

106 days from Brussels

THE EU CLINICAL TRIALS REGULATION, 2014 TO 2026

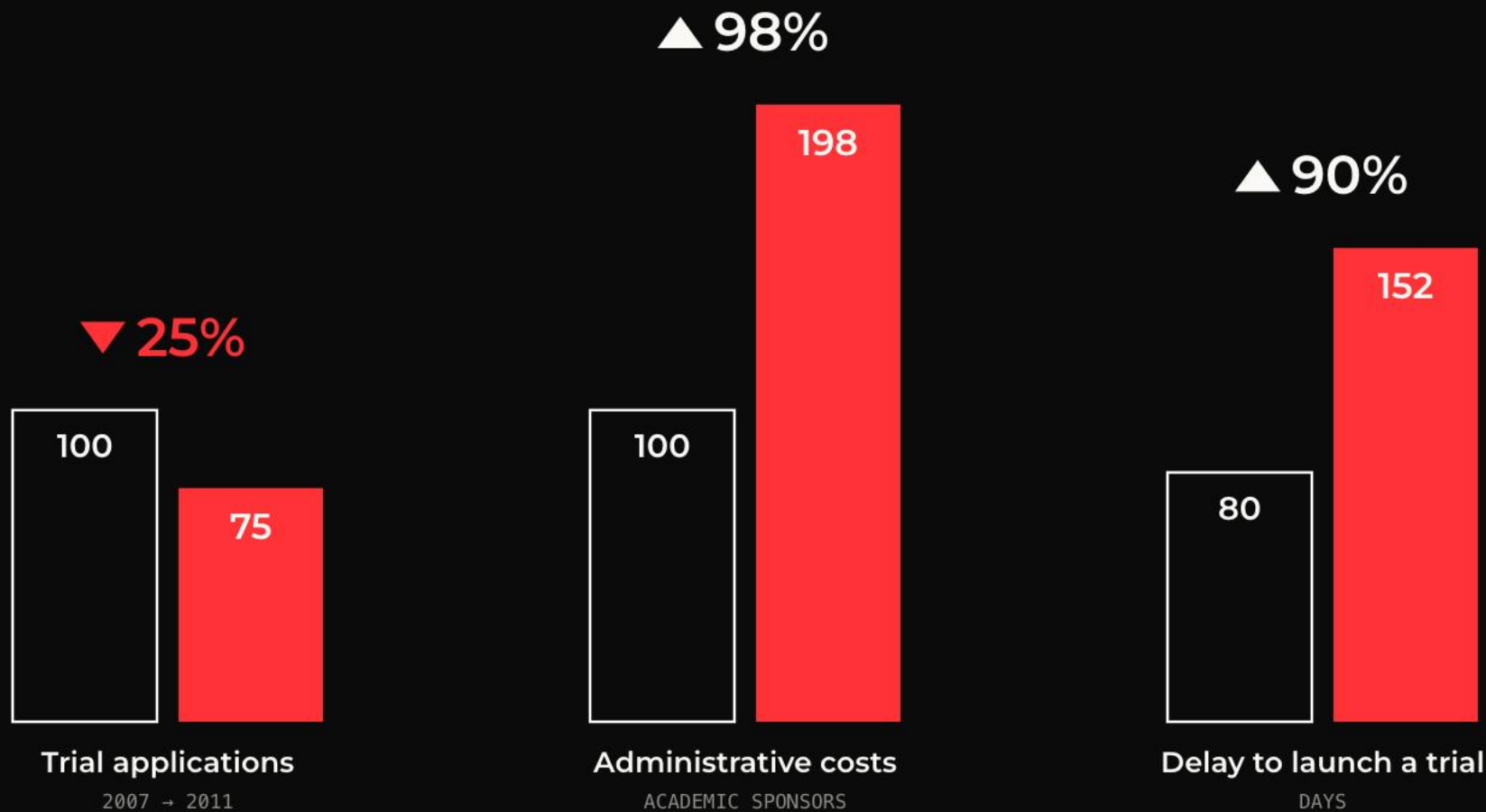
ZINA SARIF · YENDOU · OCTOBER 2026



ACT I · THE PROMISE

The promise

By 2012, trial applications had fallen 25% and launch delays had nearly doubled



In 2014, Regulation 536 set out to fix it

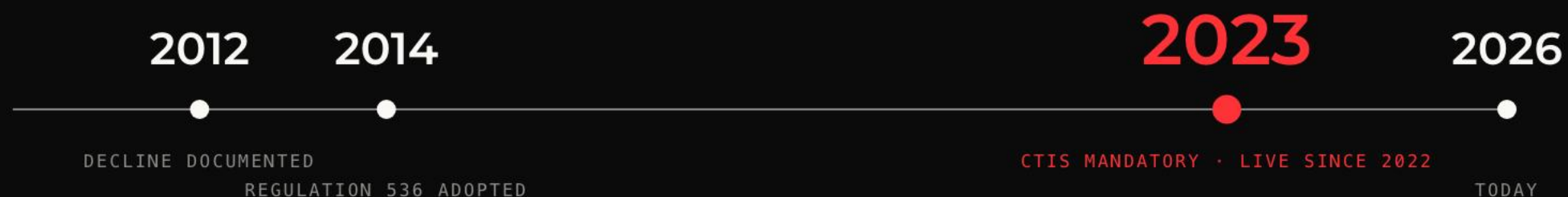
One application.

One portal.

One decision.

60 days.

Since January 2023, every new EU trial application has gone through CTIS



Objective one: a faster, simpler authorisation process

1 application

one dossier, submitted once to every Member State concerned

1 portal

a single entry point for the Union, CTIS

60 days

to a decision, with defined timelines for every step

Objective two: keep the EU an attractive location for clinical research



RECITAL 8

“The Union remains an attractive place for conducting clinical trials.”

“I am convinced that the new rules will ensure a big boost for research and development in the EU for the benefit of patients.”

Commissioner Tonio Borg, 2 April 2014, the day Parliament voted

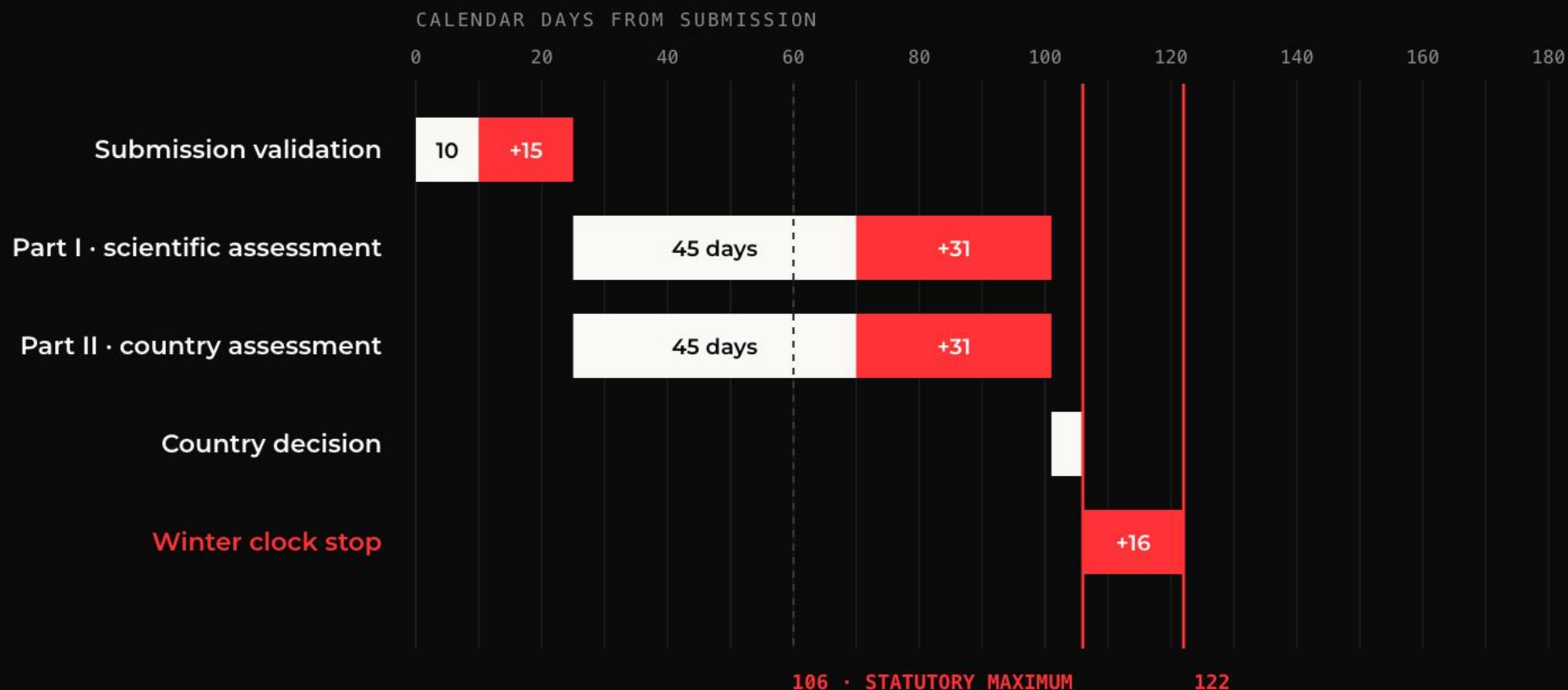
ACT II · THE CLOCK

The clock

The Regulation sets a 60-day authorisation timeline



Requests for information extend the statutory maximum to 106 days



Source: Reg. 536/2014 Art. 5 to 8 · validation request 10 + 5 days · assessment request 12 + 12 + 7 days · EMA winter clock stop, 22 December to 7 January

