



Innovative Medicines Initiative

# *A European Public-Private Partnership in Healthcare*

*Michel Goldman, MD, PhD  
Executive Director*



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*ITMAT 2010, 27 October 2010*



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# EFPIA Member Companies

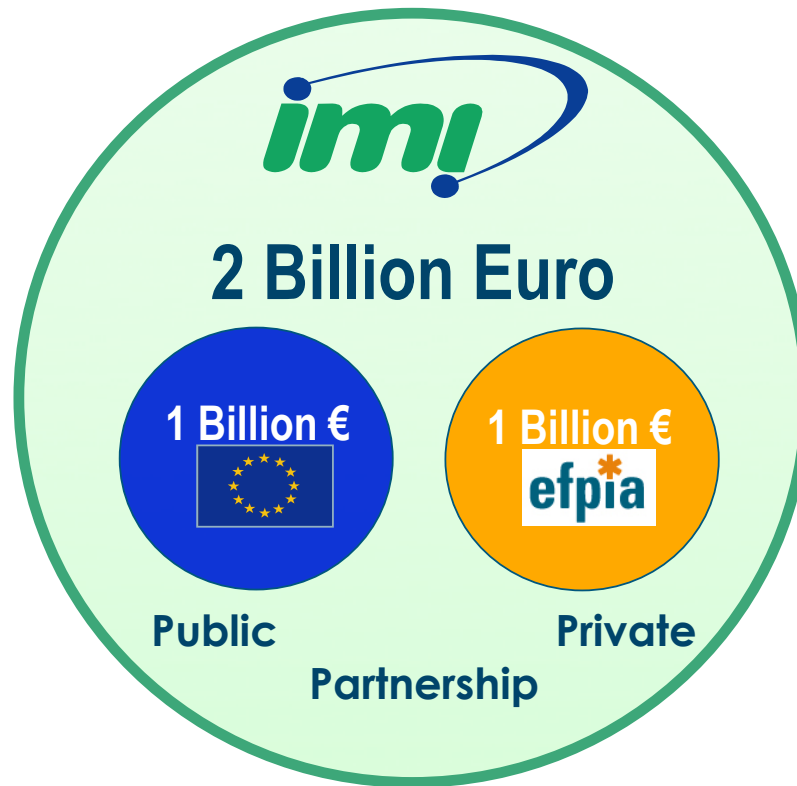


Participating companies (September 2010):



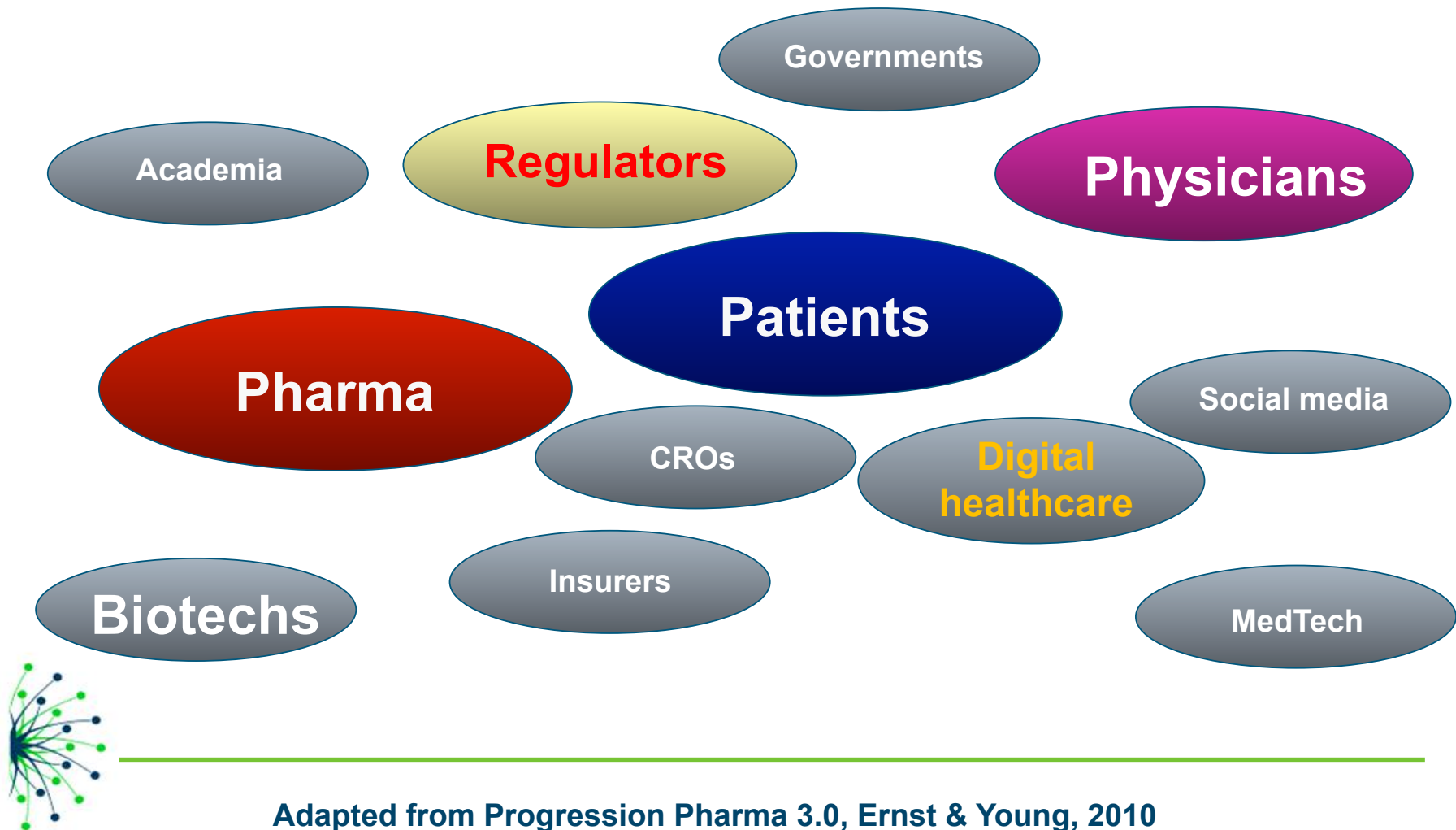
# Innovative Medicines Initiative: the Largest PPP in Life Sciences R&D

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# Towards the Pharma 3.0 Ecosystem

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Adapted from Progression Pharma 3.0, Ernst & Young, 2010

# Key Concepts

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- Open Innovation
- Pre-competitive research



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# The Path to Innovative Medicines

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nature  
medicine

## Mechanism matters

**The path of drug development is fraught with hurdles. Gaining a clear understanding of how a drug works before it enters clinical trials is the intelligent route to drug discovery and could increase the likelihood for drug success.**

**D**rug development is a risky business. According to the US Food and Drug Administration (FDA), only eight percent of drugs that enter clinical trials are eventually approved. For a drug to gain FDA approval, it must be safe and show some efficacy. Because the FDA does not require any understanding of the mechanism by which a drug acts, it could be tempting to move into clinical trials without this knowledge. However, this may set the stage for failure. An investigational

It is true that we use many highly prescribed drugs without a clear idea of how they work—which targets they hit, what processes they alter and which of these actions are required for therapeutic efficacy. For instance, lithium, used to treat bipolar disorder, modulates many molecular targets, but which—or how many—of these are required for its beneficial effects is uncertain. Nevertheless, understanding a drug's mechanism could guide drug development and help to prevent late-stage failures such as Dimebon's.

**nature medicine volume 16 | number 4 | April 2010: 347**

# Drug Safety: The Need for Novel Approaches

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- Individual susceptibility
- Combination therapies
- Unwanted reactions to targeted therapies
- Late effects



The NEW ENGLAND JOURNAL of MEDICINE

# Perspective

MARCH 11, 2010

## The Missing Voice of Patients in Drug-Safety Reporting

Ethan Basch, M.D.

