



Science For A Better Life

NINDS workshop:  
Optimizing the predictive value of  
preclinical research;  
June 20-21, 2012, Washington

# Experiences in collaborating with academia

## **Khusru Asadullah, MD**

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Professor of Dermatology and Immunology, University Hospital Charité, Berlin



## Overview

- Challenges in Pharmaceutical industry
- General aspects of Partnerships
- BHC approach to Partnerships
- Summary

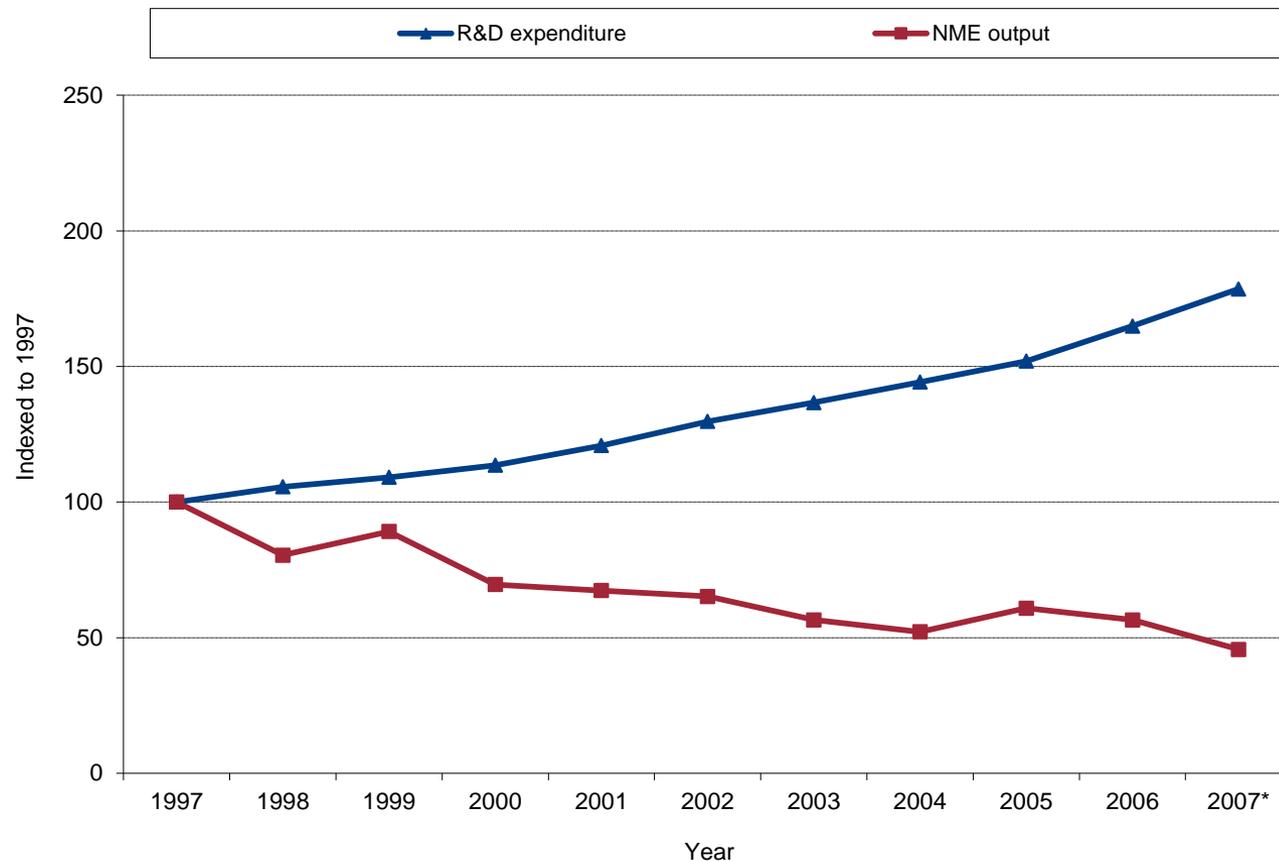
# The pharmaceutical industry is facing unprecedented change around the globe



## Environmental Pressures

- Increasing regulatory and safety requirements
- Generics
- Pricing pressures
- Payers eclipsing doctors as decision makers
- Shifting portfolios from primary care to specialist-driven therapies
- Increasing R&D costs
- Slowing industry innovation

# The Innovation Challenge in Pharmaceutical Industry



**Rising R&D expenditures but fewer new drugs approved**

→ lack of innovation

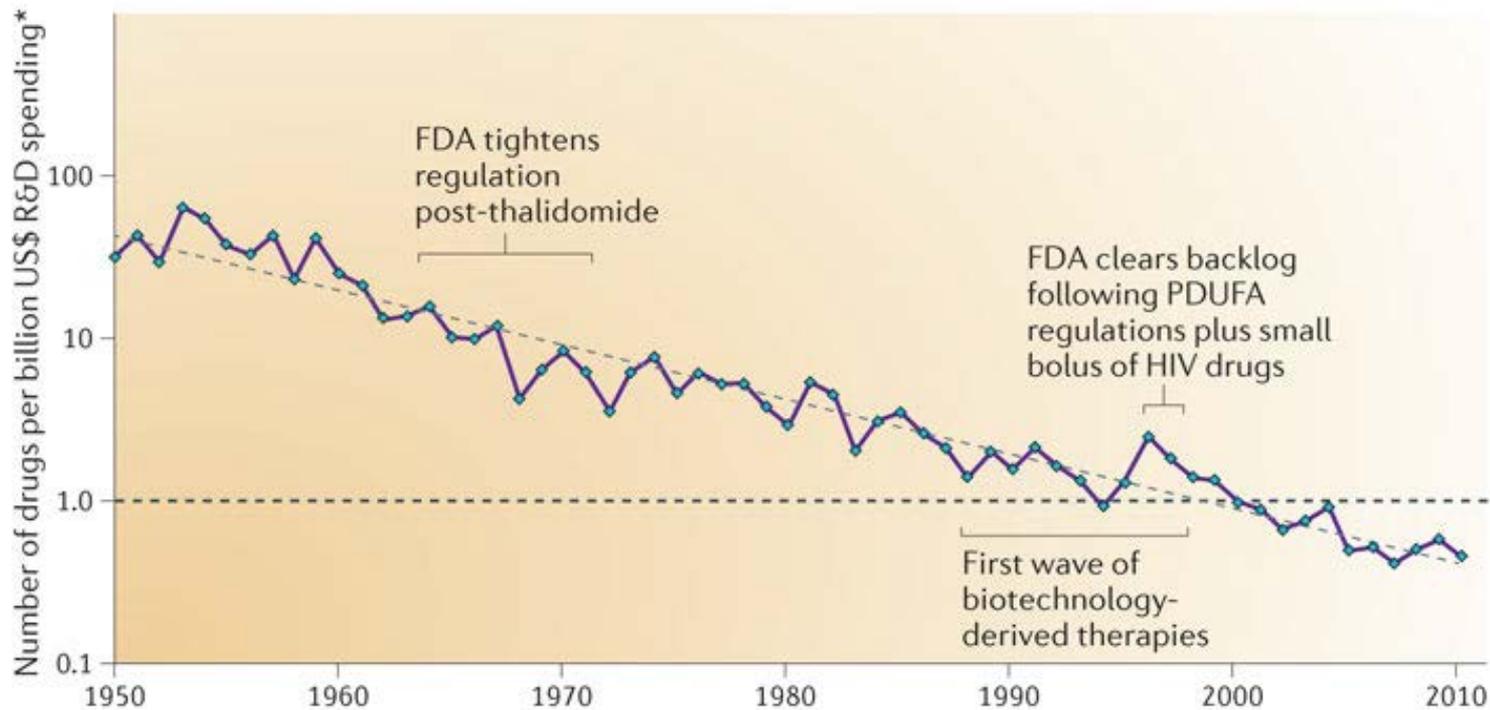
→ high costs

\* The development time data point for 2007 includes data from 2006 and 2007 only  
Source: CMR International & IMS Health

# Challenges in Drug Discovery



**a Overall trend in R&D efficiency (inflation-adjusted)**

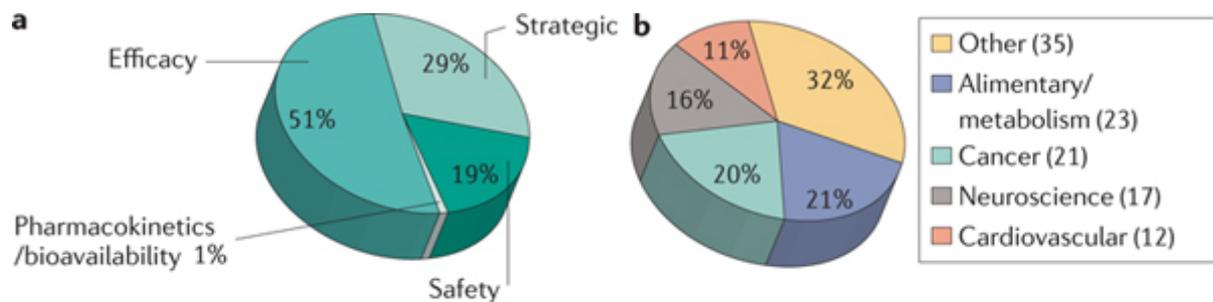


➔ The number of FDA approved drugs per billion US dollars of R&D spending has halved approximately every 9 years

*Scannell et al., 2012 (11) Nature Reviews Drug Discovery*

# High and increasing Phase II failures

.... **success rates** for new development projects in phase II have fallen from 28% to **18%**, with insufficient efficacy as the most frequent reason

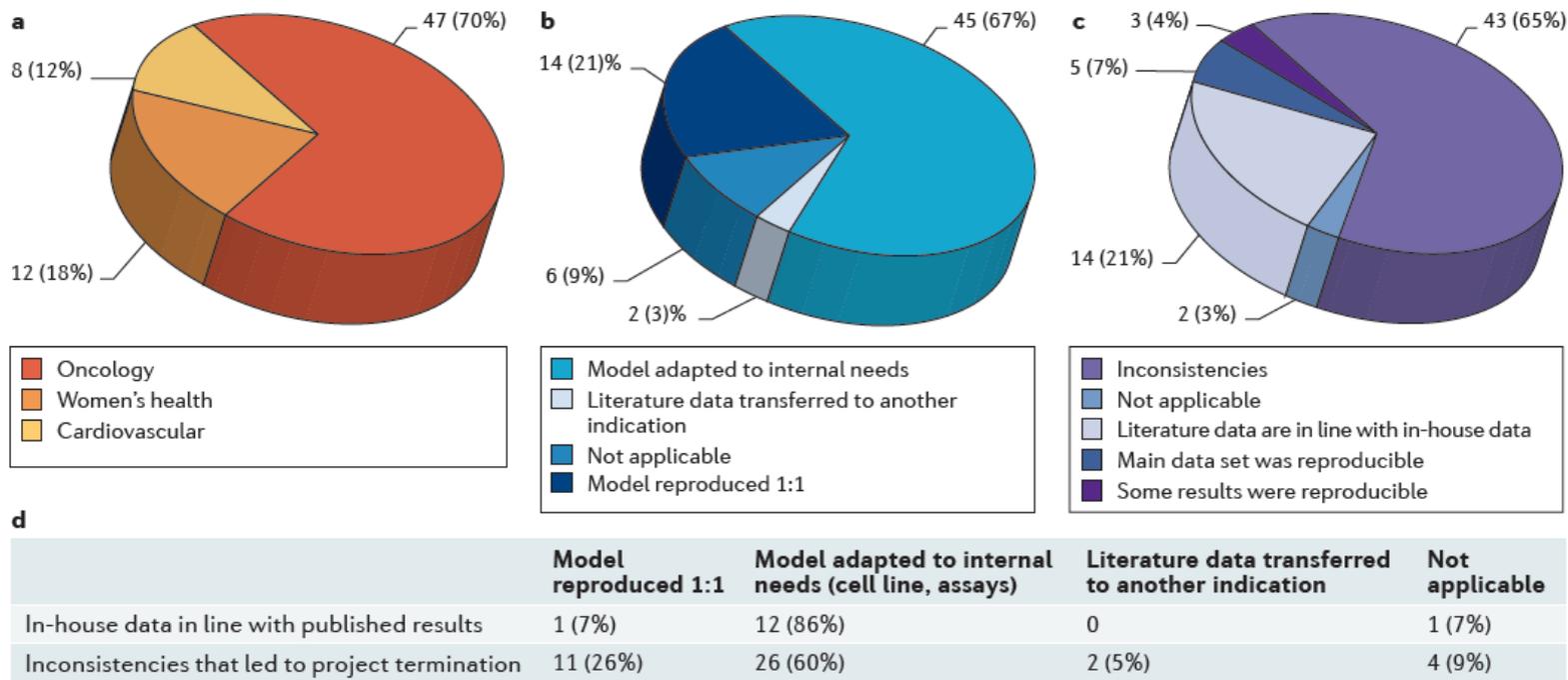


Nature Reviews | Drug Discovery

The 108 failures are divided according to reason for failure when reported (87 drugs) (a) and therapeutic area (b)