With requests for information, the timeline approaches the pre-reform 152 days

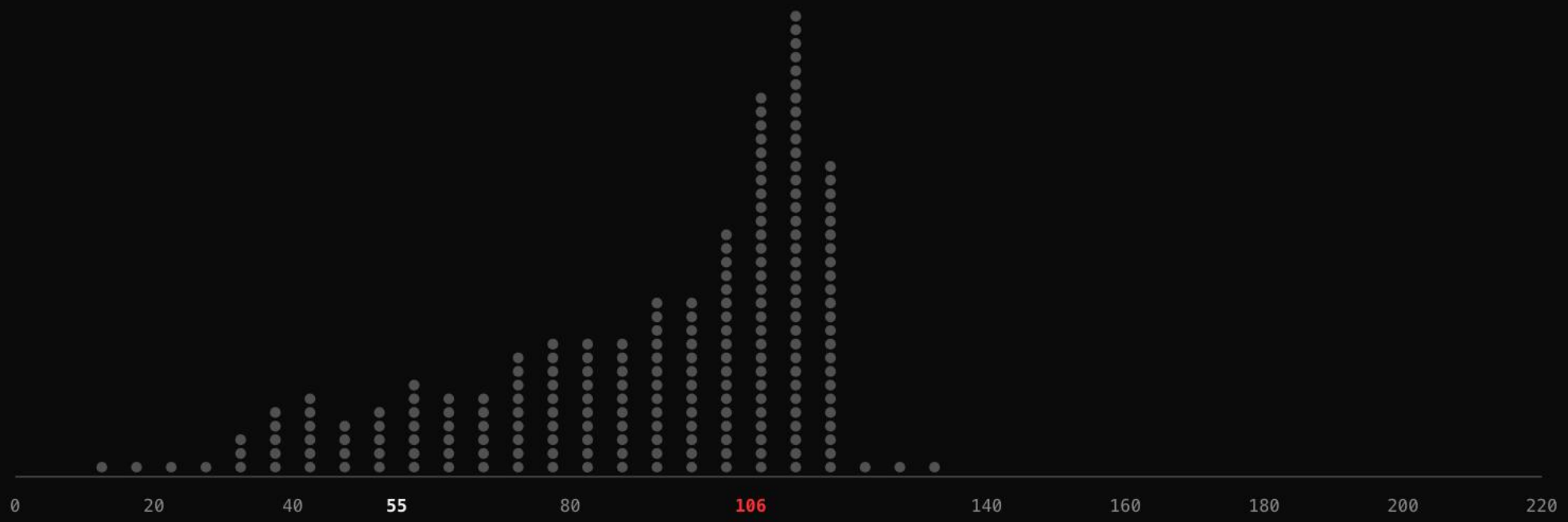


The EMA's reported median of 109 days exceeds the statutory maximum



We placed every new application from the public CTIS register on one line

ONE DOT = 25 NEW APPLICATIONS · DAYS FROM SUBMISSION TO PART I CONCLUSION

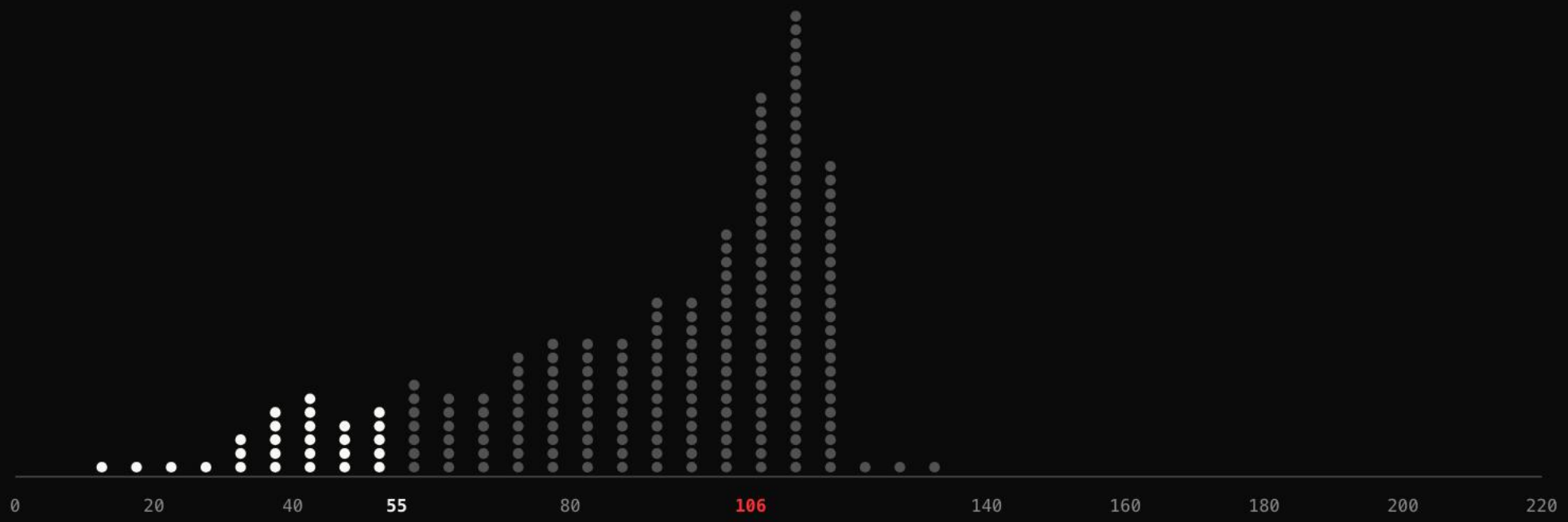


Only 14% complete assessment without a request for information

ONE DOT = 25 NEW APPLICATIONS · DAYS FROM SUBMISSION TO PART I CONCLUSION

14%

UP TO 55 DAYS



Half fall between the target and the statutory maximum

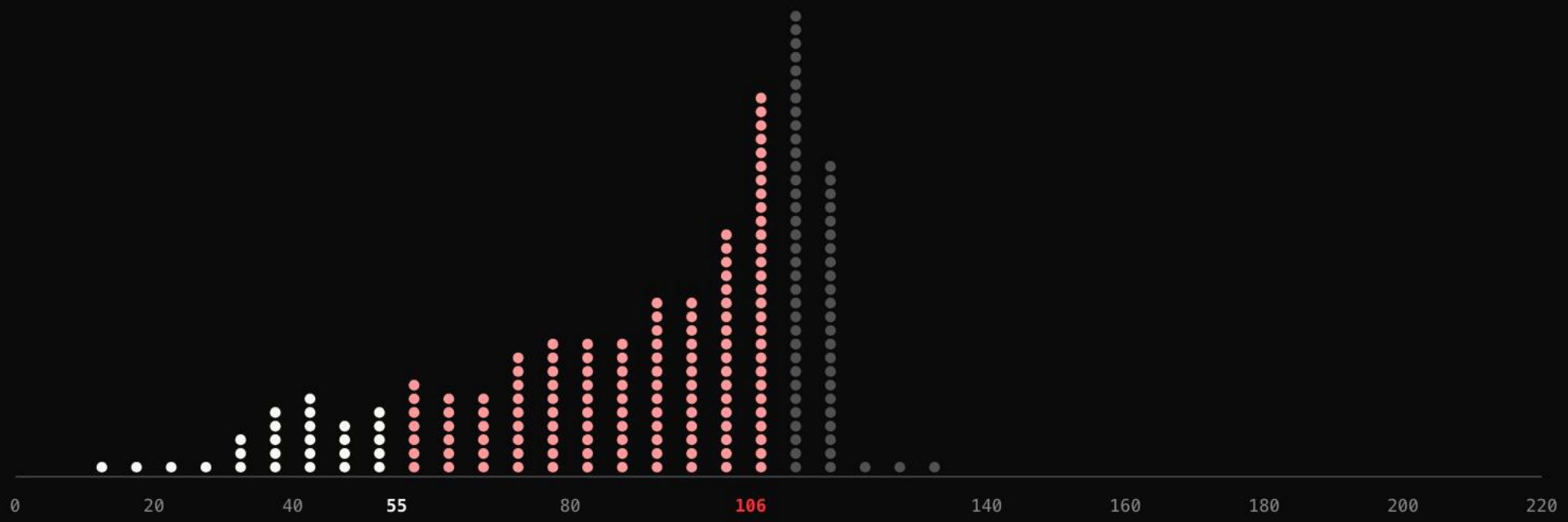
ONE DOT = 25 NEW APPLICATIONS · DAYS FROM SUBMISSION TO PART I CONCLUSION

14%

UP TO 55 DAYS

50%

55 TO 106 DAYS



Source: Yendou Country & Site allocation decision intelligence · 5,436 new applications with a clean Part I interval

