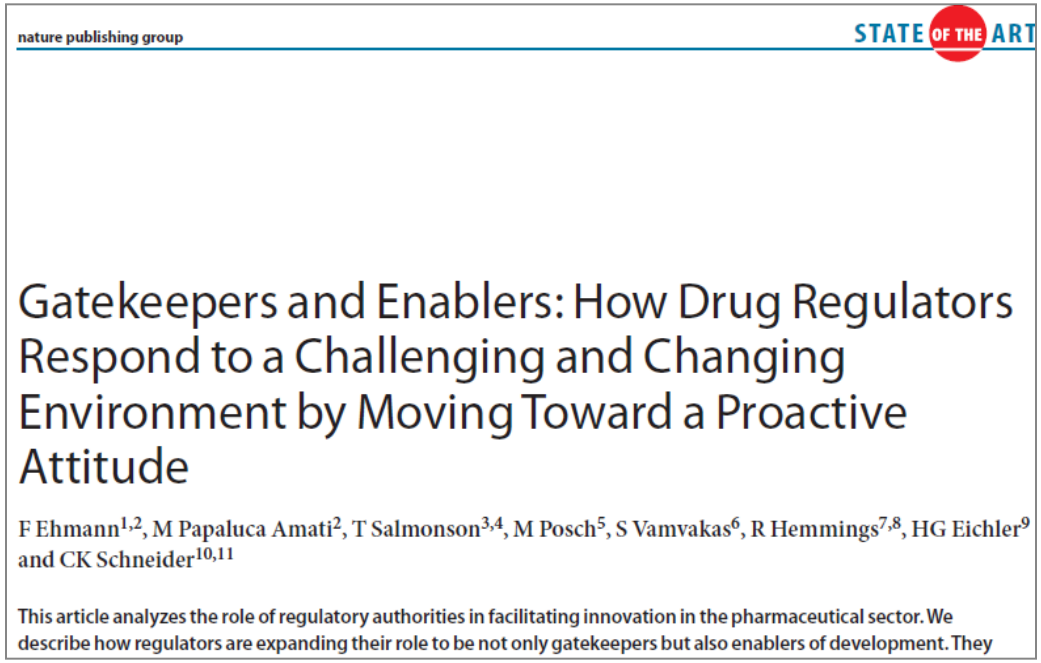
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Coalition Against Major Diseases and FDA 2015 Annual Scientific Workshop

FDA White Oak Campus

Manuel Haas on 15th October 2015
Head of Central Nervous System Office, Evaluation Division, EMA

Innovation & collaboration - A shared focus for EMA and CAMD



nature publishing group

STATE OF THE ART

Gatekeepers and Enablers: How Drug Regulators Respond to a Challenging and Changing Environment by Moving Toward a Proactive Attitude

F Ehmann[1,2], M Papaluca Amati[2], T Salmonson[3,4], M Posch[5], S Vamvakas[6], R Hemmings[7,8], HG Eichler[9] and CK Schneider[10,11]

This article analyzes the role of regulatory authorities in facilitating innovation in the pharmaceutical sector. We describe how regulators are expanding their role to be not only gatekeepers but also enablers of development. They

Alzheimer's disease - Another shared focus for EMA and CAMD

Workshop on Alzheimer's disease

Final programme

24-25 November 2014

European Medicines Agency, London, United Kingdom

Room 3A

COMMENT

The European Medicines Agency's strategies to meet the challenges of Alzheimer disease

Manuel Haas[1], Valentina Mantua[2]*, Marion Haberkamp[3]*, Luca Pani[2], Maria Isaac[1], Florence Butlen-Ducuing[1], Spiros Vamvakas[1] and Karl Broich[3]*

Regulatory agencies have a key role in facilitating the development of new drugs for Alzheimer disease, particularly given the challenges associated with early intervention. Here, we highlight the strategies of the European Medicines Agency to help address such challenges.

