Who owns genetic research data?
Point of view Pharmaceutical industry

09 March 2016 / Tarja Jalava Head CPM SM Oncology I
Disclaimer

The views and opinions expressed in the following presentation are my own and do not represent the official policy or position of Bayer.
Drugs Do Not Work in Everybody

Percentage of patients for whom drugs are ineffective

- Depression: 38%
- Asthma: 40%
- Cardiac Arrhythmias: 40%
- Diabetes: 43%
- Migraine: 48%
- Arthritis: 50%
- Osteoporosis: 52%
- Alzheimer's: 70%
- Cancer: 75%

Personalized Medicine: Tailored Treatments

Current medicine: one treatment fits all

Future medicine: personalized treatment

Cancer patients with e.g. colon cancer

Blood, DNA, urine and tissue analysis

Biomarker diagnostics

Effect
No effect
Adverse effects

Effect
Precision Medicine

Speaking at a White House event to announce the initiative on 30 January, President Obama said that the goal of the **precision medicine initiative** will be to understand the differences between people, such as differences in their genetic makeup, to enable individualized treatments that would be most likely to be effective for each person. The approach, Obama said, promised to make it possible to deliver “the right treatments, at the right time, every time, to the right person.”

**Objectives of the Precision Medicine Initiative:**

More and better treatments for cancer: NCI will accelerate the design and testing of effective, tailored treatments for cancer by expanding genetically based clinical cancer trials, exploring fundamental aspects of cancer biology, and establishing a national “cancer knowledge network” that will generate and share new knowledge to fuel scientific discovery and guide treatment decisions.

‘**Precision oncology**’: unexplained drug resistance, genomic heterogeneity of tumors, insufficient means for monitoring responses and tumor recurrence, and limited knowledge about the use of drug combinations.”

*Collins et al, N Engl J Med 30 Jan 2015*
Selection biomarkers in oncology: Tools to select the right patients for treatment

Protein levels – IHC (e.g. Ventana)
- HercepTest
  - Breast cancer; tumor HER-2 protein (IHC)
  - No Herceptin
  - Herceptin

Gene amplification / deletion – FISH (e.g. Ventana)
- PathVysion
  - Breast cancer; tumor HER-2 gene amplification (FISH)
  - No amp → No Herceptin
  - Amp → Herceptin

Gene mutations (e.g. Qiagen)
- DxS K-Ras Mutation Test
  - Colorectal cancer; tumor K-Ras muts (DNA)
  - wt → Vectibix, Erbitux
  - mut → No Vectibix, Erbitux
Personalized Medicine in R&D
Genetic Research Data

- Disease targets using genetic data
- Knowledge of biological pathways and gene variants helps development
- Biomarker based patient selection
- Personalized treatment by combining drug with molecular diagnostic test
Personalized Medicine in R&D
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- Disease targets using genetic data
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10,000 Test compounds
<250 Test compounds
<5 Test compounds

1 drug approved by health authorities

Personalized treatment by combining drug with molecular diagnostic test
Personalized Medicine in R&D
Bio-Samples for drug development

Drug Research
- Target Identification
- Target validation
- Lead Development
- Pre-Clinical
- Clinical Trials
- Market

Biomarker activities

Research Biobank
- companion diagnostics (cDx)
- Trial Subjects
Biobank Samples

The Finnish biobank law (1.9. 2013):

Protection of donors’ rights
• Informed consent
• Privacy protection
• Knowledge of sample use

New research results returned
National Genomic Center – Possible Research Collaboration

Finland’s Genome Strategy Proposal 2015

Confirm ethical principles for use of genomic data
Prepare legal framework for use of genomic data
Implement National Genomic Center

- Serve as a single point of contact for research, contractual and commercialization services
- Implement collection and management of consents required for use of genomic data.
- Promote ethical practices in use of genomic data
- Standardize and streamline ethical evaluation of research projects
Clinical Trials - Main international standards of ethical practice

The Declaration of Helsinki
• Since 1964 and now 7th version

ICH-GCP: International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
• Since 1996
Informed Consent of Trial Subjects

- Informed decision of trial subject
  - **Documented** by written, signed, and dated informed consent form
- Trial subject grants access for data to research
- Methods and materials reviewed and approved by IEC &IRBs (and HAs as applicable)
R&D Transparency

Disclosure of clinical trial registry information
www.ClinicalTrials.gov
http://www.who.int/trialsearch

Disclosure of clinical trial results information
Display of Results on ClinicalTrials.gov

Sharing of clinical trial data with qualified researchers
Anonymized patient-level data
Summary

For researched-based pharmaceutical companies

- informed consent of subject
- sensitive handling of genetic information
- compliance with strict data protection regulations

form the basis of their scientific work.
Thank you!