

# RA2day

19 November 2021 | Amsterdam | from 12:00 onwards

**12.00 – 13.00 REGISTRATION INCLUDING LIGHT LUNCH**

**13.00 – 13.15 INTRODUCTION TO HID, ZWIERS AND RA2DAY**

**13.15 – 14.30 A DECADE OF NEW ONCOLOGY DRUGS**

The period between 2010 and 2020 marked the increase in the number of authorisations for anticancer drugs and the rise of highly innovative therapies. This lecture presents an overview of these developments providing patients with more options.

**14.30 – 15.15 REGULATORY APPROVALS OF ANTICANCER DRUGS IN THE EU: WHAT DETERMINES PROCEDURAL TIMELINES?**

The key results of a Zwierts study on procedural timelines of marketing authorization applications for anticancer drugs in the EU are highlighted. Specific focus is on special EMA regulatory programs to expedite, scientific advice and company size.

**15.15 – 15.30 THE REGULATORY TOOL BOXES OF EMA AND FDA...AND THE APPLICANT**

This concise briefing will bring the audience up to speed with concepts like breakthrough therapy, fast track, priority review, RMAT, accelerated assessment, conditional approval.

**15.15 – 15.45 COFFEE BREAK**

**15.45 – 16.00 THE “WHAT? WHY? WHEN? HOW?” OF ADVISORY COMMITTEE MEETINGS (US) AND SCIENTIFIC ADVISORY GROUPS (EU)**

This briefing informs on US Advisory Committee Meetings (ACM) and EU Scientific Advisory Groups (SAG). What is their purpose? When and how are they performed?

**16.00 – 16.45 FDA VS. EMA ONCOLOGY APPROVAL TIMES: WHO IS THE FASTEST?**

Differences in submission and total review times for oncology products approved in the EU and US are shown in this presentation. It addresses the impact of regulatory tools applied and of ACM or SAG meetings and how to solve potential delays.

**16.45 – 17.30 FROM FIRST CLINICAL TRIAL TO APPROVAL**

Which are the major determinants of the time between 1st clinical trial and marketing approval? We aim to show the complete picture and factors delaying and optimizing total time for anticancer drugs to get to the market.

**17.30-17.40 THANKS FOR YOUR FEE**

The registration fee will be donated to NKI.

**17.40 DRINKS AND NETWORKING**



Join us in celebrating 10 years of solid RA/PV service