A patient wants to know about symptoms she may have from a prescription drug she is taking. Consulting the label's "Adverse Reactions" section, she finds a wealth of data. Little does she realize that

drug-development cycle if reporting by patients were standard practice.

Before a drug has received marketing approval from the Food and Drug Administration (FDA),

*N ENGL J MED 362: 865-869, March 11, 2010*

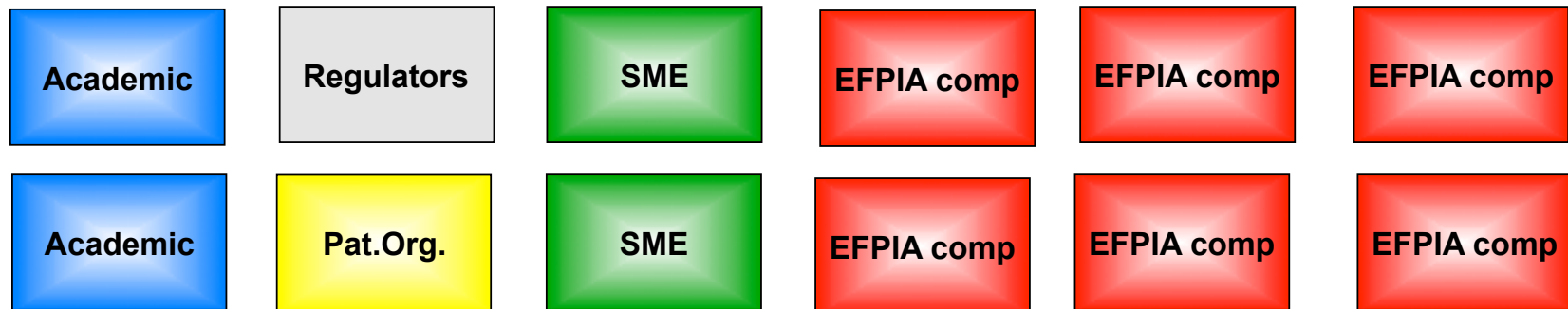


# The Four Pillars of the Innovative Medicines Initiative

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# Overall Structure of Research Projects



**“Applicants consortium”**

IMI beneficiaries

**“EFPIA consortium”**

EFPIA *in kind*  
contribution  
(no public funding)





# IMI Executive Office as a Neutral Third-Party

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- To implement programmes and activities in the common interest of all stakeholders
- To monitor the combined use of public funds and industry investment
- To guarantee fair and reasonable conditions for optimal knowledge exploitation and dissemination



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# Successful Applicants

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- Interested in patient-centric biomedical/pharmaceutical research
- Open to collaboration with large pharmaceutical companies



# Ongoing Projects (1st Call)



*15 Projects*

*395 Teams*

*Total budget:  
281 M€*

<i>Acronym</i>	<i>EFPIA Coordinator</i>	<i>Budget (M€)</i>
<b>SAFE-T</b>	<b>Novartis Pharma</b>	<b>35.9</b>
<b>PROTECT</b>	<b>European Medicines Agency</b>	<b>29.8</b>
<b>SUMMIT</b>	<b>Boehringer Ingelheim</b>	<b>28.4</b>
<b>PHARMA-COG</b>	<b>GSK</b>	<b>27.7</b>
<b>IMIDIA</b>	<b>Sanofi-Aventis</b>	<b>25.4</b>
<b>NEWMEDS</b>	<b>Lundbeck</b>	<b>24.0</b>
<b>U-BIOPRED</b>	<b>Novartis Pharma</b>	<b>20.6</b>
<b>EUROPAIN</b>	<b>AstraZeneca</b>	<b>18.2</b>
<b>PROactive</b>	<b>Chiesi Farmaceutici</b>	<b>16.7</b>
<b>MARCAR</b>	<b>Novartis Pharma</b>	<b>13.3</b>
<b>E-TOX</b>	<b>Novartis Pharma</b>	<b>12.9</b>
<b>EMTRAIN</b>	<b>AstraZeneca</b>	<b>7.7</b>
<b>EU2P</b>	<b>F. Hoffman-La Roche</b>	<b>7.2</b>
<b>Pharma Train</b>	<b>Eur. Federation of Courses</b>	<b>6.6</b>
<b>SafeSciMET</b>	<b>F.HoffmanLa Roche</b>	<b>6.3</b>