NATURE REVIEWS | DRUG DISCOVERY

HMA Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

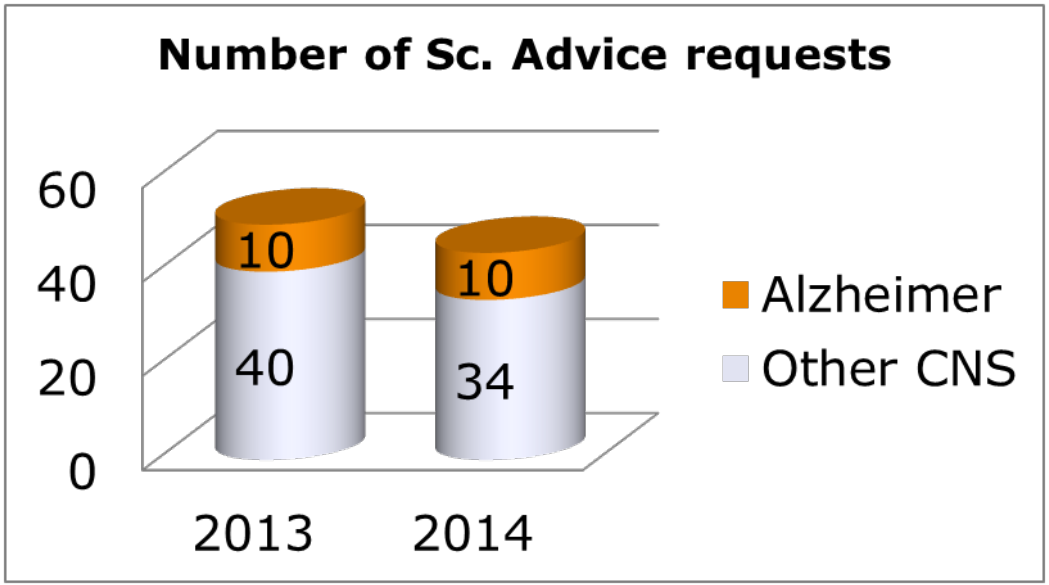
27 March 2015
EMA/MB/151414/2015

EU Medicines Agencies Network Strategy to 2020

Working together to improve health

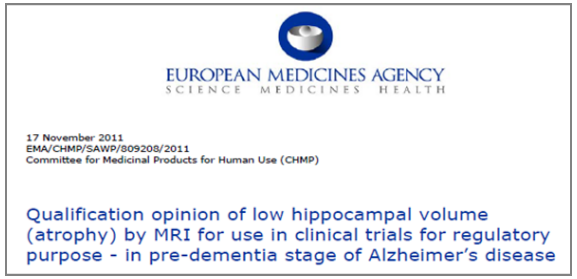
The network will explore other areas that could benefit from regulatory initiatives in the next five years such as dementia. Also, the network's contribution to ensuring that the needs of special populations

High activity in Scientific Advice



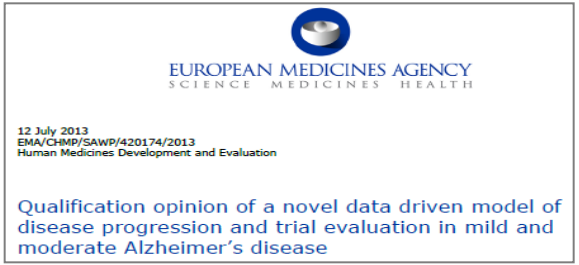
- Pipeline activity
- Value of Sc. Advice
- Need for new solutions for CTs in AD?

High activity in the Qualification Procedure


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 November 2011
EMA/CHMP/SAWP/809208/2011
Committee for Medicinal Products for Human Use (CHMP)

Qualification opinion of low hippocampal volume (atrophy) by MRI for use in clinical trials for regulatory purpose - in pre-dementia stage of Alzheimer's disease

