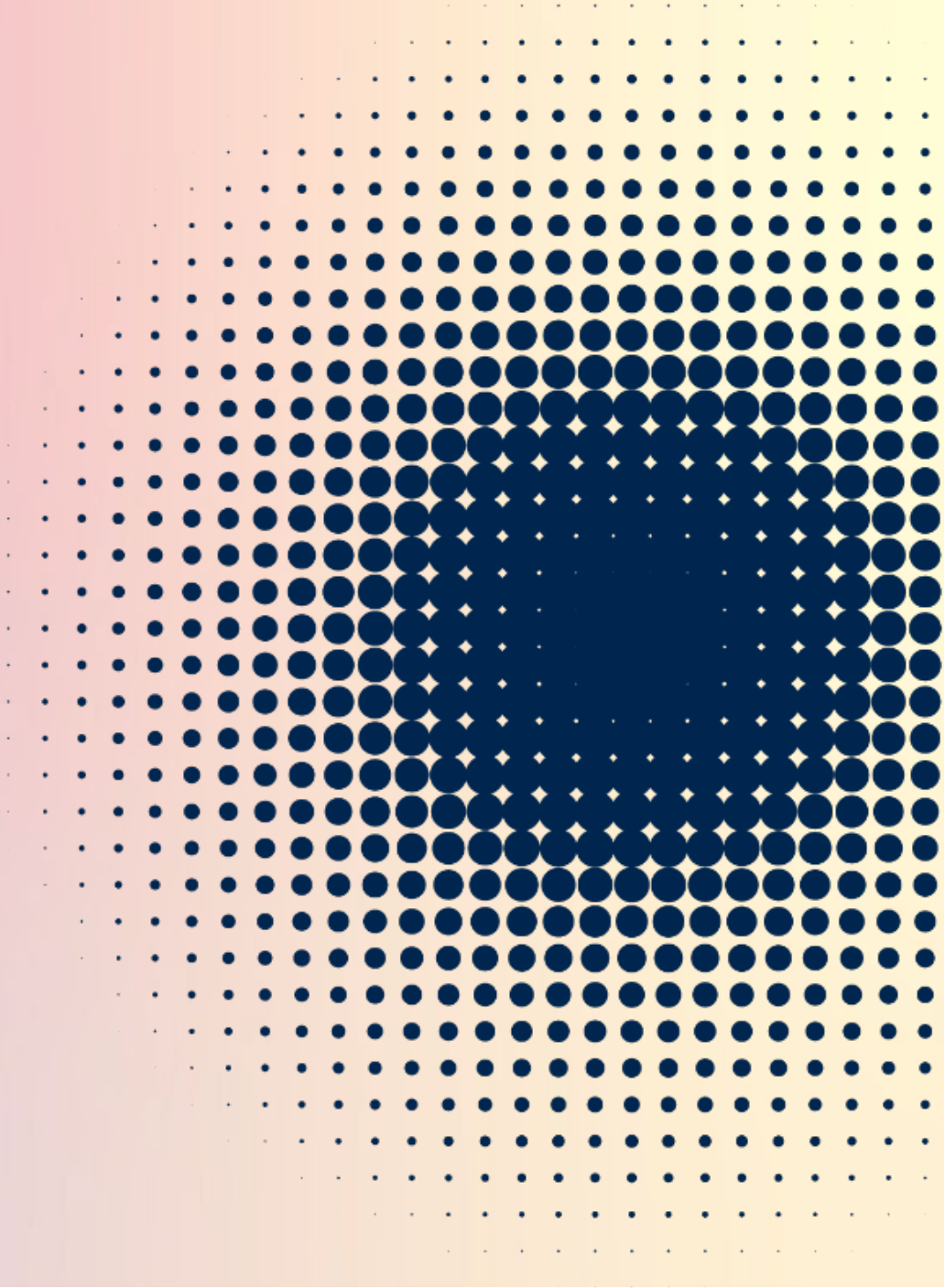
EMA
EUROPEAN MEDICINES AGENCY

From lab to patients

A fast path from innovation to safe and effective medicines



A single medicine approval in all EU countries

Benefits of an EU-wide approach

Medicines are authorised in all EU countries + Iceland, Liechtenstein and Norway at the same time

Safety is monitored centrally

All EU patients have access to the same information and recommendations

Experts from all over Europe are involved

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The journey of a centrally authorised medicine

~8–15 years

Step 1

Research & development

~1 year

Step 2

Evaluation

~2 months

Step 3

Authorisation

Step 4

Access

Throughout medicine's lifecycle

Step 5

Safety monitoring

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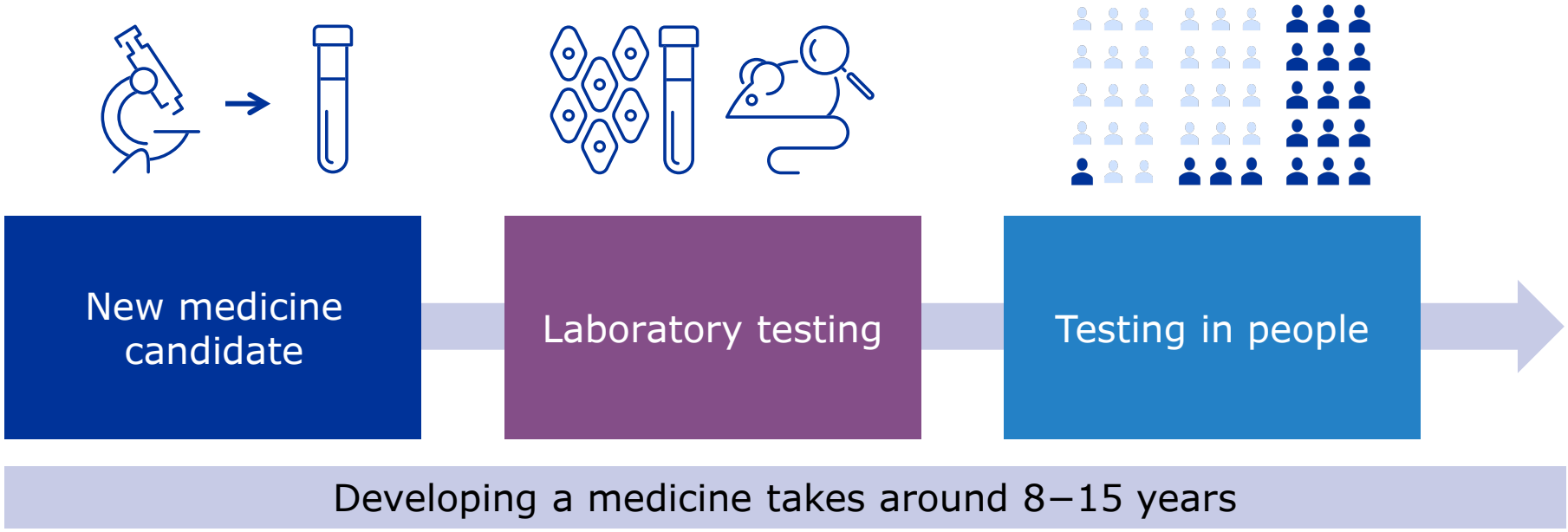
Step 1 – Research and development

Who develops medicines?

- Pharmaceutical or biotechnology companies
- Academic groups

Why are medicines tested?

- To understand how the medicines work
- To evaluate their benefits and side effects



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Step 1 – Supporting development of safe and effective medicines

Bring innovation to patients faster

Develop scientific guidelines

Provide scientific advice to developers

Encourage development in specific areas

- Rare diseases
- Children
- Diseases lacking medicines

Did you know?
Incentives are available to academia and small companies to help them develop innovative medicines.

