



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction and objectives

PCWP/HCPWP workshop on personalised medicines

Presented by Guido Rasi on 14 March 2017
Executive Director, European Medicines Agency

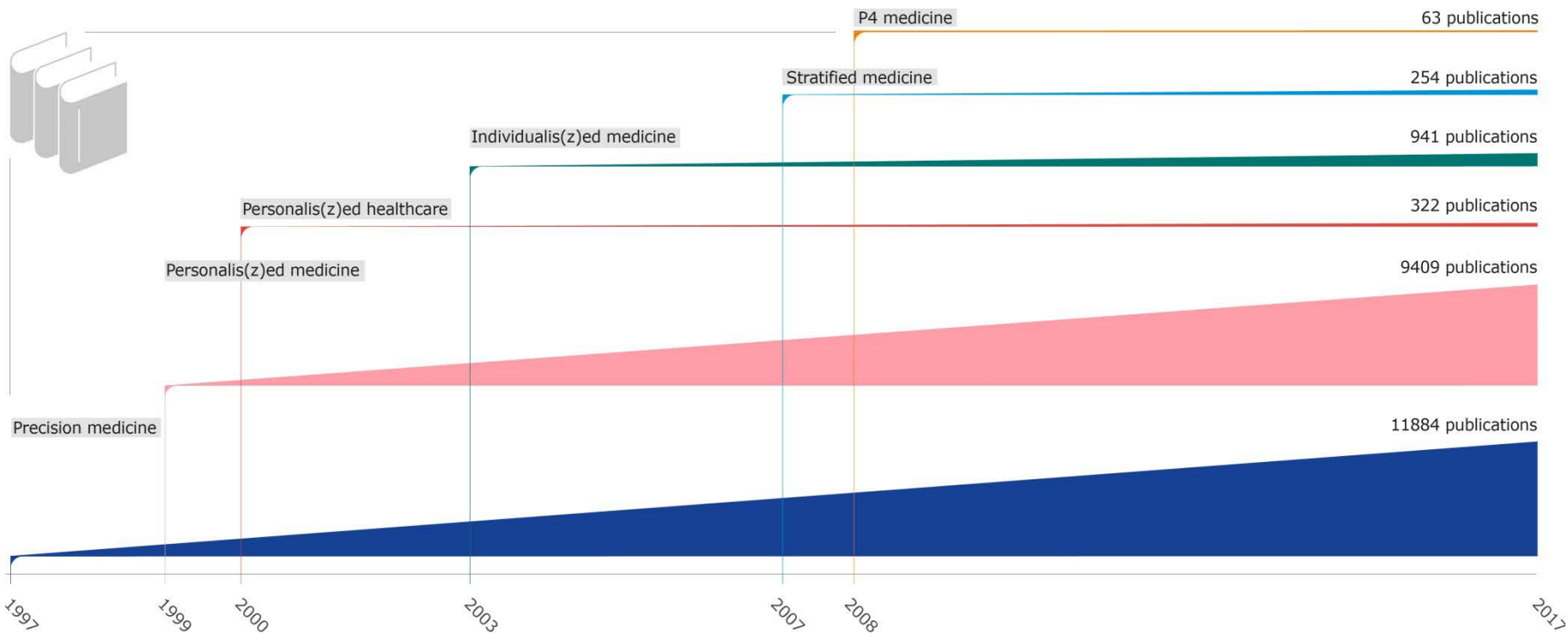
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“It is more important to know what sort of person has a disease than to know what sort of disease a person has.”