36% exceed the statutory maximum

ONE DOT = 25 NEW APPLICATIONS · DAYS FROM SUBMISSION TO PART I CONCLUSION

14%

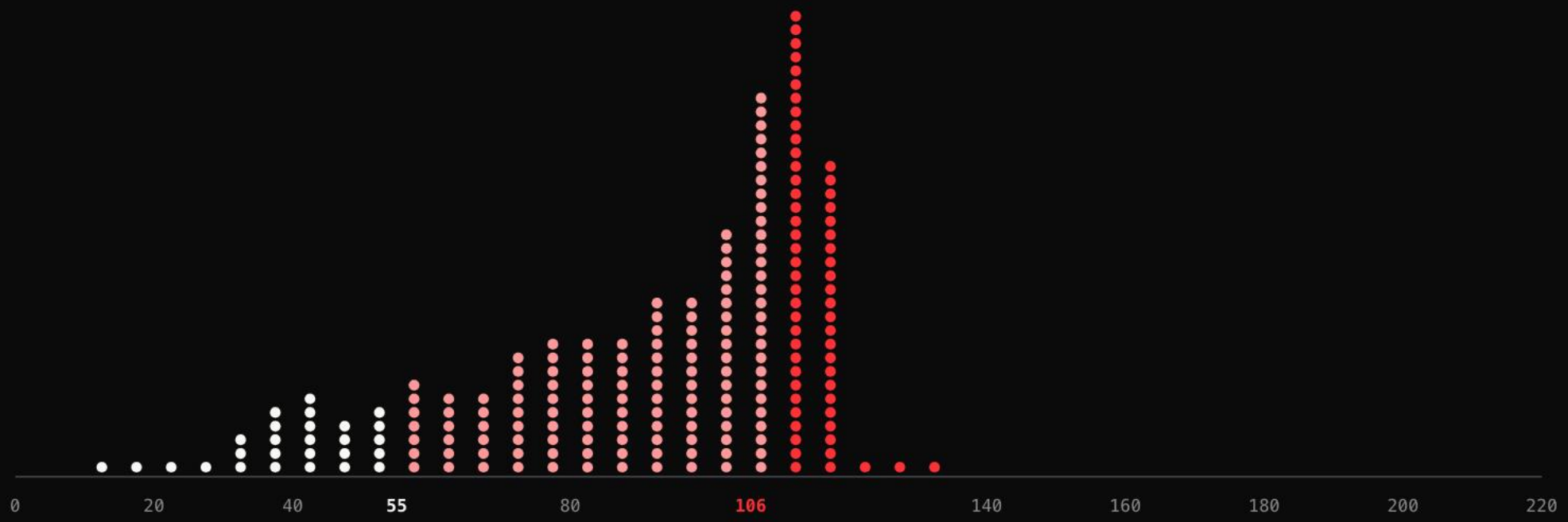
UP TO 55 DAYS

50%

55 TO 106 DAYS

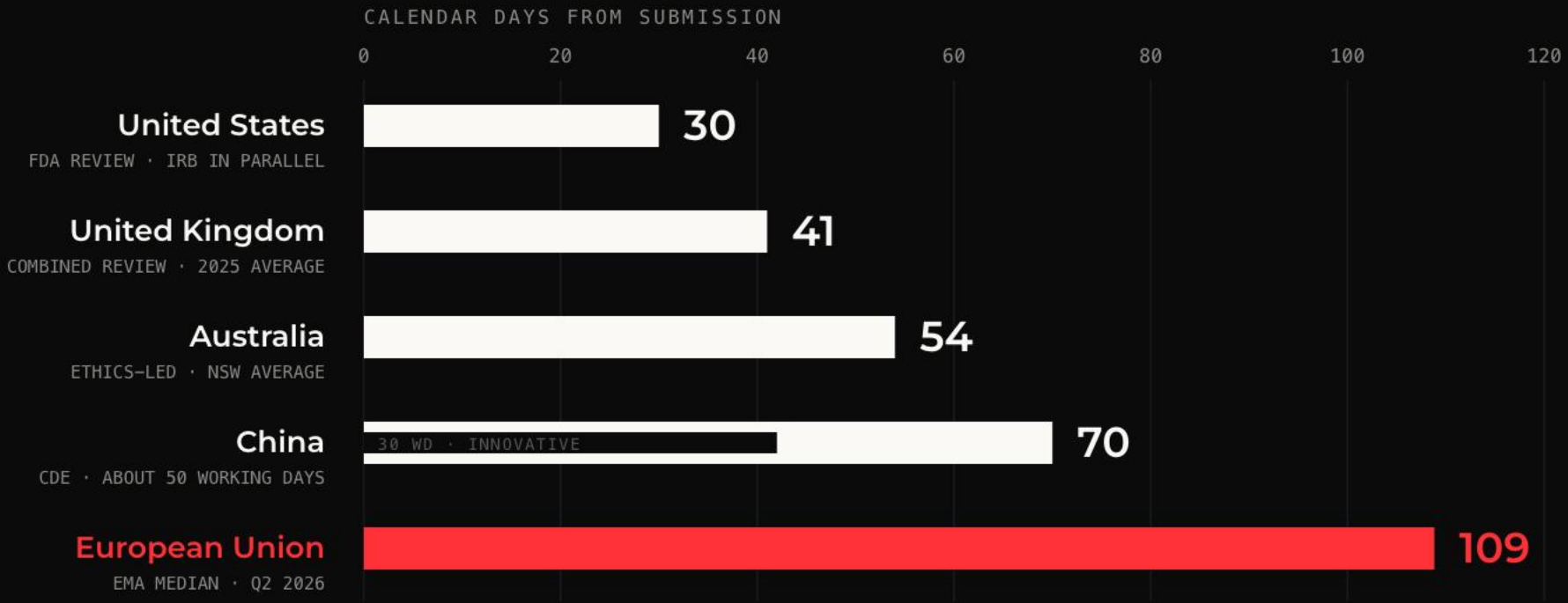
36%

BEYOND 106 DAYS

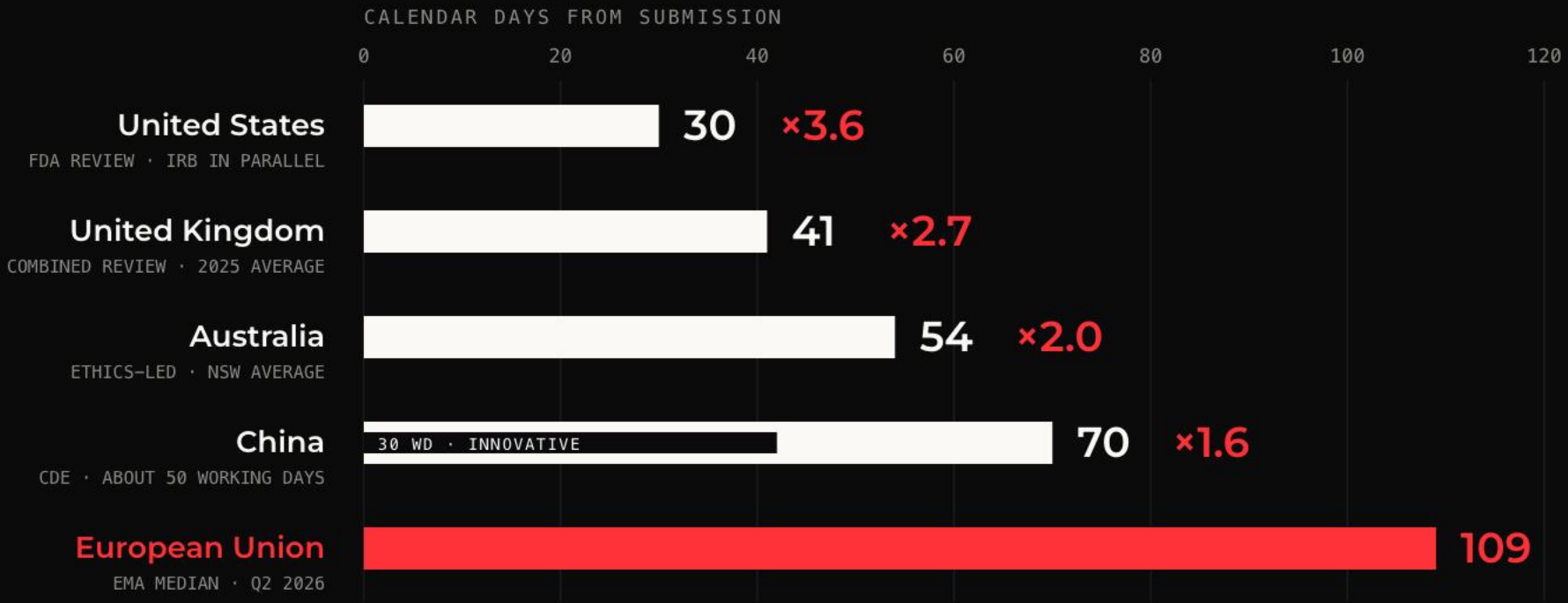


Source: Yendou Country & Site allocation decision intelligence · 5,436 new applications with a clean Part I interval

Started on the same day, the EU is the last major market to reach a decision

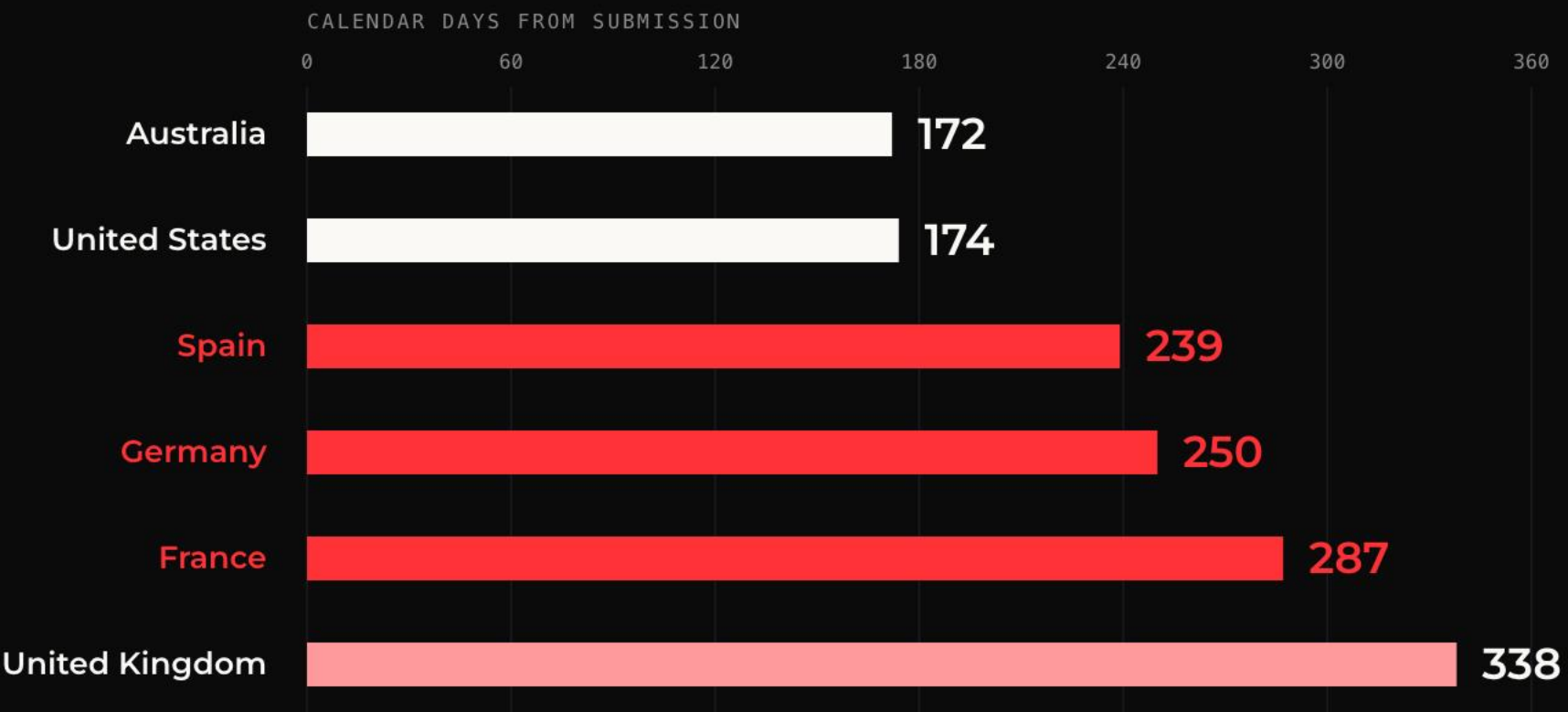


Europe's observed timeline is 1.6 to 3.6 times that of competing markets



Source: Yendou Country & Site allocation decision intelligence · EU median (109 days) as a multiple of each market
· 21 CFR 312.40 (FDA review · IRB approval runs in parallel) · MHRA 2025 · NSW OHMR · CDE and NMPA 2025 No. 86
(working days × 7/5) · ACT EU Q2 2026

From submission to first patient dosed, the US and Australia lead Europe's largest markets by two to four months



Source: Yendou Country & Site allocation decision intelligence · UK Office for Life Sciences, 2026, Table 7A-B · Clarivate CMR · commercial novel-medicine trials, 2023 · earliest ethics or regulatory submission to first patient dosed, median days

OBJECTIVE ONE

Did the EU become faster?



OBJECTIVE ONE

Did the EU become faster?

No.



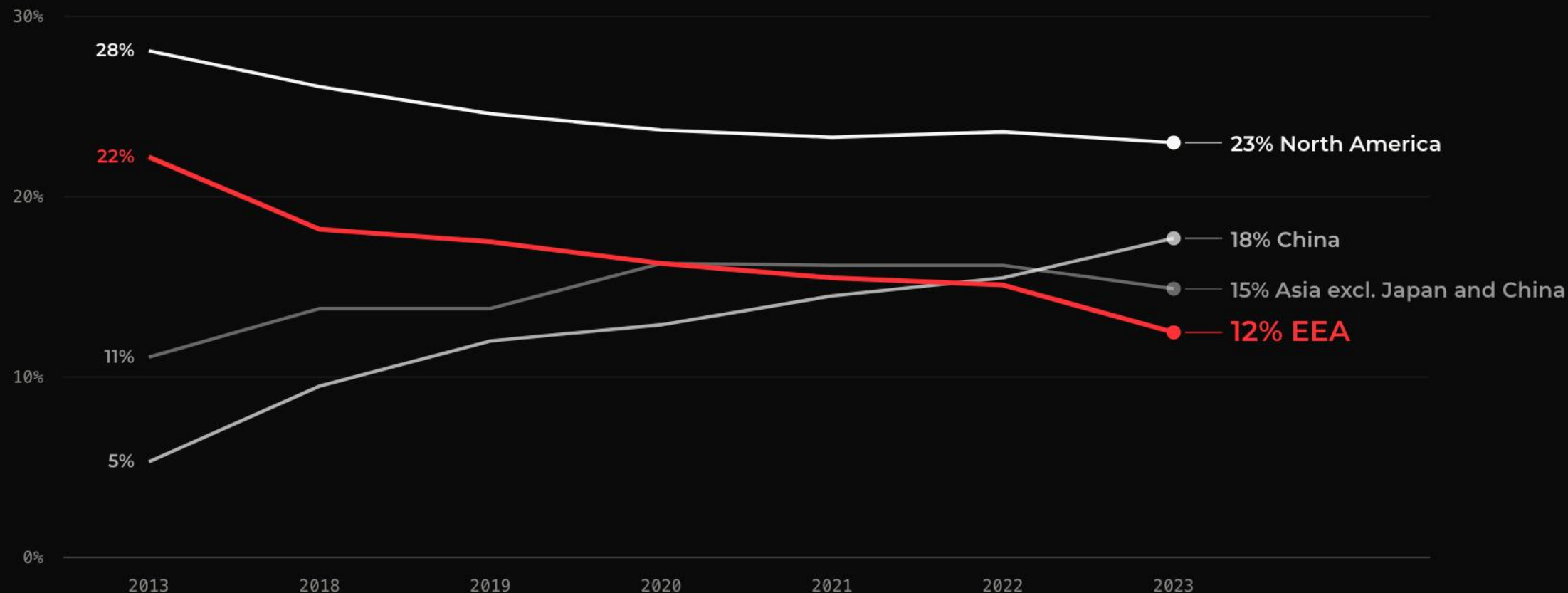
ACT III · THE MARKET

The market

Objective two: has the EU become more attractive for clinical research?

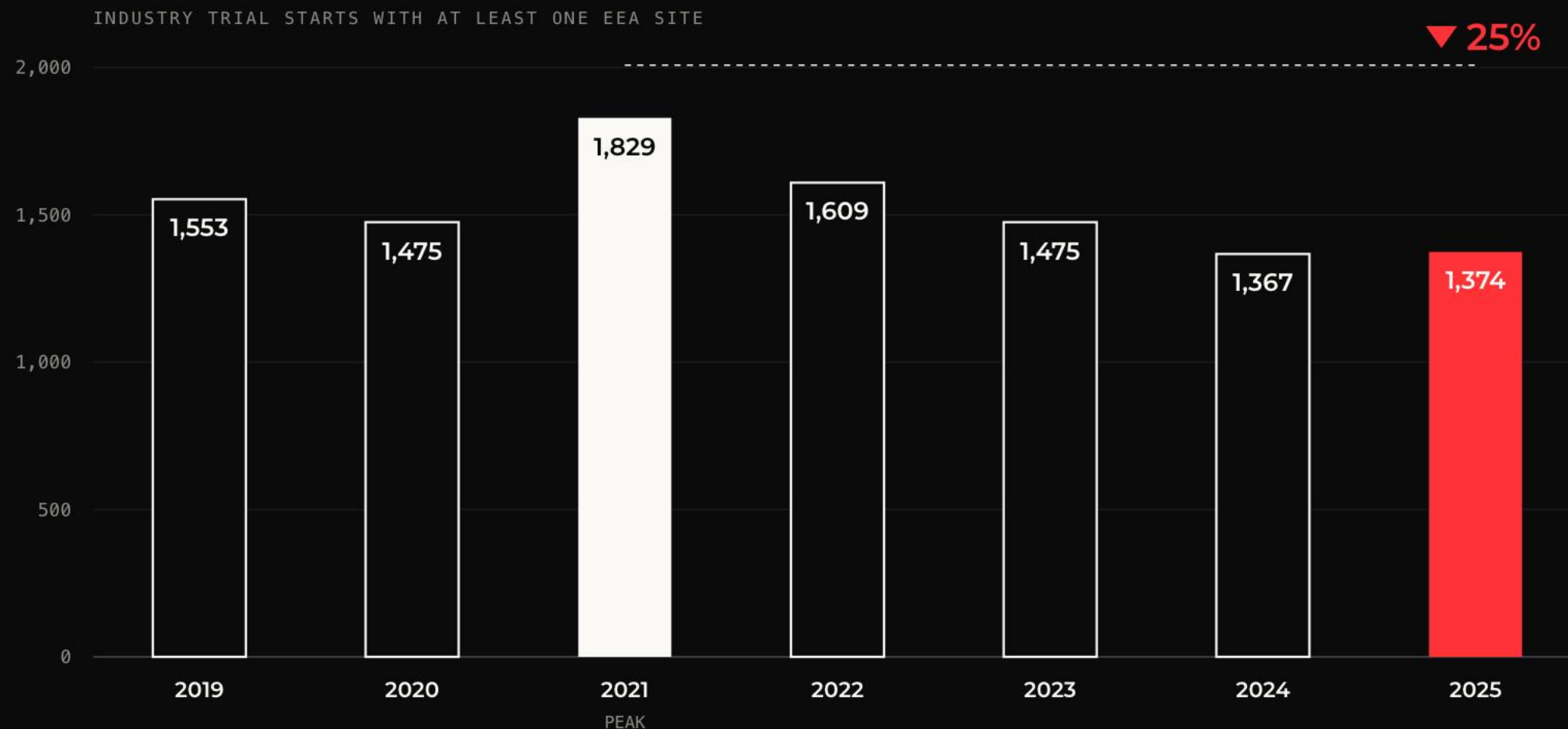
Europe's share of commercial trials fell from 22% to 12% as China's rose from 5% to 18%

SHARE OF GLOBAL COMMERCIAL TRIAL STARTS

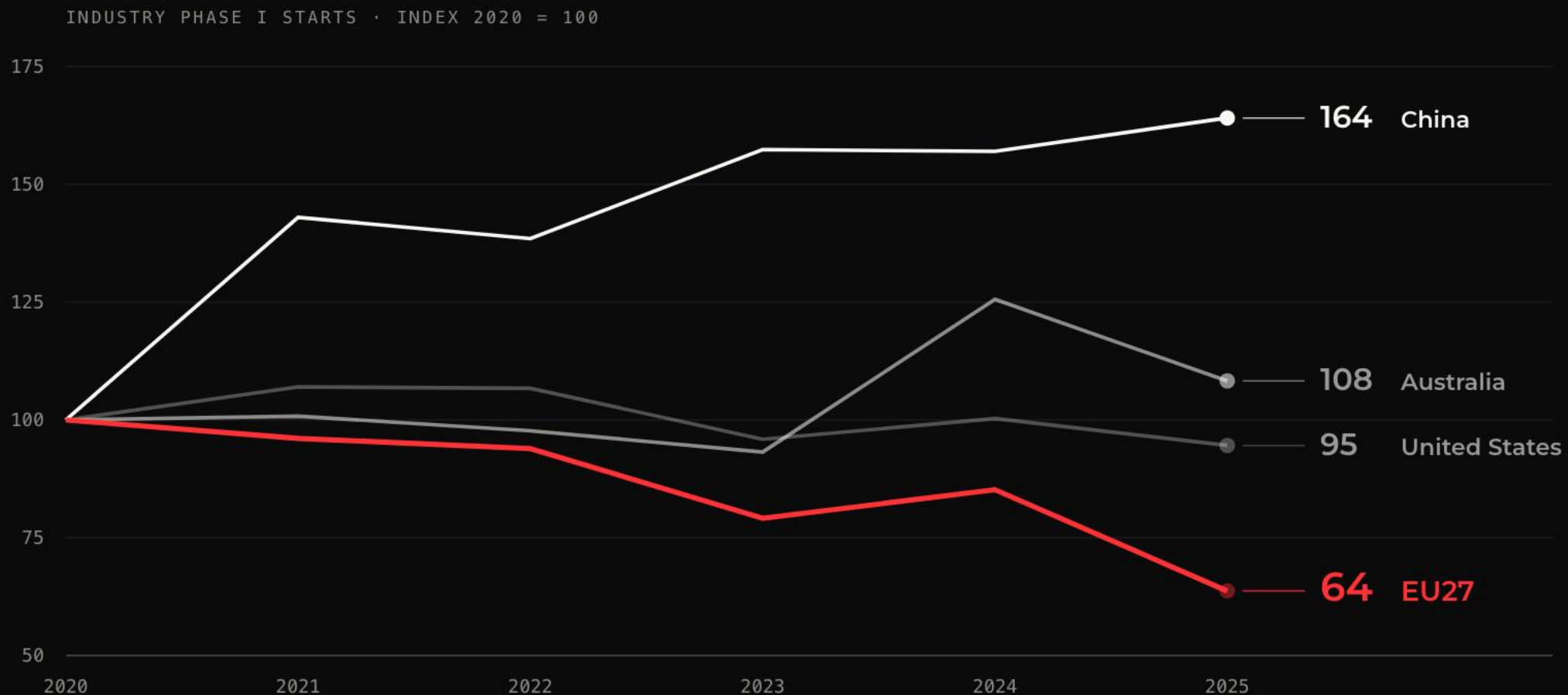


Source: Yendou Country & Site allocation decision intelligence · share of global commercial trial starts, Phase I to IV · a multi-region trial counts once in each region · latest published year 2023