John Arrowsmith: Phase II failures: 2008-2010: Nature Reviews Drug Discovery Volume 10, May 2011, 1

# Reproducibility of published data



NATURE REVIEWS | DRUG DISCOVERY

**a** | Distribution of projects analysed in this study. **b** | Several approaches were used to reproduce the published data. **c** | Relationship of published data to in-house data. **d** | A comparison of model usage in the reproducible and irreproducible projects is shown. **n=67 inhouse projects**

Prinz F, Schlange T, Asadullah K: Nature Rev Drug Dis 2011; 10 (9)

# Questions



- **What are factors influencing reproducibility rate?**
- **Can it be that we are wrong?**
- **What are the reasons for the low reproducibility?**
- **What are our conclusions ?**



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# Different categories of Collaborations



# Value of Alliances



Organizations and people only actively engage in collaboration when the benefit they derive is greater than the time and effort it takes to collaborate

$$\text{BENEFIT OF COLLABORATION} = \frac{\text{VALUE OF RESOURCES LEVERAGED}}{\text{TIME AND EFFORT TO COLLABORATE}} > 1$$

HOW DO WE MAXIMIZE THIS RATIO?

*Modified from "Collaborative Networks are the Organization"*

*By Jeffrey Shuman and Janice Twombly © 2009*

# Fostering Collaborative Skills and Mindset



- Analysis of Core Competencies for Alliance and collaboration management revealed 10 Core Competencies which can be categorized in 4 main areas

## Relationship management

- Peer relationships
- Negotiating
- Directing others
- Integrity and Trust

## Conflict management

- Conflict management
- Problem solving

## Positioning skills

- Organisational agility
- Innovation management

## Cross Cultural Skills

- Managing Diversity
- Cross cultural Sensitivity

➔ Initiation of tailored trainings to foster collaborative skills and competencies



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# Innovative Partnership Models@BHC

- Models applied have to match the question to be addressed
- BHC Innovation sourcing → 2- Level Strategy

## Strategic Alliances with key centers of Expertise

- Alliances with selected centers
- Know-how interchange
- Joint Projects
- Example: DKFZ

Risk and reward sharing  
Joint financing 1mio/a each



**dkfz.** DEUTSCHES  
KREBSFORSCHUNGSZENTRUM  
IN DER HELMHOLTZ-GEMEINSCHAFT



## Broad Search Strategy

- Connect to know-how on a world-wide basis
- Useful to address specific questions (e.g. animal models; novel targets)
- Clear processes; filtering
- Example: Grants4targets



# Innovative partnership models – our “Grants4Targets” Initiative



## Background

- Numerous targets exist, but are “invisible” for us
- The knowledge outside > inside



## Idea

- Join forces with academia and biotech start ups to translate innovative targets into drugs
- Provision of grants to evaluate and validate novel targets – “Grants4Targets”

## Approach

- Easily accessible Internet site and submission tool
- Low bureaucratic burden for both partners
- Clear communication on “needs” – what are we looking for ?
- Fast processing of requests



# Grant types within G4T program



**Support Grants** (€5,000-10,000) to further advance research on targets or biomarkers that are at a very early stage of discovery; fixed grant approval letter;

**Focus Grants** (€10,000-125,000) for more mature ideas, e.g. to address specific aspects of a target or biomarker as a first step towards transferring it to the drug-discovery process; fixed grant approval letter;

**IP rights remain with the applicant**

## Bayer HealthCare: Science For A Better Life

Pharmaceuticals

Contact us | FAQ » Bayer Group



### FROM TARGETS TO NOVEL DRUGS



Grants4Targets

#### Publication

Lesli M. et al. (2011) *Drug Discov Today*, 16, 288-292

"Grants4Targets – an innovative approach to translate ideas from basic research into novel drugs"

[read more >>](#)

#### Community feedback

Dr. Kallio, University of Turku, Finland:

"This program is a fantastic opportunity to forward pre-clinical target discovery and validation. It can serve as an important bridge funding or allow execution of a few critical assays."

[read more >>](#)

Home



What are we looking for



What are we offering



Why apply?



Application & submission process



Submission



Status report



Community feedback



### Welcome to our "Grants4Targets" initiative

Our company's mission is to provide new treatment options for diseases with high unmet medical need.

✓We are committed to innovation and to translating ideas from basic research into novel drugs.

✓We are dedicated to fostering collaborations with excellent academic groups and start-ups.

✓We strive for pooling expertise on common research topics and joining forces for mutual benefit.

Bayer HealthCare allocates grants for the exploration of attractive, novel **drug targets** in the fields of:

- **Oncology**
- **Gynecology**
- **Cardiology**
- **Hematology**

We look forward to hearing about your innovative ideas! On the following pages you will find more information on this initiative and the submission process.

The annual submission deadlines are **March 31** and **September 30**.

# Initiative Announcement



Started in May 2009:

- Flyers and poster distributed at scientific and partnering meetings
- Approx. 2,500 targeted emails sent to potential multipliers/interesting target groups
- Advertising campaign in different scientific journals (print & online):

**FROM TARGETS TO NOVEL DRUGS**

Grants4Targets

Call for proposals:

**FROM TARGETS TO NOVEL DRUGS**

Bayer HealthCare allocates grants for the exploration of attractive, novel drug targets and biomarkers in the fields of:

**ONCOLOGY • GYNECOLOGY • CARDIOLOGY • HEMATOLOGY**

Grants are provided to support research on promising novel molecular targets as well as biomarkers. In addition, we offer to bring in expertise, tools and technologies to help develop your ideas. Please visit our website [www.grants4targets.com](http://www.grants4targets.com) for terms and conditions, further information and online submission.

Annual submission deadlines: March 31 and August 31

[www.grants4targets.com](http://www.grants4targets.com)

**nature.com**  
The world's best science and medicine on your desktop

**nature  
medicine**

**Gynecologic and  
Obstetric Investigation**

**Laborjournal  
online**

**aerzteblatt.de**

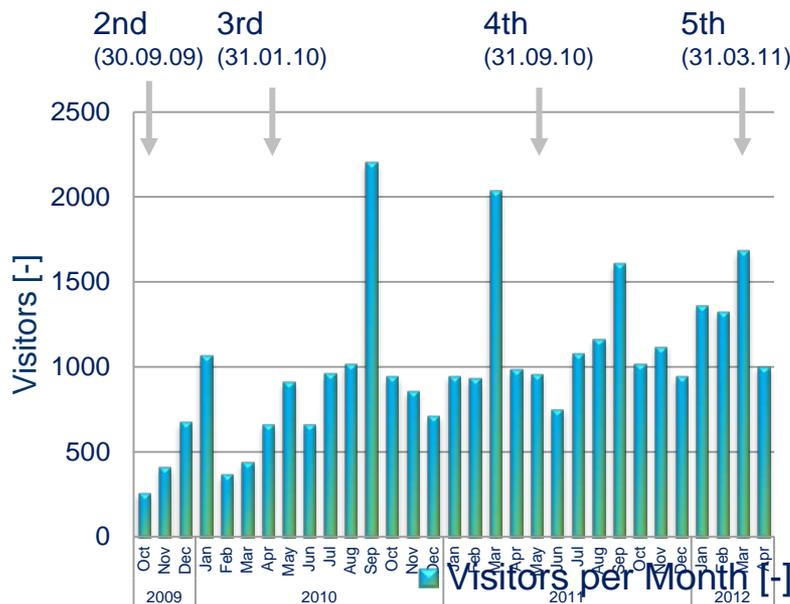
**endometriosis.org**

**Science**

**Next Deadline August 31, 2012**

# WebTrends on www.grants4targets.com

## Analysis of website clicks overall

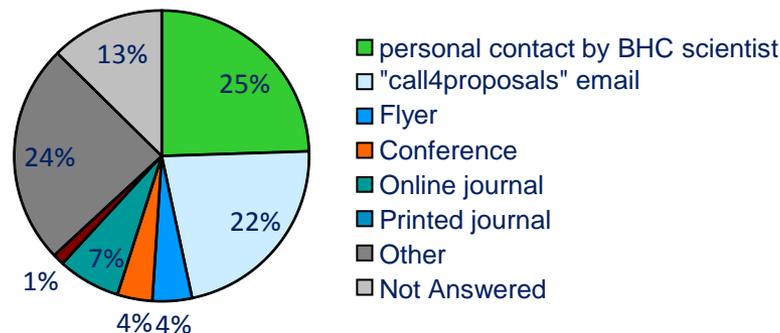


[www.grants4targets.com](http://www.grants4targets.com)

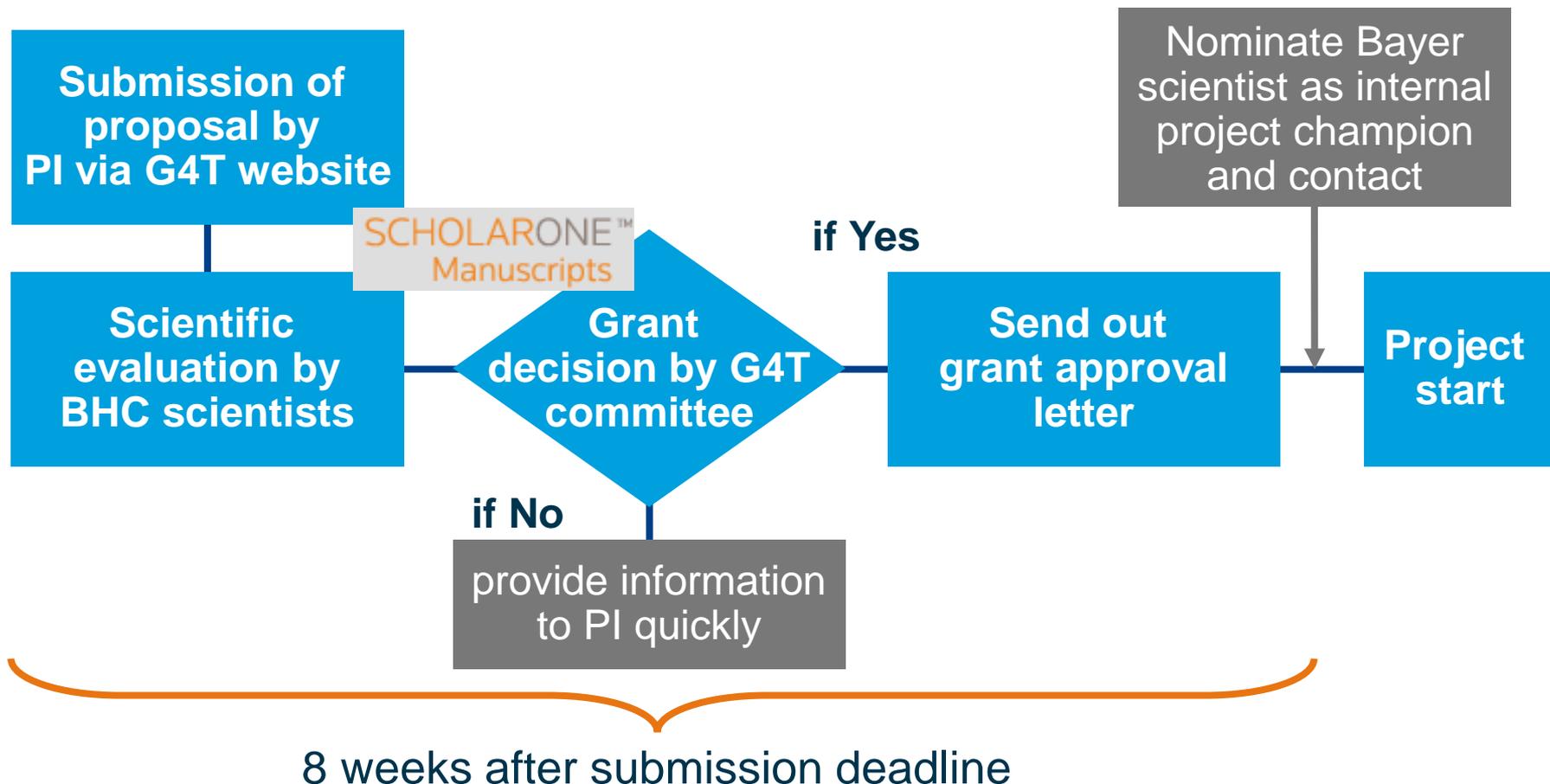
Despite very little promotion we got noticed very well

## How did you become aware of us?

(round 4 - 7, Aug 2010 – May 2012, n=392)



# Grants4targets – process and timelines



PI = Principal Investigator

# Overall Status: Submissions and Results

1st line evaluation

## Submissions

1<sup>st</sup> call: Jun 30, 2009 (n=68)  
 2<sup>nd</sup> call: Sep 30, 2009 (n=148)  
 3<sup>rd</sup> call: Jan 31, 2010 (n=59)  
 4<sup>th</sup> call: Sep 30, 2010 (n=112)  
 5<sup>th</sup> call: Mar 31, 2011 (n=119)  
 6<sup>th</sup> call: Sep 30, 2011 (n=85)  
 7<sup>th</sup> call: Mar 31, 2012 (n=109)  
**~95 % from academia**

