



Gabinete de Promoção dos
Programa Quadro ID&I

A investigação clínica no contexto do Horizonte 2020

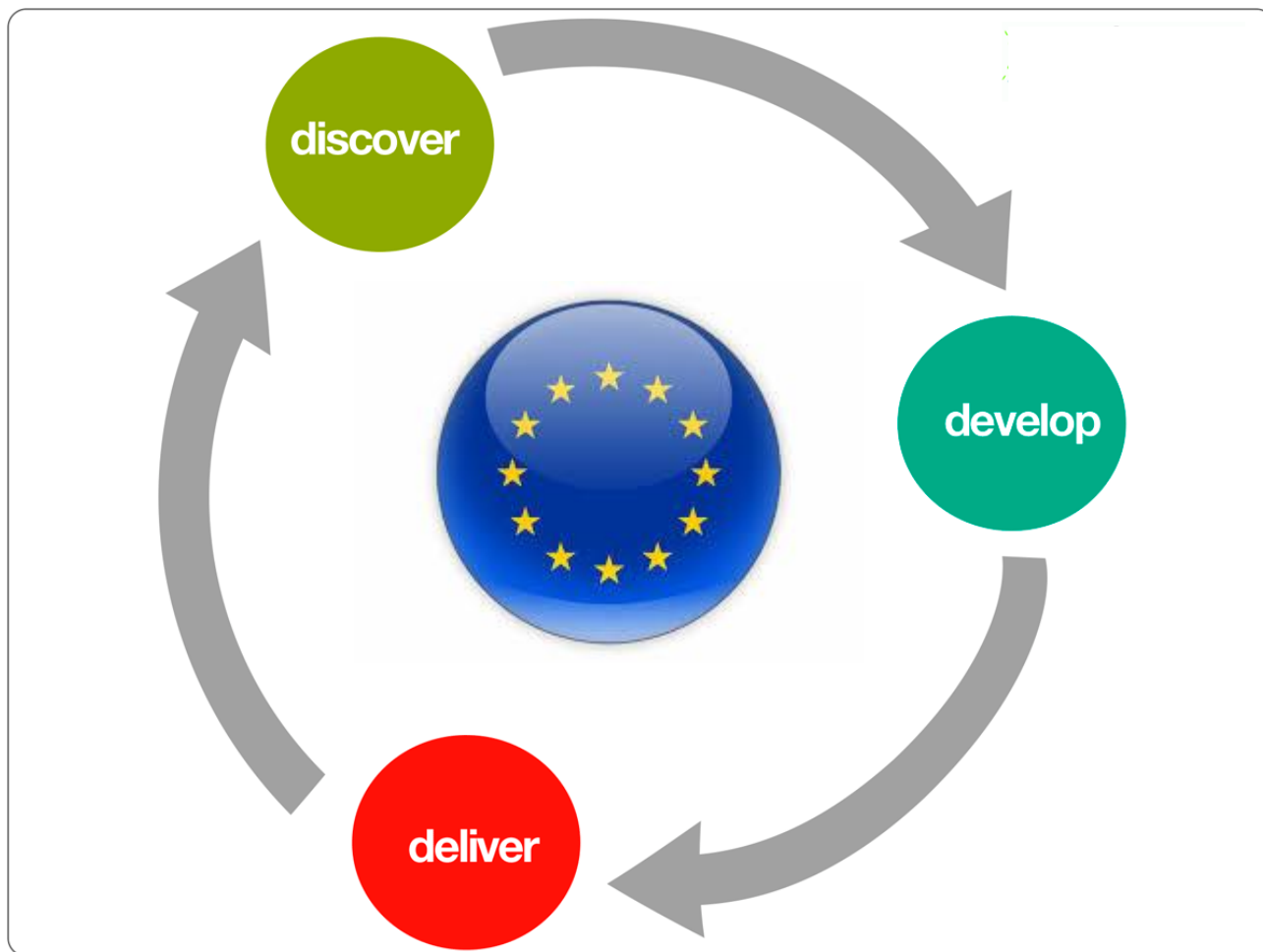
Patrícia Calado

iBET, Oeiras

9 de Julho de 2015



O QUE É O HORIZONTE 2020?



