Current use of Genetic and Genomic (G&G) strategies in drug development

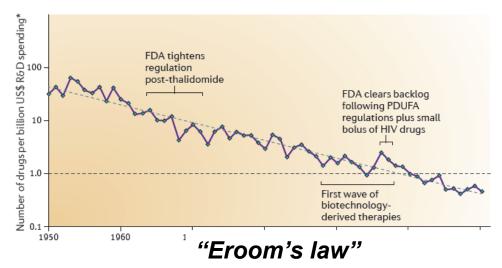
Nick Davies, Ph.D. Partner Pharma Strategy PwC

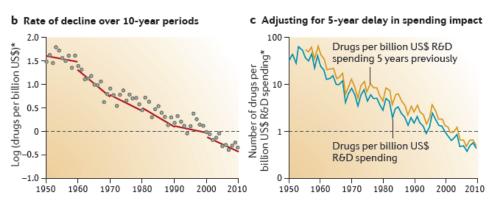
March 21, 2012

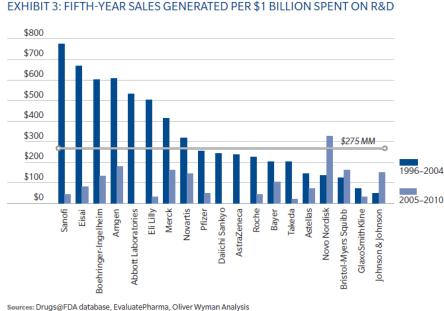
Nicholas.davies@us.pwc.com



The beatings will continue until morale improves







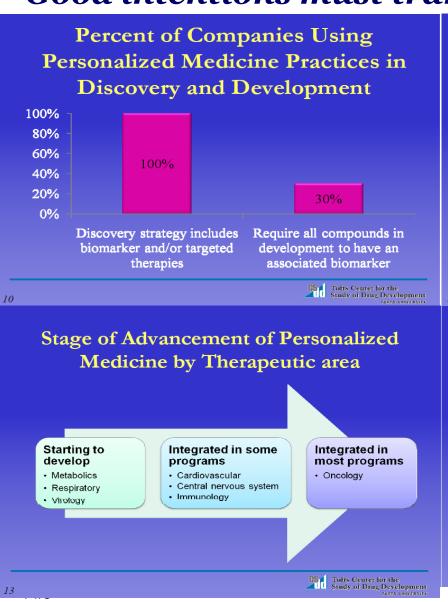


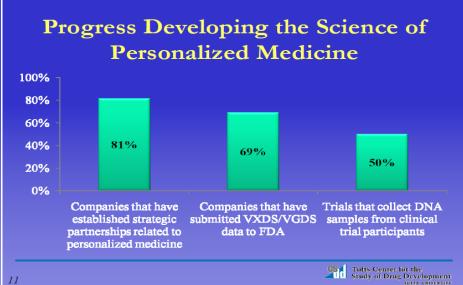
"The Truly Staggering Cost Of Inventing New Drugs"

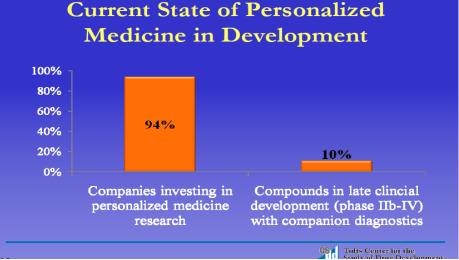
"Patent expiries cripple Pharma"

45 phase III failures in 2010

Good intentions must translate







[&]quot;A form of medicine that uses information about a person's genes, proteins and environment to prevent, diagnose and treat disease"

Pharma investment in G&G - no stand outs

- Average of 13-19% of sales invested in R&D in 2011 \$125 billion in
- Estimated 5% \$6 billion spent annually on G&G**
- Varying models of internal *vs* external mix
- Academic partnerships bloom
- Applied at every step of Pharma value chain
- Oncology poster child
- Value of targeted therapies uncertain outside of oncology assets
- Regulatory constraints require increased dialogue
- Commercial model immature
- Payers and providers remain unconvinced
- Physicians untrained
- Patients confused

We've never had it so good?



Huge apparent improvements in efficiency and quality in many research inputs:

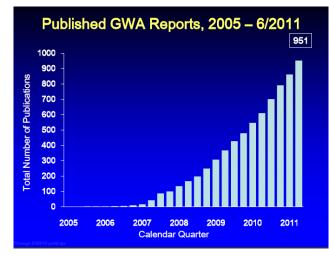
- · Approximate Moore's Law improvements in many cases
- Qualitative improvements in other cases

Small changes in success of molecules entering clinical trials over the past 50 years Eroom's Law: increase in cost per approved molecule

illumına¹

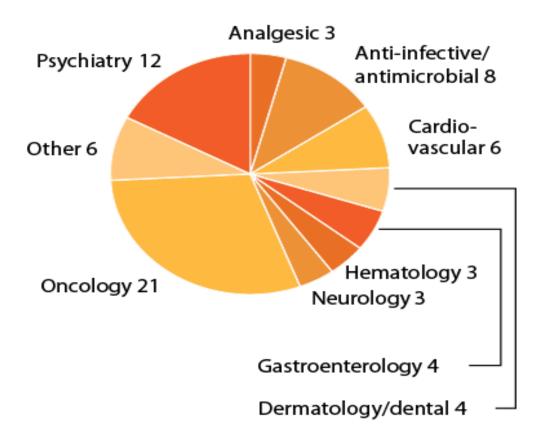
- Cost of DNA sequencing 1 billionth of original
- GWAS unraveling complex disease
- "Polyomics" distraction?
- Translation to disease understanding?
- Impact on quality and cost of healthcare?

"...there are more ways of not knowing about human health and disease than anyone could have imagined a decade ago."



Hindorff LA, MacArthur J (European Bioinformatics Institute), Wise A, Junkins HA, Hall PN, Klemm AK, and Manolio TA. A Catalog of Published Genome-Wide Association Studies. Available at: www.genome.gov/gwastudies. Accessed [date of access].

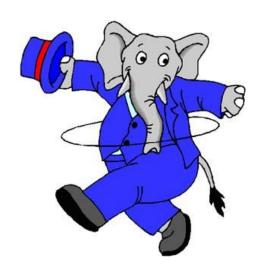
70 Marketed drugs with PG biomarkers on label*



Companion diagnostic market to reach 42 billion by 2015**

Such information may appear in a number of places on the label, including the indications and usage section, the dosage and administration section, in boxed warnings, and so on, and may relate to clinical response variability, risk for adverse events and mechanism of action, among other things.

Focus, focus and then focus again



- Does G&G give us a reason to believe?
- Disease understanding
- Targets
- Rapid translation to the clinic
- Patient selection
- Diagnosis
- Targeted therapies
- Differentiation
- Improved outcomes
- Access and reimbursement

Healthcare trends-how can G&G give us hope?

- Cost effective outcomes driven
- Cost neutral to Health Systems
- Targeted ("personalized")
- Preventative
- Patient centric



- How can Pharma investment in G&G enable?
- What partnerships will drive value
 - What is the next SNP consortium?