And the decline continues: EEA industry trial starts are 25% below their 2021 peak



Early development declined most: EU industry Phase I starts fell 36% since 2020



China's growth is driven primarily by its own biotech industry

70 %+

of trials run only in China
are sponsored by Chinese
companies

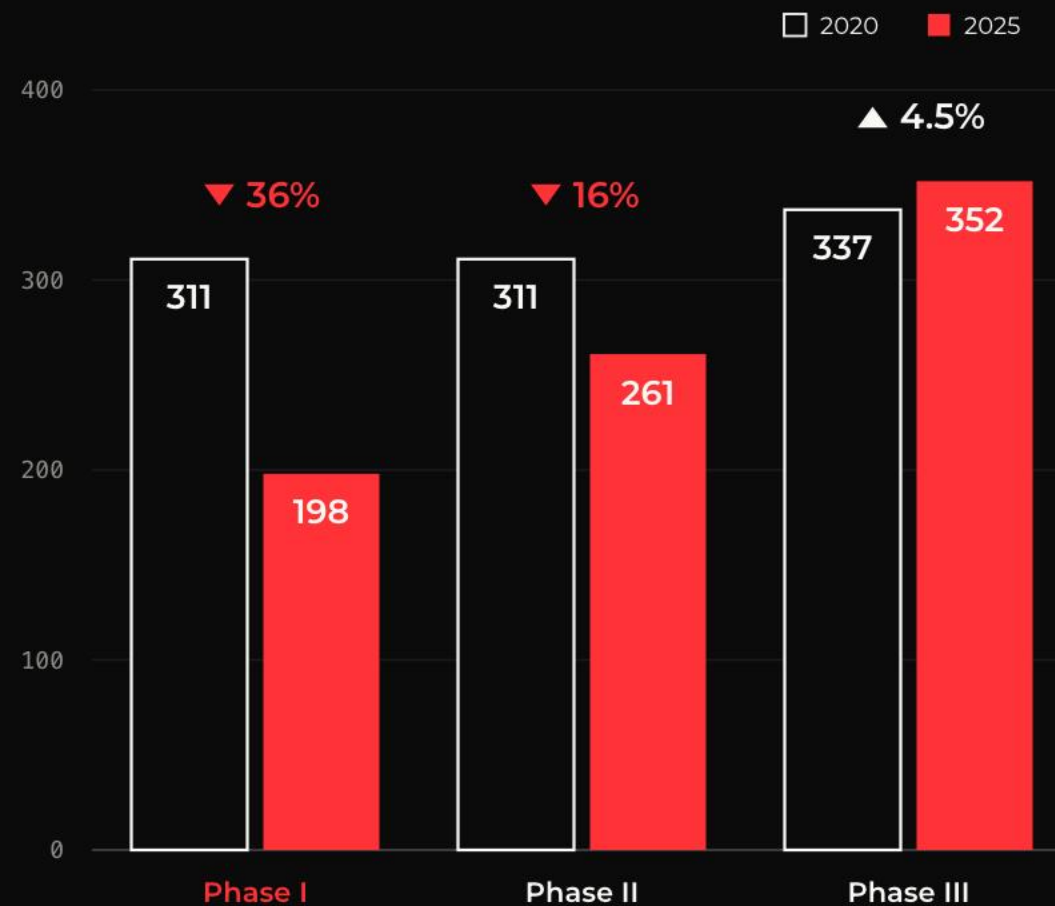
120

new drugs approved in
China in 2025, a record

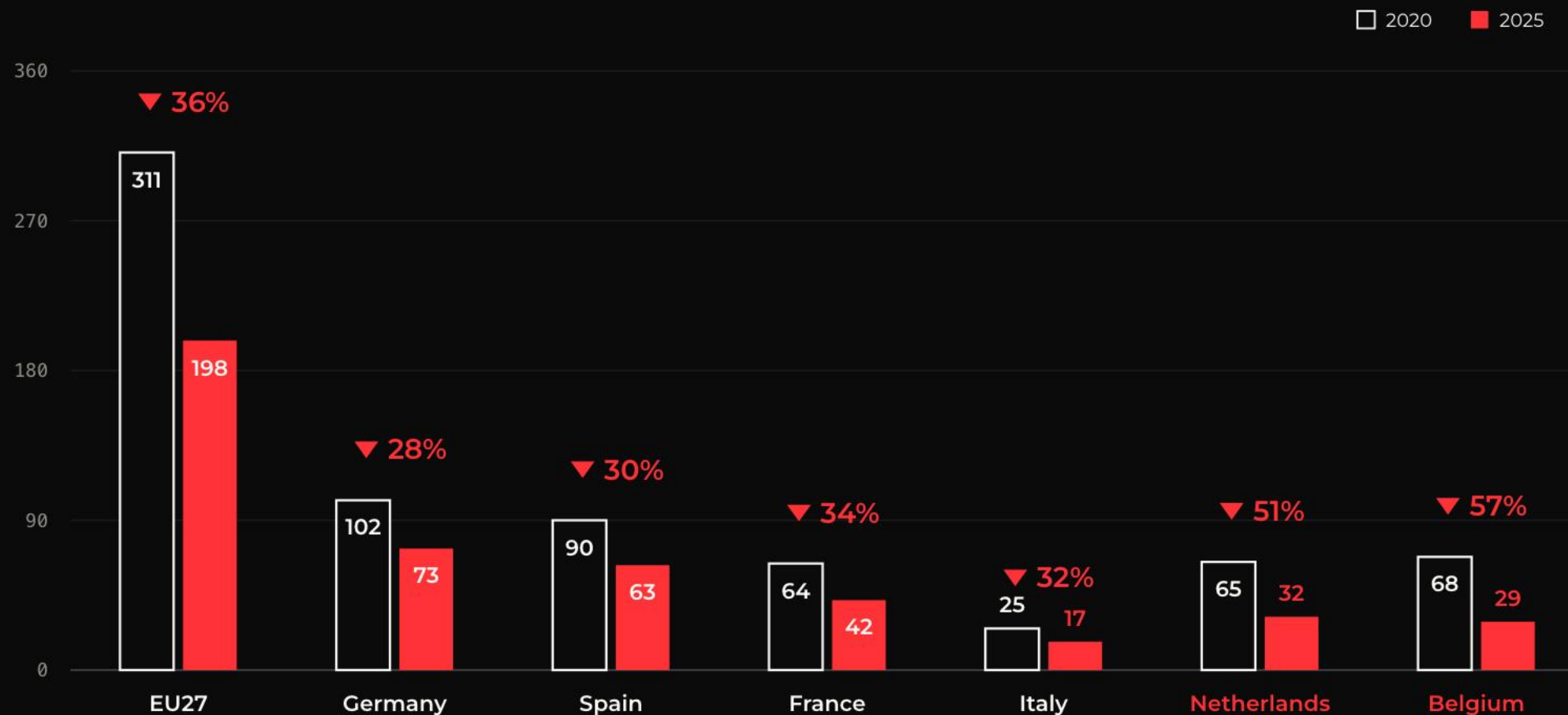
61

of them approved in China
first, before any other
market

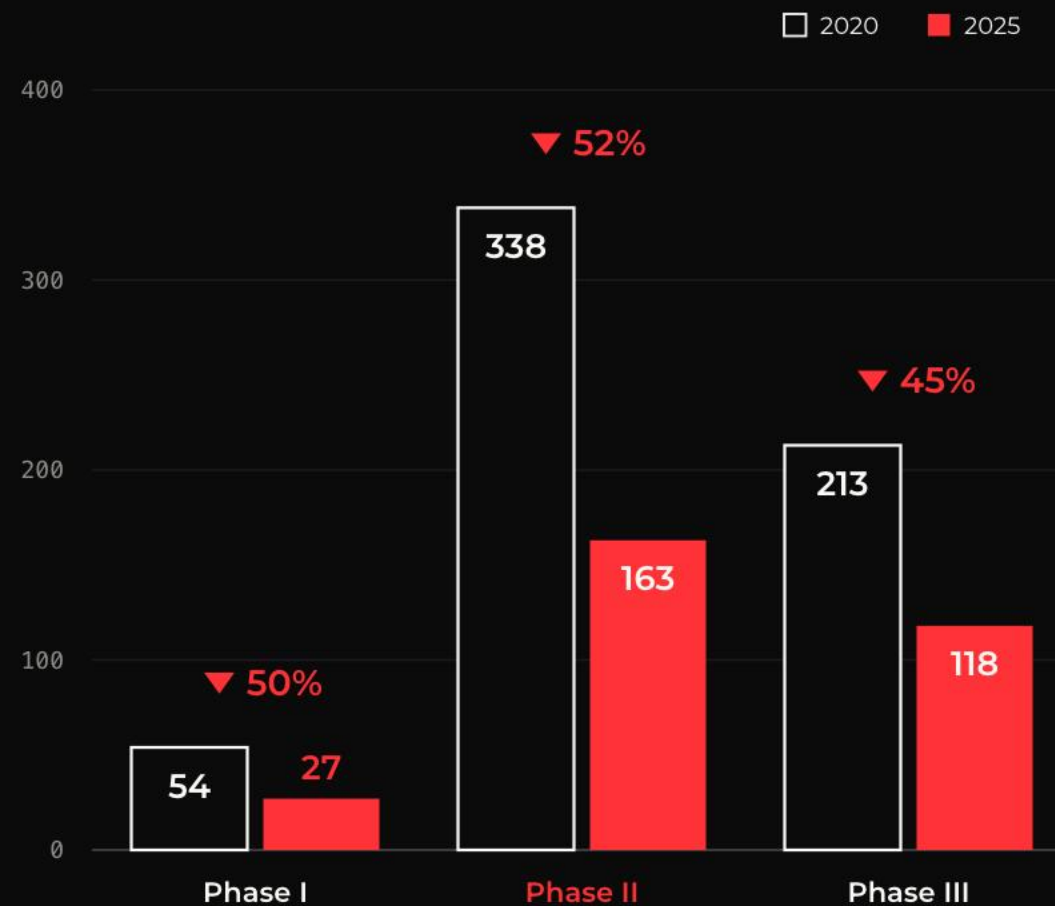
Europe is retaining late-stage trials while losing early development



Belgium and the Netherlands, Europe's Phase I hubs, lost more than half of their starts

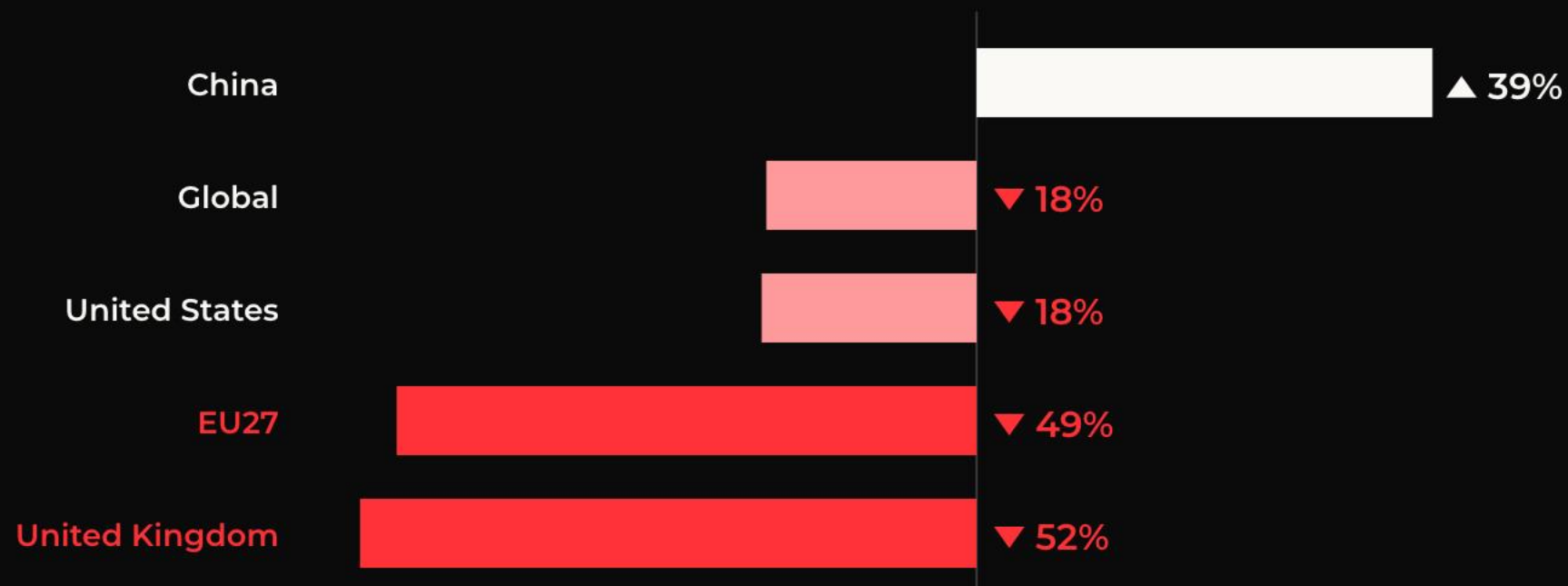


Academic and public-sector trials in the EU fell by half



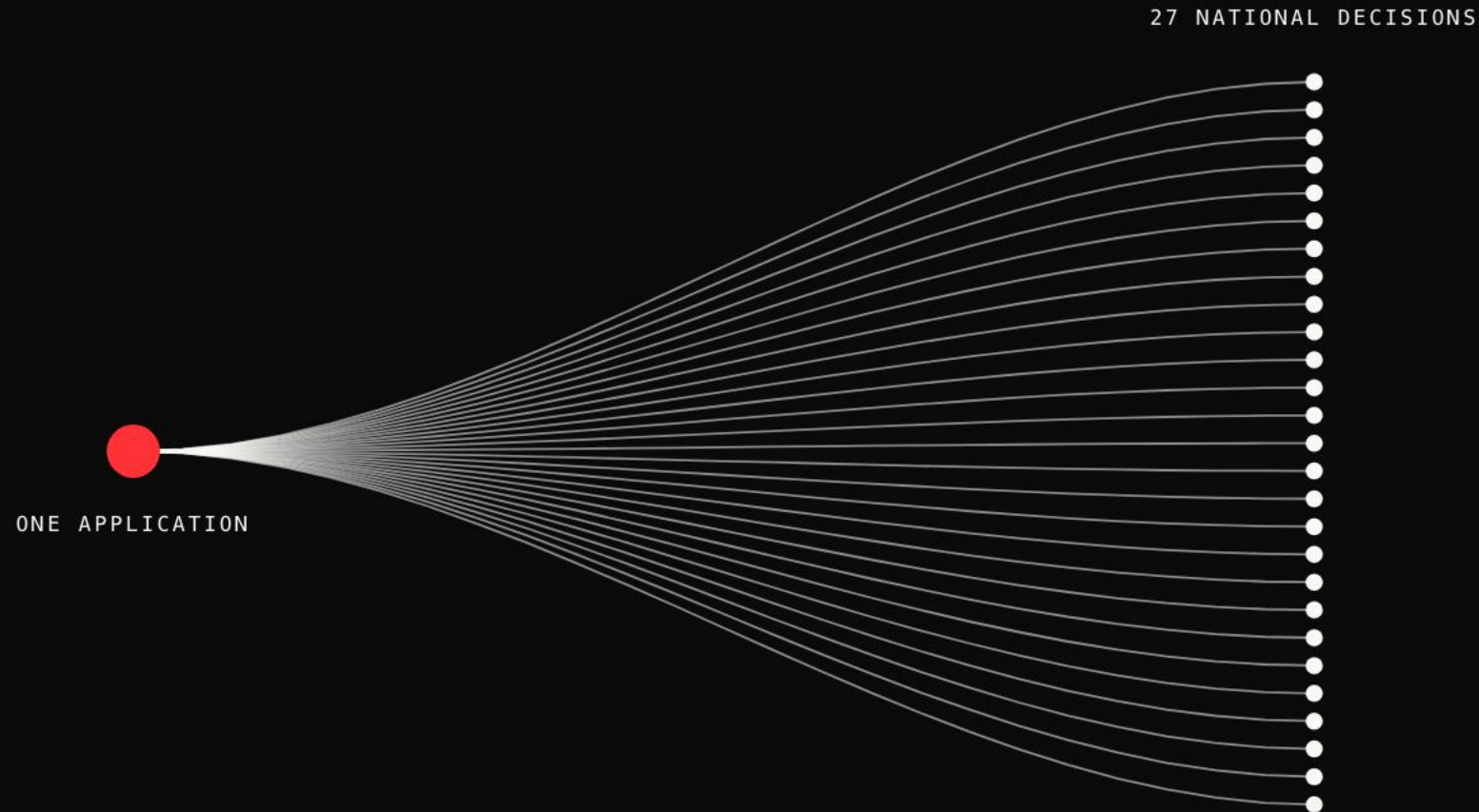
Academic trials declined everywhere except China; Europe's fall was nearly three times the global rate