80 B €

2014-2020

PORQUÊ CONCORRER AO H2020?.....







COMO CONSEGUIR FINANCIAMENTO DO H2020?.....





2380

2392

2405

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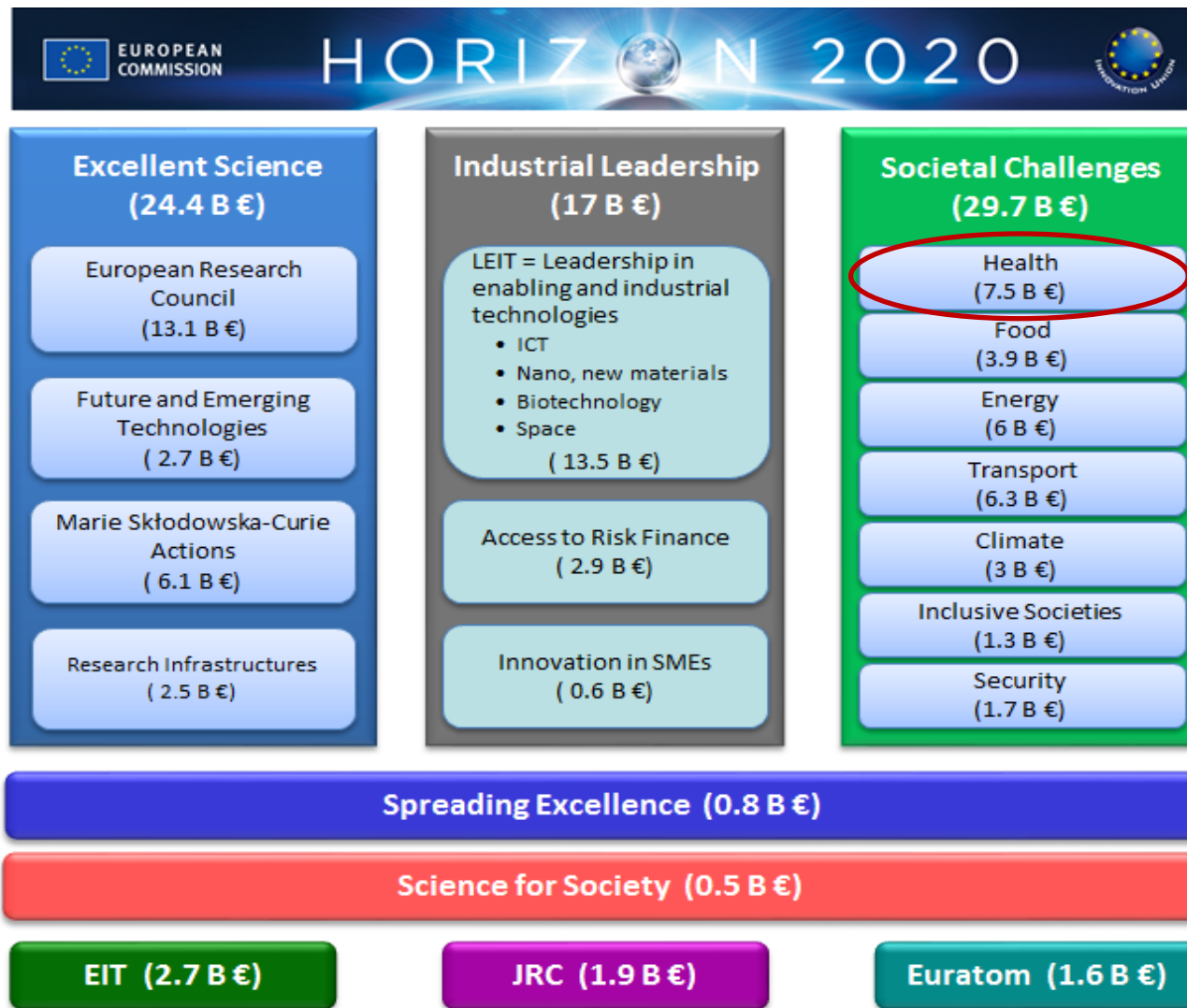
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ESTRUTURA GERAL DO H2020



