are not engaged
- Public confidence is paramount

Unresolved Issues

- Existing drugs vs new drugs
- More, less, better regulation?
- Impact on innovation/business models
- Monogenic paradigm for genetic diseases – validity?
Does it still apply?
- Clinical trial structure: Randomised? How many?
Enrichment? Ethnicity?
- Timescales to mainstream healthcare
- Changing professional roles, education and training
- Achieving benefits for all rather than few? Equity of access. Not testing?
- Discrimination legislation

Emerging issues for international action

- Leadership
- Validation and qualification of biomarkers
- Economic incentives (orphan drug lessons)
- Facilitation of collaborative research (international, interdisciplinary)
- The development of public-private partnerships to address various issues
- Sample collections (harmonisation)