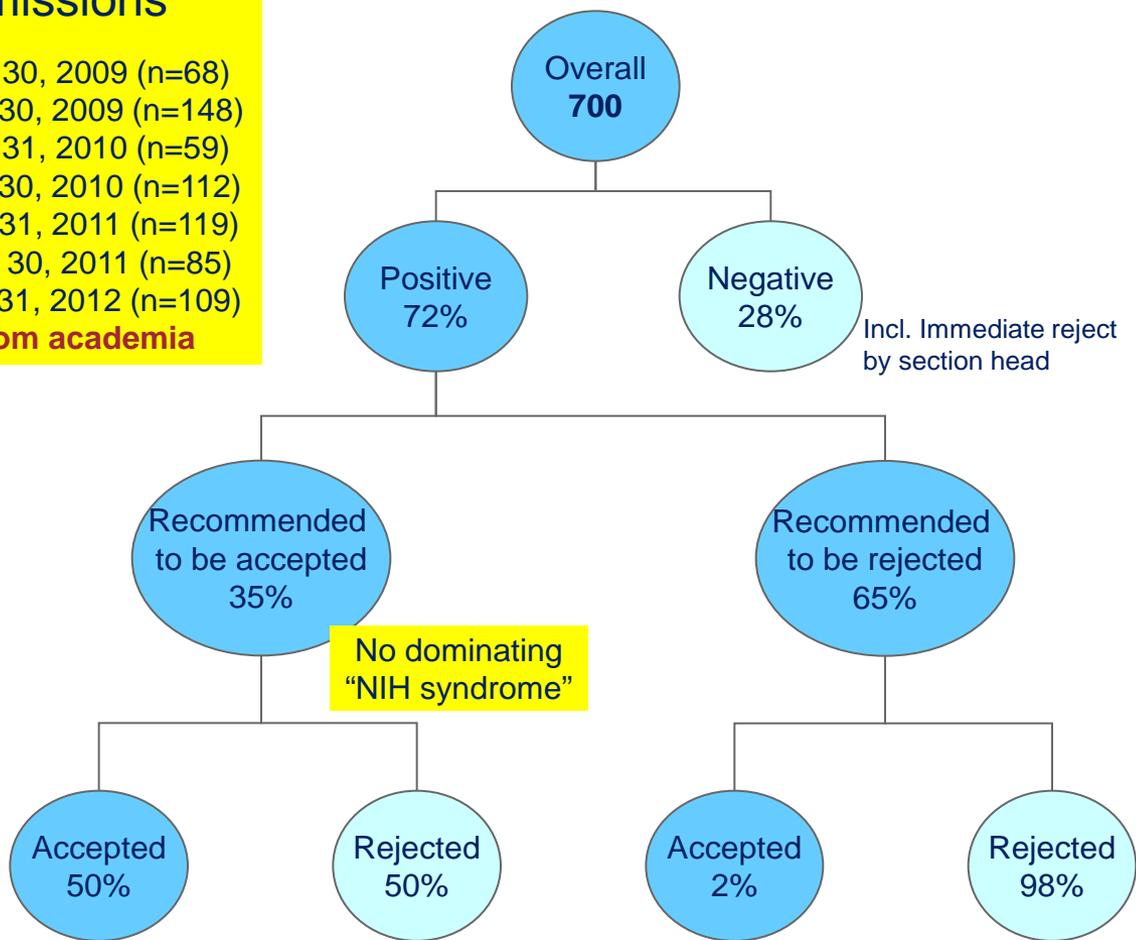
Scientific review

(+ ER moderator input)

Grant committee meeting

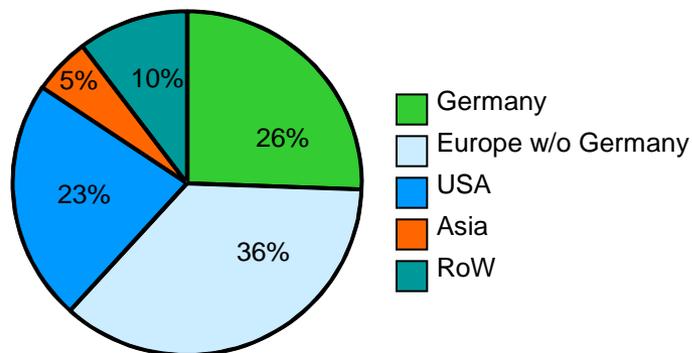
**Total :**  
 Accepted 93  
 Rejected 607