H2020 – MAIOR SIMPLIFICAÇÃO

1. Regras iguais para todos os financiamentos H2020

(menos instrumentos e mais flexíveis)

2. Reembolso mais simples: 1 projeto = 1 taxa de reembolso

- 100% dos custos elegíveis (70% nas IA)
- Taxa fixa de custos indirectos (25% dos custos elegíveis)

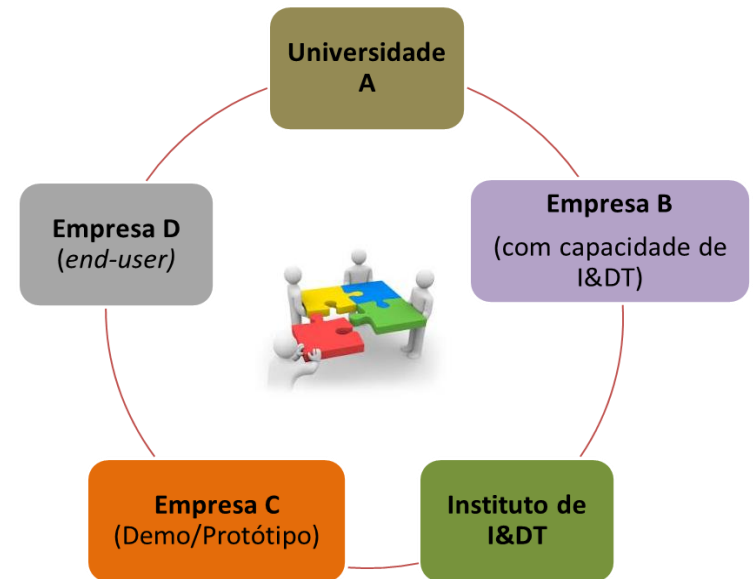
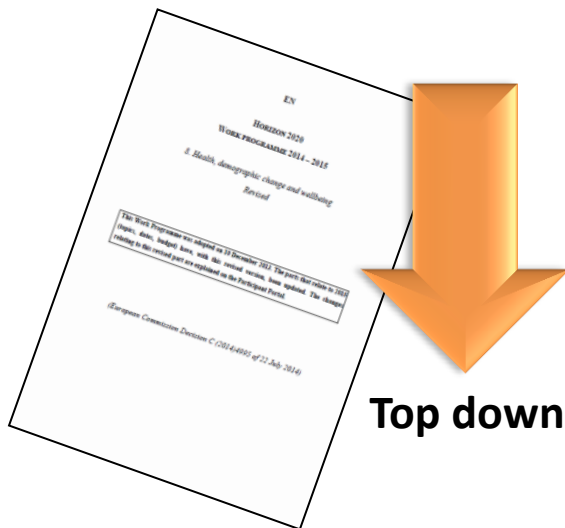
3. “Time to grant” mais curto

(8 meses após o deadline de submissão)



FINANCIAMENTO NO PILAR 3 – COMO FUNCIONA?

- Programas de Trabalho bianuais
- Projetos em colaboração (mínimo 3 MS ou AC)



Better health for all

- 1 *Understanding health, wellbeing and disease*
- 2 *Preventing disease*
- 3 *Treating and managing disease*
- 4 *Active ageing and self-management of health*
- 5 *Methods and data*
- 6 *Health care provision and integrated care*



Orçamento (2014-2020): EUR 7.642 M

(9,7% do orçamento H2020)

OBJETIVOS PROGRAMA DE TRABALHOS DS1 2016-2017

Strategic orientation - “promoting healthy ageing and personalised healthcare”

Research priorities:

- Personalised medicine
- Rare diseases
- Human bio-monitoring
- Mental health
- Comparative effectiveness research
- Advanced technologies
- e/mHealth
- Robotics
- Patient empowerment
- Active and healthy ageing
- Data security
- Big data
- Valorisation
- Anti-microbial resistance
- Infectious diseases (incl. vaccines)
- Maternal and child health
- Silver economy



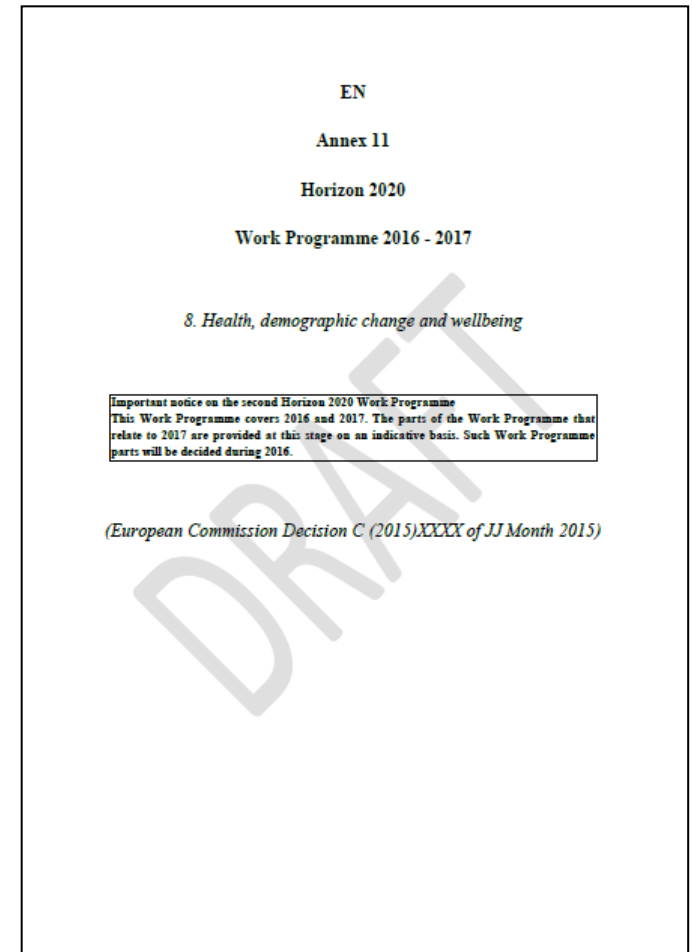
CARACTERÍSTICAS DO PROG. TRABALHOS 2016-2017

- Orçamento total: **~950 M€**
- Vários **tipos de instrumento**: acções de investigação e inovação em colaboração (RIAs), SME Instrument, prémios, financiamento inovador, cofinanciamento de programas (COFUND), ERA-NETs, Iniciativas de Programação Conjunta (JPIs) e acções de suporte e coordenação (CSAs).
- **Sinergias** com actividades no âmbito da **IMI2**, do **EDCTP**, do programa **AAL** e alinhamento com as prioridades da **EIP-AHA**.
- Investigação e inovação **responsáveis**, incluindo **aspectos éticos** e ciência sociais e humanidades (**SSH**).



PROGRAMA DE TRABALHOS DS1 2016-2017

- **Personalised Medicine (PM):**
22 tópicos (13 DG-RTD; 9 DG-CNECT)
- **Co-ordination Activities (HCO):**
15 tópicos (8 DG-RTD; 7 DG-CNECT)
- **Other actions: 11 tópicos**
- **Outubro de 2015:** publicação das *calls*.



TÓPICOS NO PROGRAMA DE TRABALHOS

Specific challenge: apresenta o contexto, o problema a resolver e explica a intervenção necessária.

Scope: delinea o problema, especifica o foco e os limites da potencial ação (não descreve ou limita a abordagem específica).

Expected impact: descreve os elementos chave do que é esperado conseguir em relação ao desafio.

PHC 3 - 2015: Understanding common mechanisms of diseases and their relevance in co-morbidities

Specific challenge: The development of new treatments is greatly facilitated by an improved understanding of the pathophysiology of diseases. There is therefore a need to address the current knowledge gaps in disease aetiology in order to support innovation in the development of evidence-based treatments. In this context, a better understanding of the mechanisms that are common to several diseases, in particular of those leading to co-morbidities, constitutes an important challenge.

Scope: Proposals should focus on the integration of pre-clinical and clinical studies for the identification of mechanisms common to several diseases. Proposals should assess and validate the relevance of these common mechanisms and of their biomarkers (where relevant) on the development of disease-specific pathophysiology, as well as their role in the development of co-morbidities in both males and females.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact: This should provide:

- A better understanding of disease pathways and / or mechanisms common to a number of diseases
- New directions for clinical research for better disease prevention, health promotion, therapy development, and the management of co-morbidities

Type of action: Research and innovation actions



TIPOS DE ACÇÃO

Type of Action	Funding Rate	Aim
Research & Innovation Action (RIA)	100%	Collaborative research projects.
Innovation Action (IA)	70% (100% for non-profit organisations)	Produce plans & arrangements or designs for new, altered or improved products, processes or services.
Coordination & Support Action (CSA)	100%	Accompanying measures (standardisation, dissemination, policy dialogues etc.) no research.
SME Instrument	Phase 1: € 50K / project Phase 2: € 1-2.5M / project	Combination of demonstration activities (testing, prototyping, ...), market replication.



ESTUDOS CLÍNICOS

- Broad, inclusive definition of clinical studies (CS):

*A “clinical study” is ... any clinical research involving a substantial amount of work related to the **observation** of, **data collection** from, or **diagnostic or therapeutic intervention** on multiple or individual **patients/subjects**. It includes but is **not limited to clinical trials** in the sense of the EU Clinical Trials Directive (2001/20/EC).*



TEMPLATE FOR ESSENTIAL INFORMATION TO BE PROVIDED FOR PROPOSALS INCLUDING CLINICAL TRIALS / STUDIES / INVESTIGATIONS

Horizon 2020

Template for essential information to be provided for proposals including clinical trials / studies / investigations

Document history	
Version 2015callsV2	18 August 2014
Modifications (compared to previous version):	Correction: The wrongly listed topic PHC12 has been deleted from second paragraph.

This template only concerns you if your proposal contains a clinical trial/study/investigation! In the following, clinical trials/studies/investigations are collectively referred to as 'clinical studies'¹

Please see the important information under 1.9 on unit costs for clinical studies. The use of unit costs is an alternative to the use of actual costs. Its use is voluntary, i.e. each beneficiary can decide whether to be reimbursed on the basis of unit costs or of actual costs for a given clinical study.

Objetivos:

- Fornecer informação estruturada aos avaliadores
- Fornecer informação detalhada sobre CS sem limite de páginas
- Fornecer a informação necessária para solicitar “unit costs”

CLINICAL STUDIES NO H2020 – ÂMBITO DO TEMPLATE

- **Obrigatório** para determinados tópicos (listados no template)
- Informação **para cada CS** incluído na proposta, compilada num documento único final baseado no template
- Para propostas stage-1 e para tópicos não listados **não é possível** fazer upload do template (as secções podem ser usadas para orientação e a informação incluída na proposta, dentro do limite de páginas)
- Informação essencial, com base num Clinical Study Protocol (**CSP**)
- Aspectos éticos e planos de risco contingência são parte integrante da proposta e **não devem ser considerados** no template
- Informação fora do âmbito do template **não considerada** para avaliação

CLINICAL STUDIES NO H2020 – UNIT COSTS

Os “**unit costs**” são:

- um montante de reembolso **fixo**
- por cada **sujeito** envolvido
- num determinado **centro**
- calculado de acordo com uma **metodologia definida**
- baseado nos **custos históricos** do beneficiário
- para a **duração total** da ação (não é flexível, não são possíveis ajustes no decorrer da ação)

INICIATIVAS ESTRATÉGICAS



Innovative Medicines Initiative 2
www.imi.europa.eu



European Innovation Partnership on Active



Active and Assisted Living
www.aal-europe.eu



European & Developing Countries Clinical
Trials Partnership (EDCTP2)
www.edctp.org

