

Enabling Precision Medicine: “Personalized Safety”

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Disclosures

- Employee of Genentech and Roche
- Opinions represented here are personal and not necessarily those of Genentech or Roche



What is “personalized safety”?

- Maximizing the benefit/risk balance:
 - The right medicine for the right patient at the right time
 - Maximize the benefit/risk balance on an individual patient basis
 - Identify patients at risk for certain therapies and guide toxicity management
 - Bring meaningful benefit to patients and society
- Key component of the value proposition for personalized health care:
 - Patients expect it
 - Health authorities require it
 - Science demands it



Examples of genomic biomarkers impacting safety

- Abacavir and HLA B57: associated with life-threatening and severe hypersensitivity reactions (Ziagen USPI 2015)
- Carbamazepine and HLA B1502: associated with Stevens-Johnson Syndrome (Tegretol USPI 2014)
- Clopidogrel and CYP2C19: associated with life-threatening and fatal thrombosis due to incomplete formation of the active agent (Plavix USPI 2016)
- Warfarin and VKORC1 and CYP2C9: associated with variability in dosing (Coumadin USPI 2016)
- **Clinically relevant biomarkers may play an important role in identifying patients at risk, guiding their therapy, and implementing appropriate risk management measures**



Influence of pharmacogenomics on pharmacovigilance



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 September 2015
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Committee for Medicinal Products for Human Use (CHMP)

Guideline on key aspects for the use of pharmacogenomics in the pharmacovigilance of medicinal products

Draft Agreed by Pharmacogenomics Working Party	April 2013
Adopted by CHMP for release for consultation	20 December 2013
Start of public consultation	03 February 2014
End of consultation (deadline for comments)	30 July 2014
Agreed by Pharmacogenomics Working Party	September 2015
Adopted by CHMP	24 September 2015
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*Doing now what patients need
next*