**~13 % overall acceptance rate**

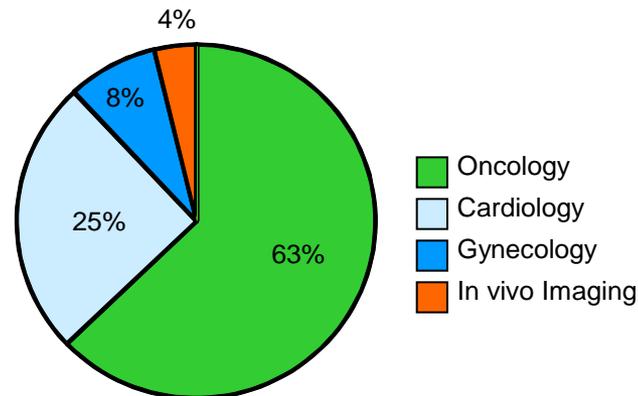


# Results from 7 rounds of G4T applications

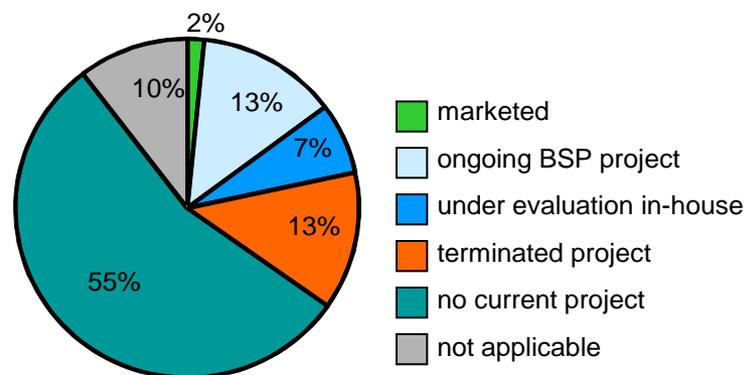
## National Distribution\*



## Therapeutic Area\*



## Internal Project Status\*



- Applications received from all over the world
- More than half of the applications are novel to us

\* of submitted applications

Lessl M, Schoepe S, Sommer A, Schneider M, Asadullah K: Drug Discovery Today 2011, Vol 16, 288-292

# 4 Good Reasons to Apply



- 1. Access to bridging funds**
- 2. Easy process**
- 3. Fast decision**
- 4. Access to a competent partner / modern drug discovery technologies**

# Feedback from the scientific Community



Dr. Kallio; University of Turku, Finland:

“This program is a **fantastic opportunity** to forward pre-clinical target discovery and validation. It can serve as an **important bridge funding** or allow execution of a few critical assays.”

Prof. Lanisnik Rizner, University of Ljubljana, Slovenia:

“The major **two advantages** of the G4T program are: a **short time needed for the application**; and a **fast response period** – as applicants we have been informed about our proposals in less than three months.”

Prof. Multhaup, Free University of Berlin, Germany:

“We have experienced an **excellent support by Bayer Scientists** and have had encouraging discussions.”

Prof. Wang, Moores UCSD Cancer Center, La Jolla, USA:

“There are two advantages in the program. The first being the **speed** with which the grant is funded. The second being the **potential of further collaboration** in the future to advance the common research interests between my laboratory and Bayer AG.”

Reviewer of our manuscript submitted to Drug Discovery Today:

“The Grants4Targets scheme is an innovative and important move towards improved academic - industrial relationships. ... **Bayer are to be applauded for setting up this scheme.** This is a useful scheme and publication of this initial data is important.”

# Conclusions



- We must not rely on published data only
- Actions are needed to improve reproducibility (e.g. standards, publication of neg. data, cultural change)
- Partnerships between industry and academia are key for innovative drug discovery. The need and interest to work together is increasing on both sides.

# Acknowledgements



Kerstin Crusius, Heidrun Dorsch, Peter Ellinghaus, Isabella Gashaw, Christoph Geserick, Monika Lessl, Stefanie Schoepe, Anette Sommer, Luisella Toschi,  
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**Thank you for your attention !**