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INICIATIVAS ESTRATÉGICAS



Innovative Medicines Initiative 2
www.imi.europa.eu



European Innovation Partnership on Active and Healthy Ageing
<https://webgate.ec.europa.eu/eipaha>



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INICIATIVA DOS MEDICAMENTOS INOVADORES (IMI2)

- Iniciativa Tecnológica Conjunta entre a **União Europeia** e a **EFPIA**
- Objectivos do IMI2 com base na Strategic Research Agenda (SRA):

1

A 30% better success rate in **clinical trials of priority medicines** identified by the WHO;

2

Clinical proof of concept in **immunological, respiratory, neurological and neurodegenerative diseases** in just five years;

3

New and approved **diagnostic markers** for four of these diseases and at least two **new medicines** which could either be new **antibiotics** or new therapies for **Alzheimer's disease**.

ORÇAMENTO TOTAL IMI2 (2014-2024): 3.276 M€

(1.638 M€ H2020 + 1.425 M€ EFPIA (*in kind*) + 213 M€ indústrias das ciências da vida)



IMI2 – 5TH CALL FOR PROPOSALS (RIA, 2-stage)

- **IMI2-2015-05-01: Patient perspective** elicitation on benefits and risks of medicinal products from development through the entire life cycle, for integration into **Benefit Risk assessments** by Regulators and Health Technology Assessment bodies (**11.2 M€**)
- **IMI2-2015-05-02: Diabetic Kidney Disease** Biomarkers (DKD-BM) (**29.8 M€**)
- **IMI2-2015-05-03: Inflammation** and **AD**: modulating microglia function – focussing on **TREM2** and **CD33** (**17.2 M€**)
- **IMI2-2015-05-04**: Understanding the role of **amyloid biomarkers** in the current and future diagnosis and management of patients across the spectrum of **cognitive impairment** (from predementia to dementia) (**24 M€**)
- **IMI2-2015-05-05**: Evolving models of **patient engagement and access** for earlier identification of **Alzheimer's** disease: Phased expansion study (**4.08 M€**)
- **IMI2-2015-05-06** : **ApoE** biology to validated **Alzheimer's** disease targets (**5.28 M€**)



INICIATIVAS ESTRATÉGICAS



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EIP ON ACTIVE AND HEALTHY AGEING

Cooperação entre a Comissão Europeia e os países da UE, as regiões, a indústria, os profissionais do setor social e do setor da saúde e as organizações representativas dos idosos e dos doentes



The Marketplace: plataforma *online* para adesão, discussão e partilha de informação



❖ Não é um mecanismo legal nem de financiamento da UE

FERRAMENTAS DE PROCURA DE PARCEIROS EU E PT

Congressos/conferências



Horizon 2020 Health Open Info Days

Open Info Day - Horizon 2020 'Health, Geographic change and wellbeing'
Centre Albert Descartes, rue Prinsart, 68, 1050 Brussels, Belgium
Friday 14 November 2014

Infodays UE



Ferramentas virtuais



Redes profissionais



Projetos financiados
(>1000 entre 2007-2013)

H2020 Health European Brokerage Event
Partnering for PHC 2015 calls



Gabinete de Promoção dos Programa Quadro ID&I



Gabinete de Promoção do Programa Quadro de I&DT

CONSULTE – NOS
😊

Publicação

Deadline

Resultado

Contrato



1º contacto
O que é o H2020
Como funciona?

Verificação da ideia
A minha ideia integra-se numa call do H2020?
Onde?

Preparação da proposta
Construção do consórcio, escrita da proposta, procura de parceiros, revisão da proposta

Avaliação da proposta
por peritos independentes

Assinatura do contrato
Procedimentos administrativos e legais

Gestão do projeto
Relatórios, alterações ao contrato, etc

Relatórios, Exploração dos resultados
Auditorias da CE, etc

3-4 meses

5 meses

3 meses



<http://www.gppq.pt/h2020/>



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Saúde

IMI



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Fissão | Fusão

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