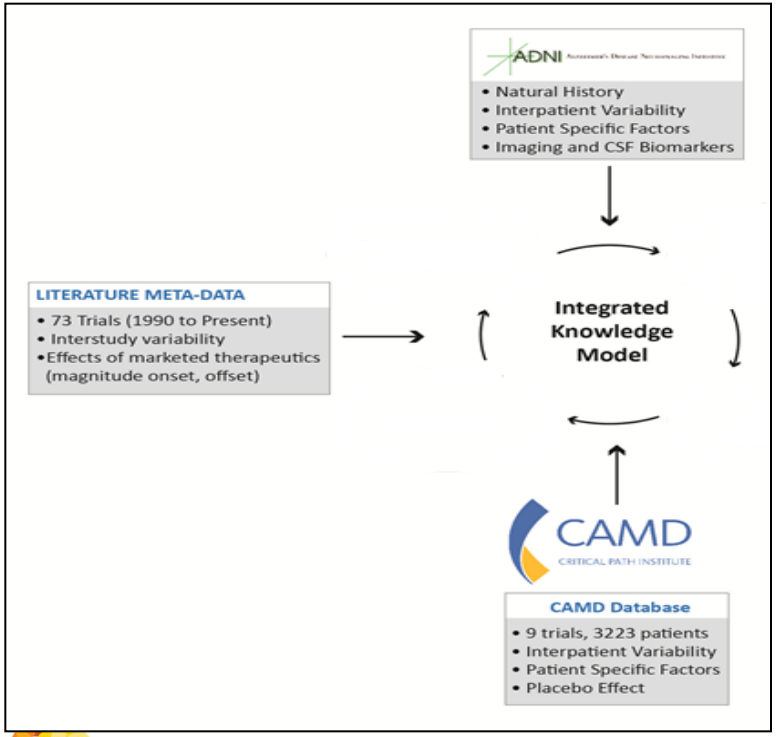

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2013
EMA/CHMP/SAWP/420174/2013
Human Medicines Development and Evaluation

Qualification opinion of a novel data driven model of disease progression and trial evaluation in mild and moderate Alzheimer's disease

- Introduced a new opportunity for innovators in 2008
- Outcome: Qualification Advice or Qualification Opinion
- Considerable experience in Alzheimer's Disease:
  - 16 qualification advices / CAMD pCOA tool
  - 4 Qualification opinions for biomarkers for enrichment / CAMD low hippocampal vMRI
  - Qualification opinion for CAMD disease and trial model for mild to moderate AD

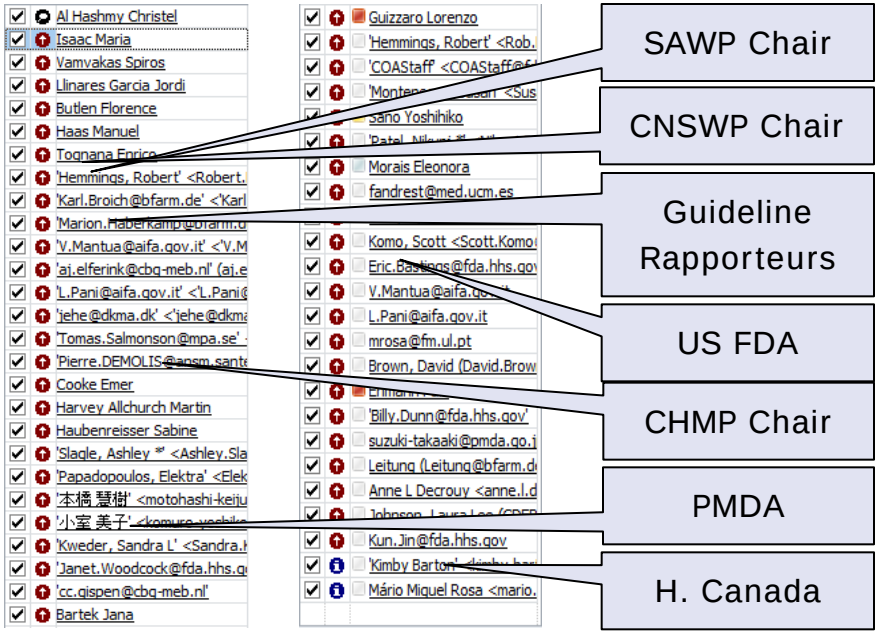
Data sharing & integration for Model Development



- Data to inform natural history of AD
- Data from multiple sponsors to inform control arm elements
  - -Placebo response
  - -Drop-out
  - -Covariate effects
- Literature meta data to inform drug responses
  - -Marketed Symptomatic Agents
  - -Magnitude, onset of effect, offset

Collaboration outside procedures - interactions over the last 12 months

The example of the 'EMA Data sharing initiative'



