

# Role of HESI in Adjuvants and Autoimmunity

Jan Willem van der Laan

Sarah Gould

# Adjuvants and Autoimmunity

- Why as an emerging issue?
- New adjuvants now introduced in US and Europe
  - MPL and aluminium in HPV vaccine
  - Oil-in water emulsions in 3 pandemic vaccines
    - MF59 in Focetria (Novartis)
    - AS03 in Pandemrix and Arepanrix (GSK)
    - AF03 in Humenza (Sanofi-Pasteur)

# Discovery and development of adjuvants

- Some developed by Big Pharma with preventive vaccines
- Many small companies
- Universities and spin-off companies

# HESI Role (1)

- Vaccines included in Scientific Mapping 2009 with
  - Relative high impact
  - Immediate (short-term) impact

# HESI Role (2)

- Cooperation between companies and other parties needed.
  - Adjuvants always secondary in MAA, focus is on clinical efficacy of the vaccine
  - Adjuvants sometimes complex mixtures with properties difficult to share
- Association with Immunotox Technical committee?

# HESI Role (3)



- Tripartite
  - Industry, government, academia
  - Government needs more confirmation of safety
  - Academia has a deep knowledge of interaction with the immune system, but with very diverse concepts
- Challenge to bring the parties together

# Present status of the field

- Scientific exchange in vaccine field organized in various commercial meeting organizations
  - Terrapin: World Vaccine Congresses
  - Meeting Management: MVADS
  - Phacilitate Vaccine Forum
  - And some others
- Just exchange of information
- No progress by intense discussions and recommendations
- No common regulatory input.

# Role of WHO

- Focus on specific vaccines in the interest of developing countries
  - Recent projects:
    - Yellow fever
    - Dengue
- Adjuvants: Organisation of a Wellcome Trust supported workshop:
  - September 1-2, 2010



# Role of HESI

- Big pharma in vaccines are members
  - Sanofi-Pasteur
  - GSK
  - Novartis
  - Pfizer (Wyeth)
- Academia involved in ITC
- Government
  - EU/SWP and VWP
  - FDA/CBER to be involved
  - MHLW proposed “vaccines” as a topic in ICH

# Workplan (1)

## September 2010 – september 2011

- Via Telecons and e-mail
  - Making a list of issues and literature search to find key-partners in academia
  - Preparing questions to be discussed.

# Workplan (2)

September 2011 – september 2012

- Workshop with exchange of recent views and state of the art knowledge
- More integrating views
- Problem-solving on key questions
- Recommendations where possible
- Further plans for cooperative research in a Vaccine Technical committee