# IMI SAFE-T Consortium

## Partners

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- **Pharma:**

- Novartis
- Almirall
- Amgen
- Pfizer
- Hoffmann-La Roche
- AstraZeneca
- Bayer Schering Pharma AG
- Boehringer Ingelheim
- Eli Lilly
- GlaxoSmithKline
- Sanofi Aventis

- **Collaborators:**

- University of Malaga/ Spanish DILI Registry
- University of Liverpool/Centre for Drug Safety Sciences

- **Academic:**

- Barcelona Cardiovascular Research Center
- Charité Hospital
- Groupe d'Etudes et de Recherches en Médecine Interne et Maladies Infectieuses - APHP
- Groupe Hospitalier Pitié Salpêtrière - APHP
- Natural and Medical Sciences Institute
- Tel-Aviv (Souraski) Medical Center

- **SMEs:**

- Argutus Medical Limited
- Experimental & Diagnostic Immunology GmbH
- Firalis SAS
- Interface Europe

- **External Advisors:**

- **European Medicines Agency**
- FDA



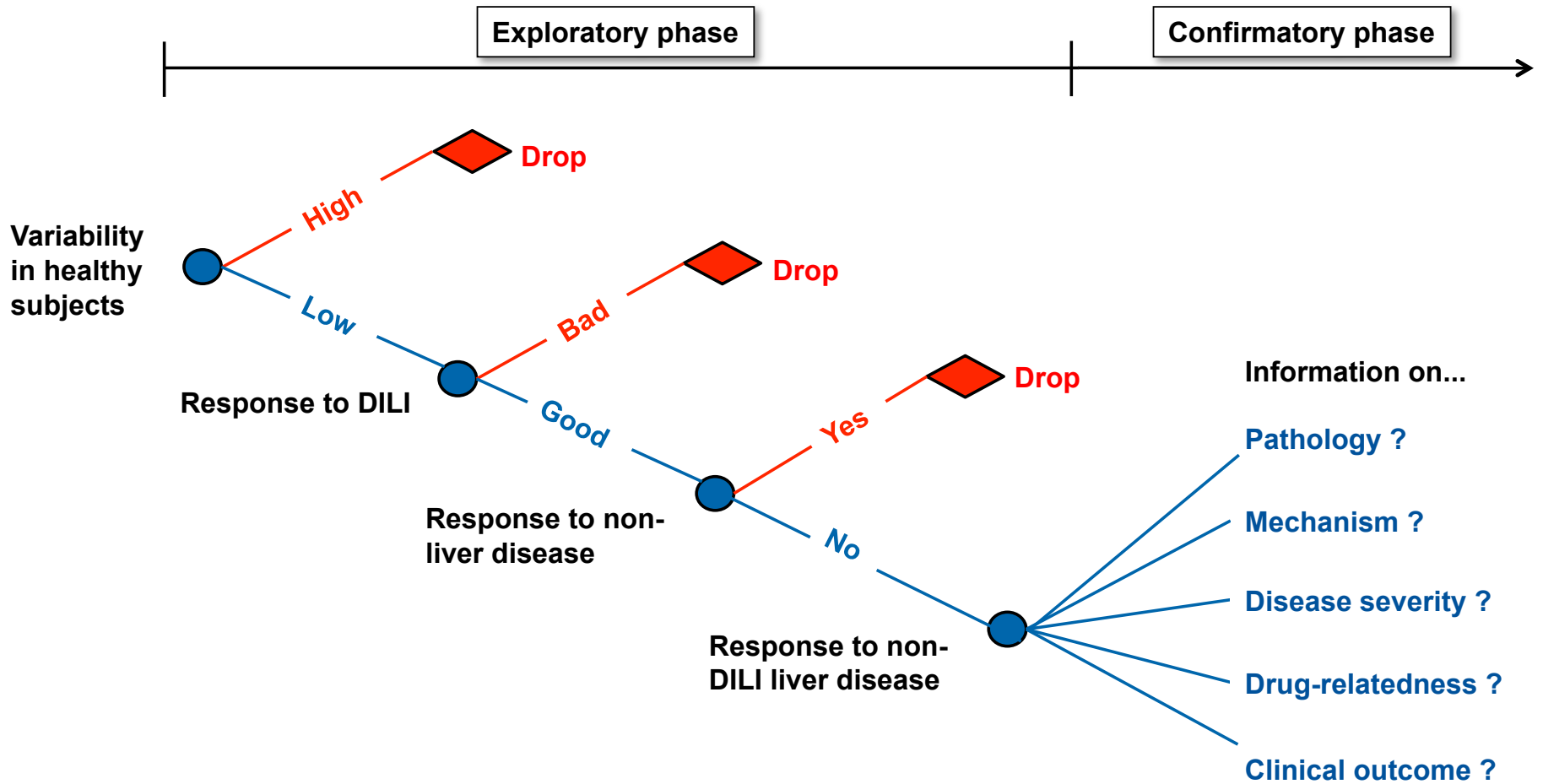
# IMI SAFE-T Consortium

## Safer and Faster Evidence-based Translation

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- *Three organs needing better clinical monitoring of drug-induced injuries:*
  - **Kidney**: current standards increase only once 50-60% of kidney function is lost
  - **Liver**: current standards are not sufficiently sensitive and specific
  - **Vascular System**: no biomarkers currently available
  
- *Consortium objectives:*
  - To evaluate **utility** of BMs for monitoring DIKI, DILI and DIVI **in humans**
  - To develop **assays and devices** for **clinical application** of safety BMs
  - To **qualify safety BMs for regulatory decision**

# Biomarker selection process





# **PROTECT :**

## *Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium*

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### **Consortium:**

- **International Alliance of Patients' Organizations**
- **6 Regulatory Bodies** including **EMA** (coordinator)
- **11 EFPIA Pharma Companies**
- **10 Academic Institutions**
- **1 SME**

**Aim:** To strengthen the monitoring of the **benefit-risk** of medicines

### **Deliverables:**

- New methods for data collection from consumers
- New methods of communicating benefit-risk decisions to all stakeholders

# Lessons from Ongoing Projects

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- **IMI is more than an industry-academia PPP:**  
successful involvement of regulatory agencies, patients' organizations and SMEs
- **First successes and enthusiasm** provide « **proof-of-concept** »  
evidence for IMI-type PPPs
- Need for dedicated tools for **data and knowledge management**



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# Proposals under Finalization (< 2<sup>nd</sup> Call)

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## *Topics*

- Knowledge Management
- Cancer
- Rapid diagnosis for infections
- Inflammatory disorders



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# 3rd Call: Indicative Topics

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- Early prediction of drug-induced liver injury
- Risk minimization of antibodies to biopharmaceuticals
- Immunosafety of vaccines
- Translational research on autism spectrum disorders
- Personalized medicine in type II diabetes
- New strategies to treat tuberculosis
- Patient awareness on pharmaceutical innovation



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# Key Challenges

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- Boundaries of precompetitive research
- Intellectual property management
- Indicators of performance
- Incentives/rewards for collaboration



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[www.imi.europa.eu](http://www.imi.europa.eu)

**THANK YOU !**



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