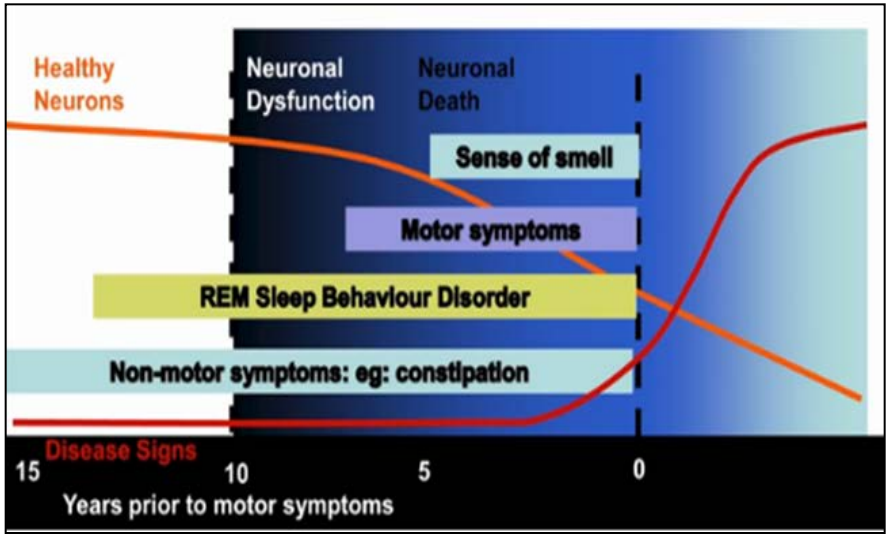
- Informal
- Maintain dialogue w/ developers
- Learn from experience
- Inform future regulatory advice/ guideline (under revision)
- Issues discussed include:
  - Target population
  - Enrichment
  - Dose selection
  - Relation BMs / clinical outcomes
  - Safety
  - Disease modification

Fostering global regulatory efficiency with partners

厚生労働省
pmda
FDA
swissmedic

Parkinson's Disease: A growing case for early intervention

One new approach being considered is to test some new drugs at an early stage in the condition. Conventionally, new drugs are tested in patients with advanced disease when existing treatments can no longer control the symptoms. But the scientific view of many new treatments



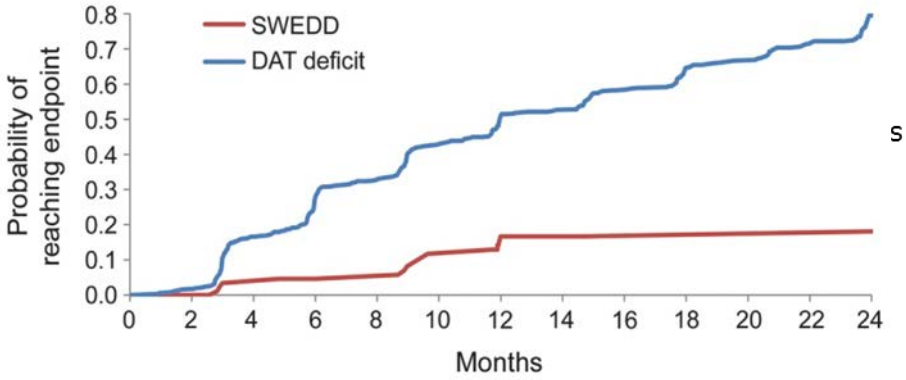
Source: Dr Richard Wade Martins; Oxford Parkinson's Disease Centre (Nov. 2013)

Challenges of disease progression and heterogeneity – CAMD focus on Parkinson's Disease

Longitudinal follow-up of SWEDD subjects in the PRECEPT Study.

Marek K[1], Seibyl J[2], Eberly S[2], Oakes D[2], Shoulson I[2], Lang AE[2], Hyson C[2], Jennings D[2]; Parkinson Study Group PRECEPT Investigators.

Figure



Need for dopaminergic therapy in SWEDD and DAT deficit subjects

- Variable subpopulations recruited into randomized clinical trials
- Moving forward: CAMD's proposed roadmap focused on enrichment strategies in early motor PD and on disease modelling
- EMA Qualification Advice ongoing for DAT SPECT

Thank you for your attention

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact