



ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA



Rethinking the role of Social Sciences and Humanities (SSH): towards a reflective and generative perspective

Francesco Ciabuschi, PhD

Professor in International Business

Research Director

Dept. Of Business Studies,

Uppsala University (Sweden)



UPPSALA
UNIVERSITET

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Emilia-Romagna Region

Eu Office



WORK GROUP

2. Health, care and education:

Panelists: Francesco Ciabuschi, (University of Uppsala);
Mihaela Ionescu (ISSA); Monica Menapace (DG Research & Innovation);
Arianna Lazzari, *rapporteur* (University of Bologna)

MY PRESENTATION TODAY:

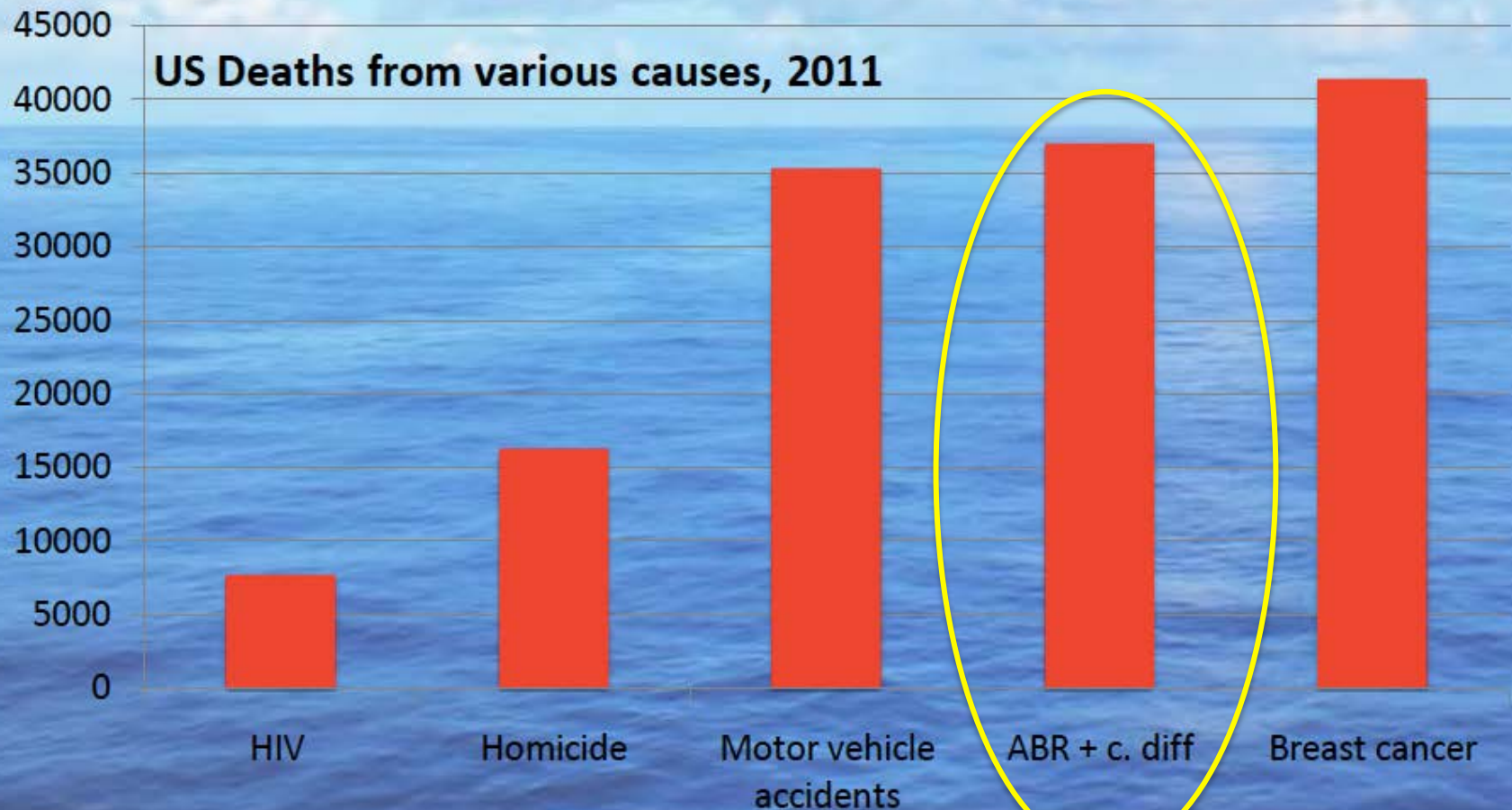
- **THEME: GLOBAL HEALTH**
- **SPECIFIC RESEARCH TOPIC: ANTIBIOTIC RESISTANCE**
- **IMI RESEARCH PROJECT: DRIVE-AB**

The starting point ...

- Growing Antibiotic Resistance
- Global access problem
- No new drugs!

ND4BBB

A Serious Problem



Source: National Vital Statistics Report (NVSr) "Deaths: Final Data for 2011." Data for ABR + c. diff. is from CDC, Antibiotic Resistance Threats in the US, 2013

Why so few new drugs?

Three big problems

1. It's hard to discover new antibiotics
2. It's hard to develop new antibiotics
3. The economic value of a new antibiotic to a developer can be close to zero

And, there is no simple solution

4. Fixing this requires us to see it as an ecosystem

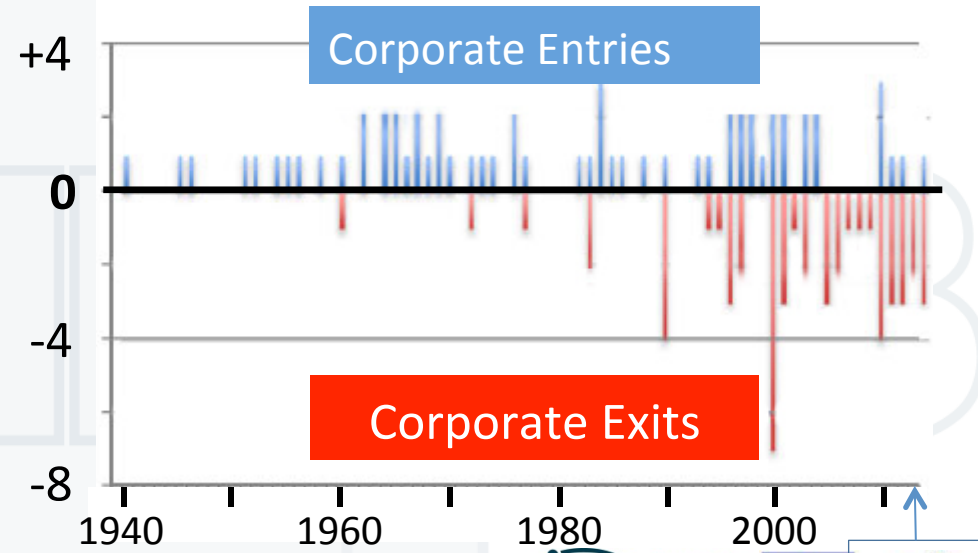
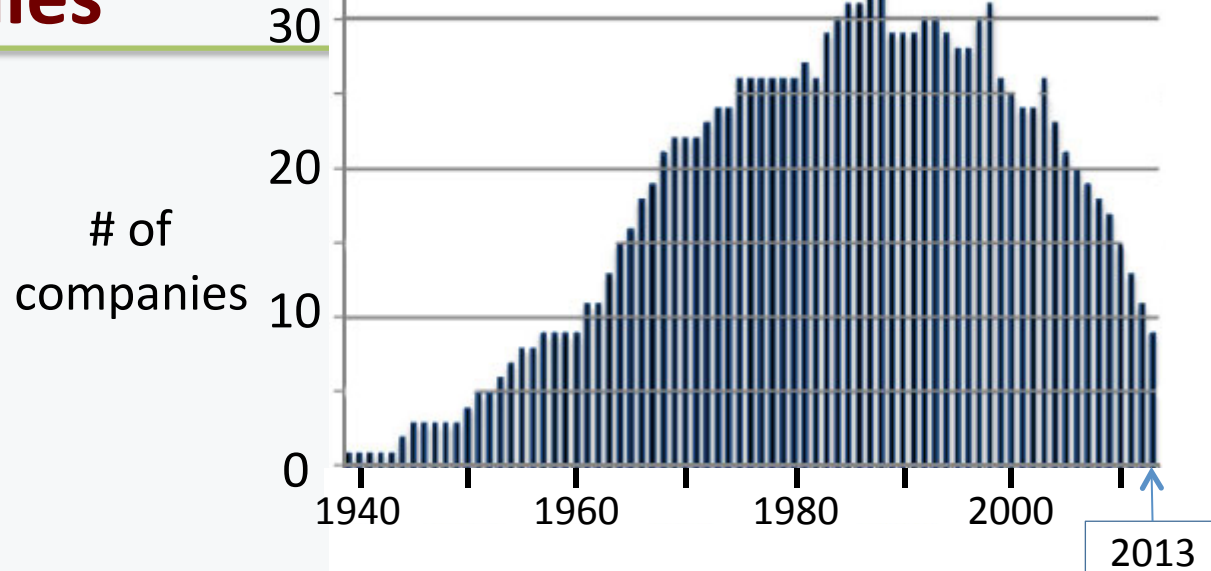
Very few companies still in the game!