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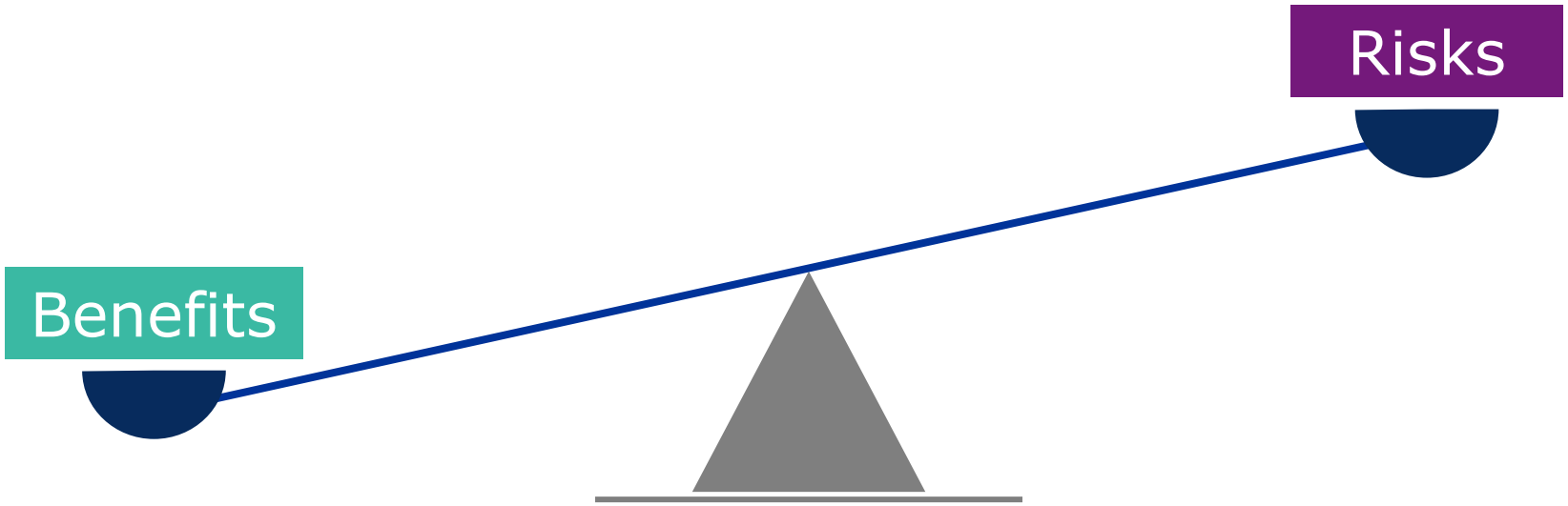
Step 2 – Evaluation of medicines by EMA

EMA recommends authorisation if the benefits of a medicine are greater than its risks



Step 2 – Evaluation of medicines by EMA

EMA recommends authorisation if the benefits of a medicine are greater than its risks

Evaluation is carried out by **experts from all EU countries**

Experts carefully **review** all data on the **quality, safety and effectiveness** of medicines

EMA's recommendation to approve (or not) is reached by **formal vote** by EU experts

Complete information for patients and healthcare professionals is compiled in the **product information**

Did you know?

- EMA checks if medicines are produced and tested according to EU and international guidelines
- Inspections can be carried out

Step 2 – Key principles of EMA evaluation

Science

EMA's work is guided by the best science and robust data

Independence

Strict rules are in place to guarantee **independence** and **impartiality**

Consultation

EMA consults patients, healthcare professionals and additional experts to get their input

Transparency

EMA ensures **transparency** by publishing assessment reports & study results

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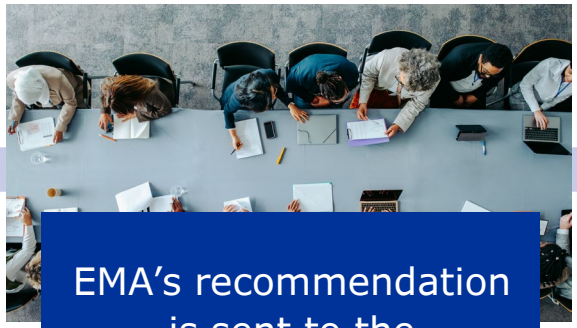
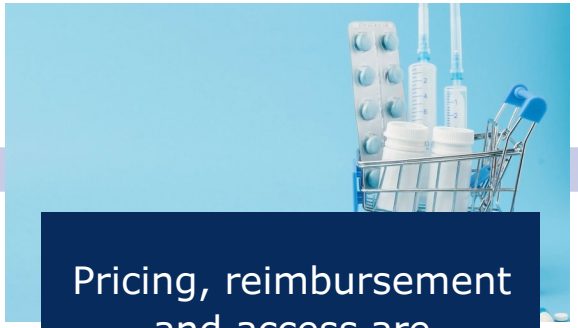
Steps 3 & 4 – Authorisation and access



EMA's recommendation is sent to the European Commission

The European Commission decides whether to authorise medicines in the EU

Marketing authorisations are valid across the EU, Iceland, Liechtenstein and Norway



Pricing, reimbursement and access are agreed at country level

Step 5 – EMA monitors the safety of medicines authorised in the EU

Learn more about this at the next station!

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Thank you.

Send a question to the European Medicines Agency

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