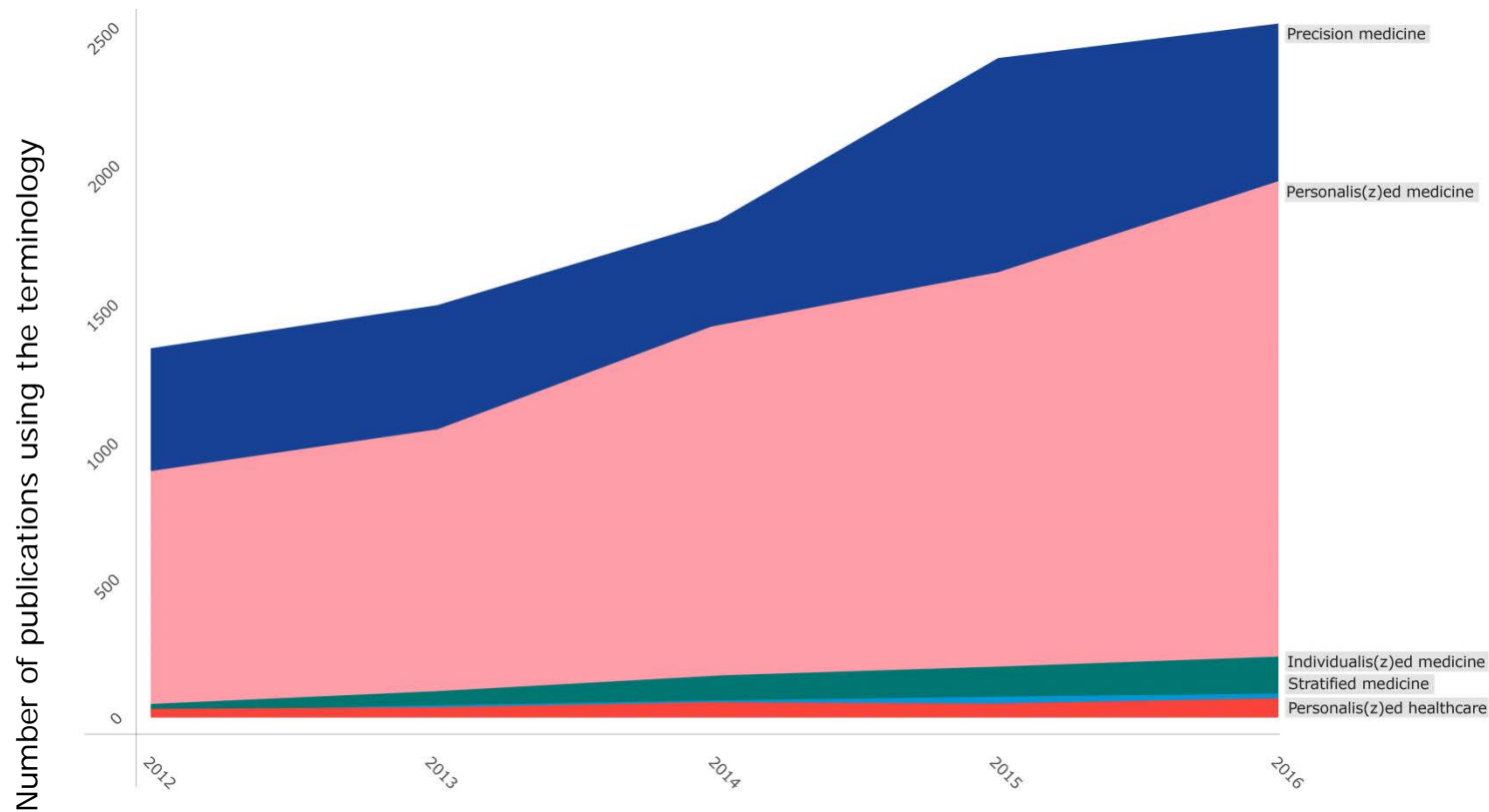
Hippocrates of Kos c. 460–c. 370 BC



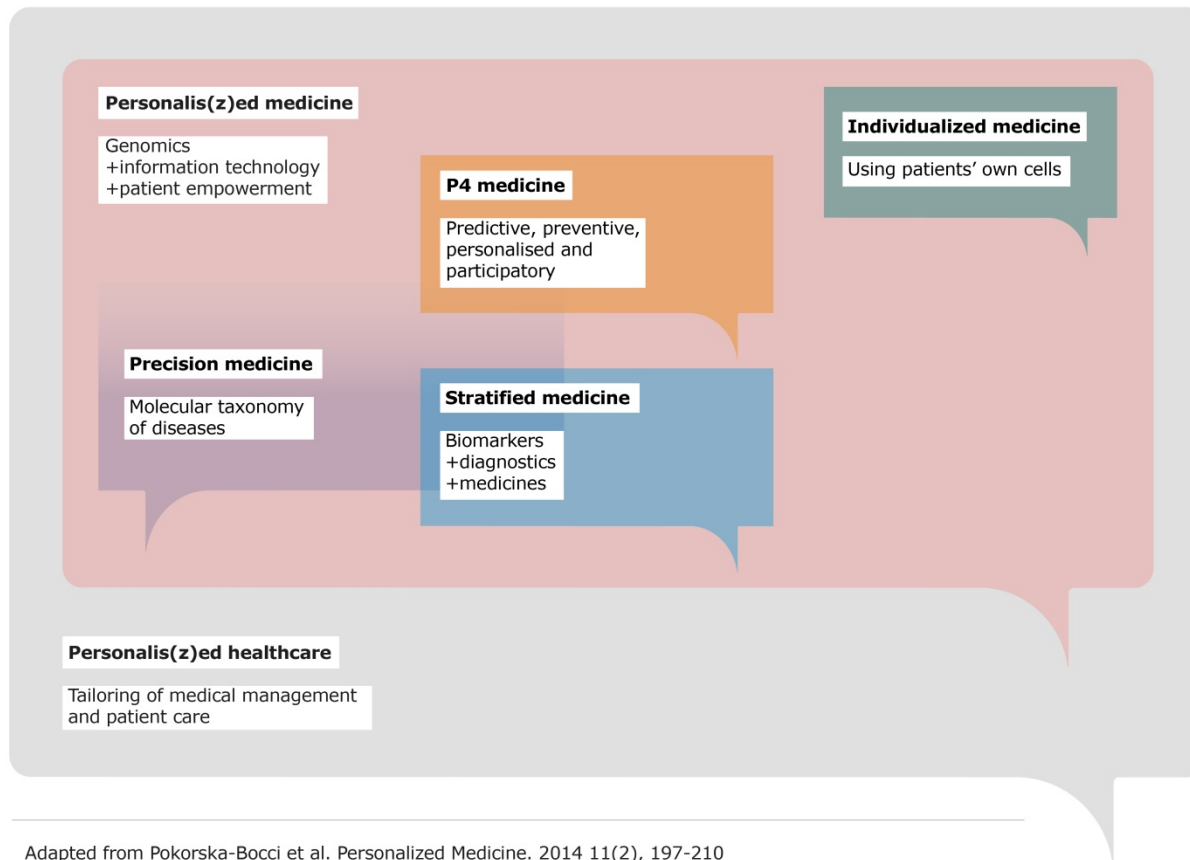
Year of emergence of terminology

PubMed search performed 8 March 2017

Cumulative number of publications using the terminology



PubMed search performed 8 March 2017



Adapted from Pokorska-Bocci et al. Personalized Medicine. 2014 11(2), 197-210



No commonly agreed definition of the term “personalised medicine”.

Widely understood that personalised medicine refers to a:

- medical model using characterisation of individuals’ phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention.
- Personalised medicines relates to the broader concept of patient-centered care, which takes into account that, in general, healthcare systems need to better respond to patients needs.

Council conclusions (7 December 2015)



Council of the
European Union



Fulfilling the potential of personalised medicine relies on:

- the active and participatory dynamics of the patient/healthcare professional relationship;
- an expanded concept of healthcare team;
- adaptability of healthcare systems to meet specific requirements.



Objectives:

- Understand how the European and global landscapes are shaping policy developments;
- Illustrate how the activities of the European Regulatory Medicines Network contribute to personalised medicine, within the existing legislation and regulatory tools;
- Discuss how clinical practice and public participation can support personalised medicine in the context of EU regulatory activities;
- Identify areas requiring attention from EU regulators, patients, healthcare professionals and civil society at large.



Thank you for your attention

Further information

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