Over the past 15 years (1998-2013)

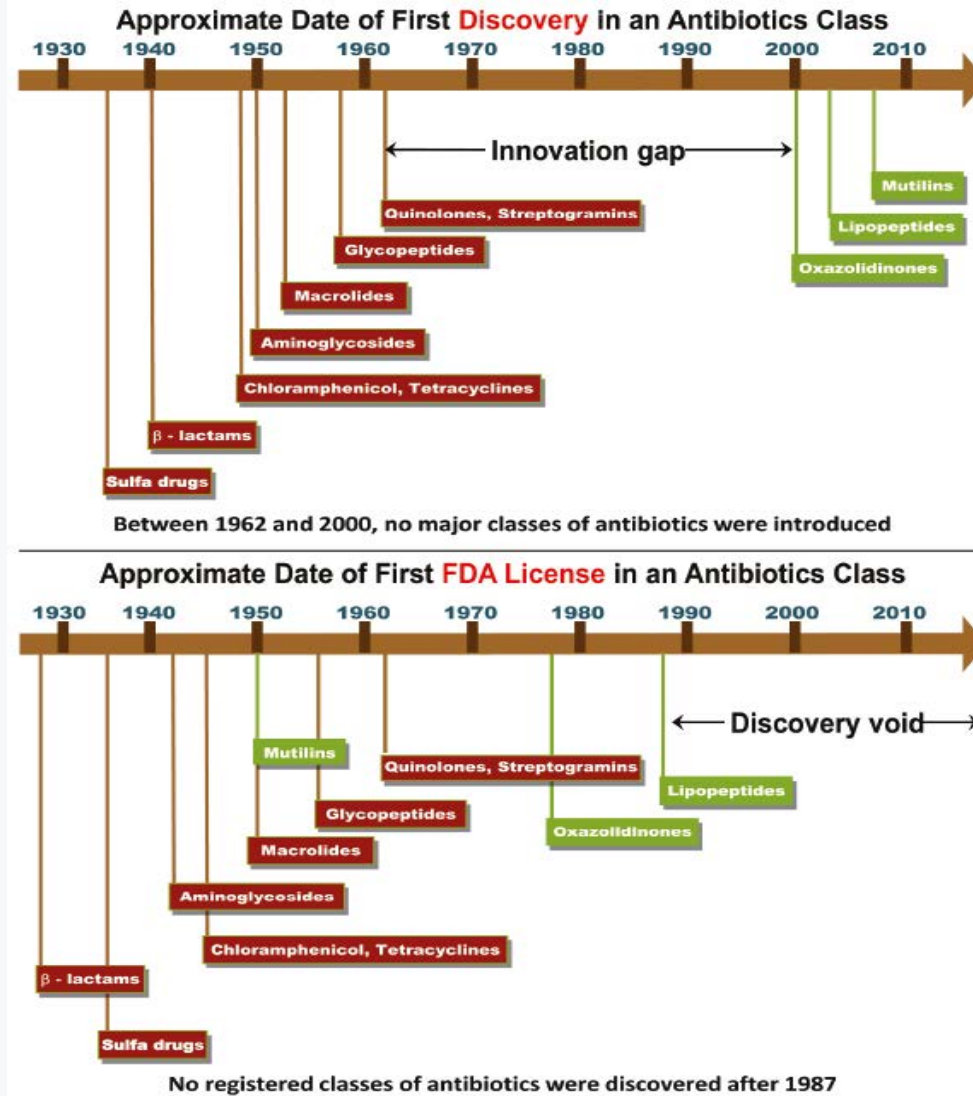
- 14 entries
- 36 exits

Graphic adapted from Kinch MS et al.
Drug Discovery Today, July 2014.

Active corporate anti-bacterial programs



Innovation gap and discovery void



Global leadership is active!

2003 et seq: IDSA: “Bad Bugs, No Drugs”



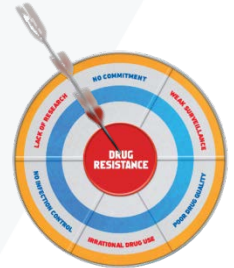
17 Sep 2009: (EU) Swedish presidency

- “Innovative Incentives for Effective Antibacterials”



7 April 2011: WHO World Health day on AMR

- “No action today, no cure tomorrow”



17 Nov 2011: (EU) ND4BB program

- PPP for Discovery & Development



2011 forward: (US & EU) FDA & EMA

- A steady stream of new guidances



2012: (US) GAIN Act

3-4 Oct 2013: (EU) Chatham House Conference

- “Antimicrobial resistance: Incentivizing Change Towards a Global Solution”



2014: (US) PCAST Report

2012-05-25: ND4BB takes flight



Innovative Medicines Initiative

IMI-GB-<decision ref>

6th Call for proposals 2012

Innovative Medicines Initiative

COMBATING ANTIBIOTIC RESISTANCE:

NEWDRUGS4BADBUGS (ND4BB)

6

Wall Street
Journal

EU Pledges Funds for Finding Antibiotics to Fight Superbugs

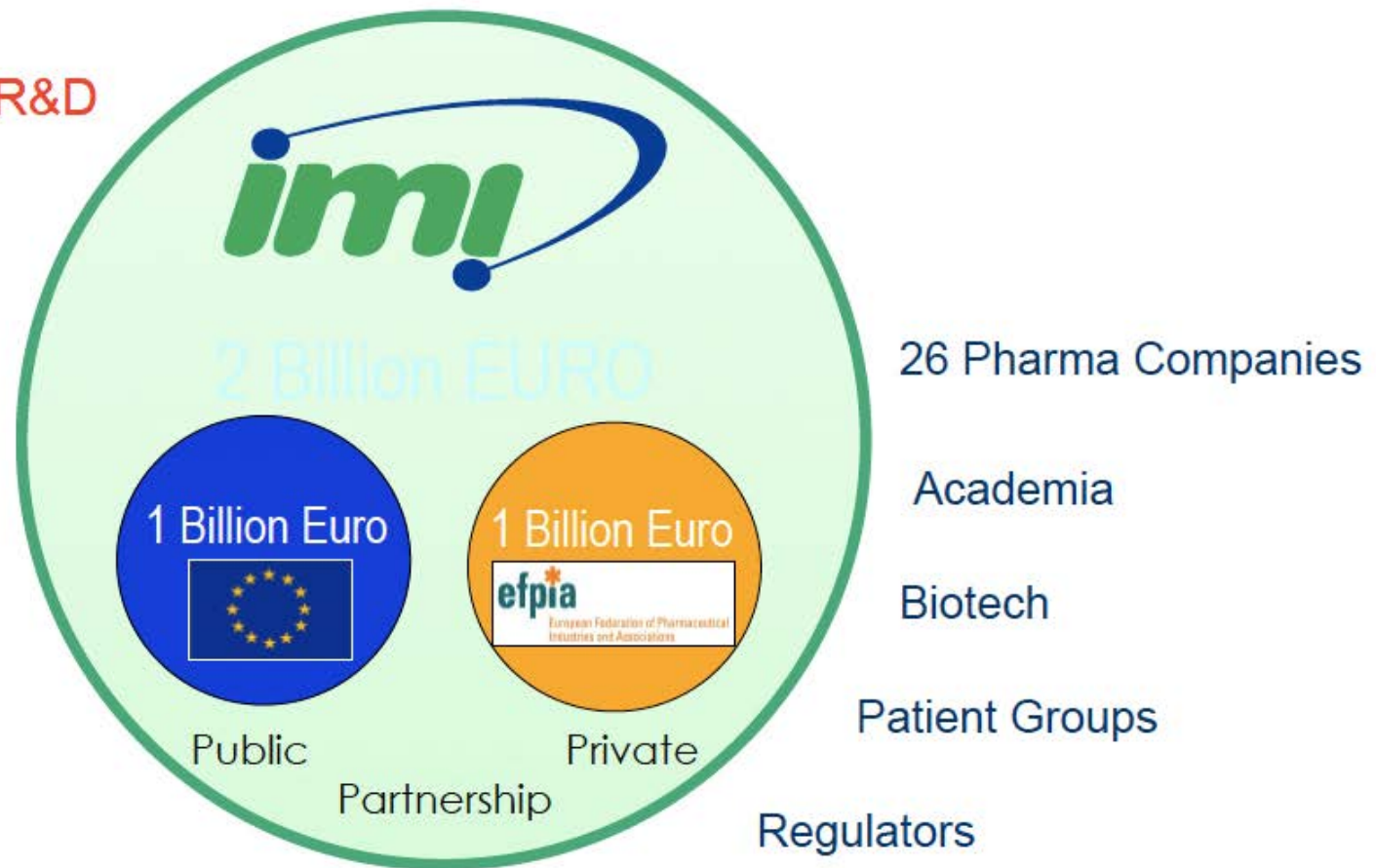
The Lancet

Europe to boost development of new antimicrobial drugs

A European public-private partnership has launched a €224 million research initiative to speed up the development of much-needed new antimicrobial drugs. Tony Kirby reports.

Innovative Medicines Initiative (IMI)

Focused on R&D



Delivering practical solutions to everyday challenges in R&D

IMI – ND4BB

Cross-project communication & collaboration

COMBACTE (Topic 1)
Enabling clinical collaboration and refining clinical trial design- Clinical dev. of GSK1322322 and MEDI4893

TRANSLOCATIO N (Topic 2)
Research on penetration and efflux in Gram-negative bacteria-Data hub and learning from R&D experience

ENABLE (Topic 3)
Discovery and development of new drugs combatting Gram-negative infections

DRIVE-AB (Topic 4)
Driving re-investment in R&D and the responsible use of antibiotics

COMBACTE CARE (Topic 5)
Clinical development of antibacterial agents for Gram-negative, antibiotic-resistant pathogens

COMBACTE-MAGNET (Topic 6)
Systemic molecules against Health-care-associated infections due to clinically challenging Gram-negative pathogens

(Topic 7)
Inhaled anti-bacterials in cystic fibrosis and non-cystic fibrosis bronchiectasis

Development-focused

Discovery-focused

Economics & stewardship

Development-focused (Gram-negative infections)

ND4BB Information Centre

All data generated is submitted and made accessible to all partners

DRIVE-AB

**Driving reinvestment in R&D for antibiotics
and advocating their responsible use**

(<http://drive-ab.eu/>)

Prof. Francesco Ciabuschi (Uppsala University)

DRIVE-AB leading group and WP2 leader

DRIVE-AB

Developing new economic models to incentivise antibiotic discovery and development activities while safeguarding the efficacy of antibiotics by researching and advocating their appropriate use.

October 2014 – September 2017

IMI grant of about 9.6 ML €

Some core activities/objectives of Drive AB

1. Develop **antibiotic valuation models** (the cost for society?)
2. Assess the specific **bottlenecks and risk perceptions** affecting the development of antibiotics
3. Assess **reward and business models in other industries** that promote conservation or that mirror key features
4. Gather a set of **public health policy options** to encourage stewardship
5. Examine the impact of potential **disruptive technologies** (e.g. diagnostics)
6. Develop and assess **alternative reward and business models**
7. Develop an **implementation plan**

Key Deliverables

- Promising reward models – an interactive meeting with stakeholders (geographically diverse policymakers (health, finance), MNCs, SMEs, venture capital reps, academics, etc.) presenting promising models from other industries and new models for discussion and feedback; followed by a detailed meeting report
- Stewardship policy recommendations – an interactive meeting with stakeholders (geographically diverse policymakers (agriculture, health), regulatory experts, professional societies, patient groups, etc.) presenting geographically specific stewardship policies for discussion and feedback; followed by a detailed meeting report

Key Deliverables

- Validated economic models – a report as well as the agent-based modeling tool with all tested reward models and their outputs
- Implementation plan – this will include a timeline, cost estimation to implement the recommendations and proposed responsible party; this will be highly integrated with ongoing efforts, such as:



TATFAR



DRIVE-AB consortium



The British Society for Antimicrobial Chemotherapy	UK
Center for Anti-Infective Agents	Austria
Chatham House	UK
London School of Economics and Political Science	UK
Norwegian Institute of Public Health	Norway
Tel-Aviv Sourasky Medical Center	Israel
Radboud University Nijmegen Medical Centre	Netherlands
University of Antwerp	Belgium
University of Geneva	Switzerland
University of Heidelberg	Germany
University of Lorraine	France
University of Rijeka	Croatia
University of Strathclyde	UK
University of Tübingen	Germany
Uppsala University	Sweden
Wageningen University	Netherlands

Astellas Pharma Europe Ltd
 AstraZeneca
 Cubist Pharmaceuticals
 F. Hoffmann-La Roche Ltd
 GlaxoSmithKline R&D
 Pfizer Ltd
 Sanofi-Aventis R&D

ND4BB

What is special about DRIVE-AB?

- **Team!**
 - Top scholars + company experts + public and private institutions representatives
- **Innovative** models to incentivize antibacterial drug R&D based on realistic data
- EFPIA Partners and many different stakeholders are involved in every part of the DRIVE-AB project
- High potential **social** impact!
- It includes:
 - Responsible use of antibiotics
 - Global scope
 - Access

The team – interdisciplinary!

- Medicine
- Global Health
- Biotech
- Pharmaceuticals
- Business & Management
- Innovation Management
- Economics
- Law
- Informatics
- STS
- Ethics
- Political Science

Expected impact on:

- Policy makers
 - Public officers
 - Academics in different disciplines
 - Practitioners (different kinds)
 - Society!
- ✓ Worldwide (because of the approach + the collaborations with global actors)

Thank you!

Prof. F. Ciabuschi

francesco.ciabuschi@fek.uu.se

ND4BBB