CHANGE IN NON-INDUSTRY TRIAL STARTS, PHASE I TO III, 2020 TO 2025



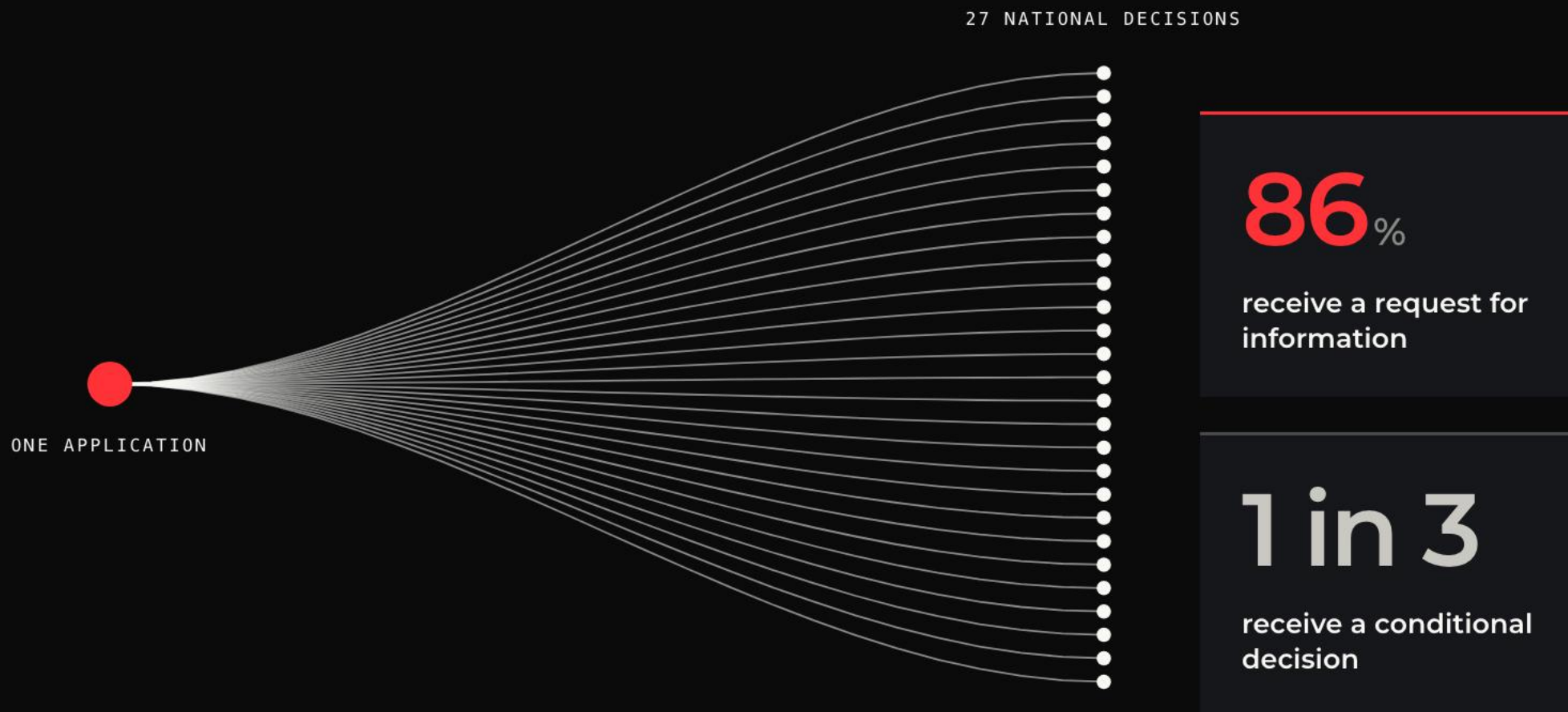
Source: Yendou Country & Site allocation decision intelligence · non-industry-led drug and biological starts, Phase I to III, 2020 vs 2025

One application still requires 27 national decisions



Source: Yendou Country & Site allocation decision intelligence · 2,581 of 7,894 new applications and resubmissions with a conditional decision · Regulation (EU) 536/2014

86% receive a request for information; one in three a conditional decision



Source: Yendou Country & Site allocation decision intelligence · 2,581 of 7,894 new applications and resubmissions with a conditional decision · Regulation (EU) 536/2014

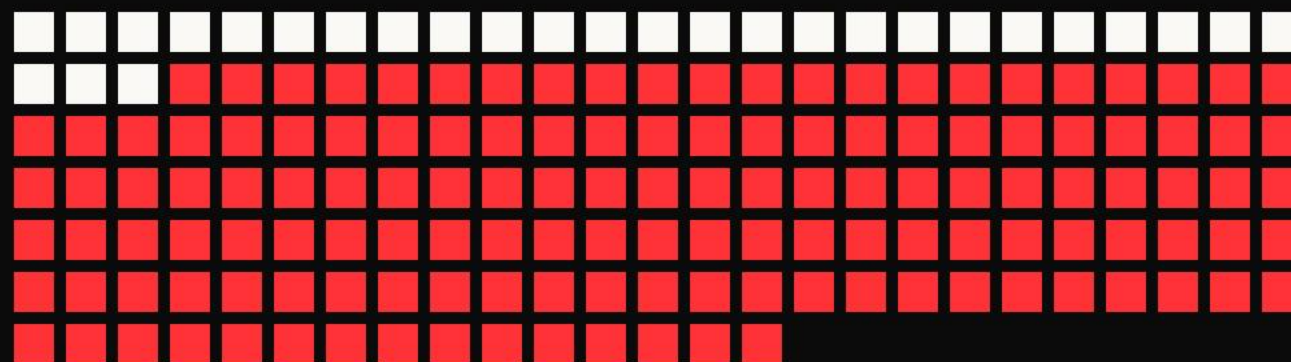
In 2025, the EU received 2,831 new trial applications



2,831
new applications

Source: Yendou Country & Site allocation decision intelligence · ACT EU monitoring reports, 2025: 2,831 new applications, 13,710 substantial modifications, 975 additional Member State applications · one square = 100 applications

and almost five times as many substantial modifications



2,831

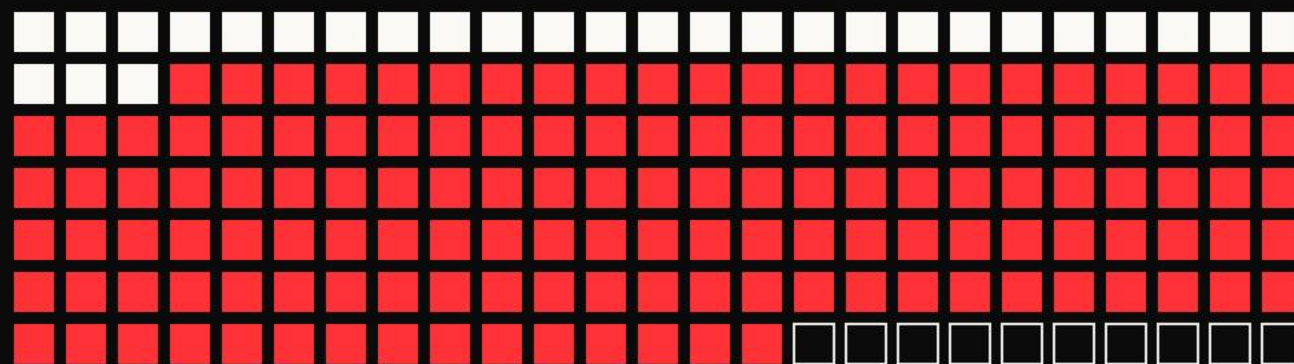
new applications

13,710

substantial modifications

Source: Yendou Country & Site allocation decision intelligence · ACT EU monitoring reports, 2025: 2,831 new applications, 13,710 substantial modifications, 975 additional Member State applications · one square = 100 applications

plus 975 applications to extend running trials to more Member States



2,831

new applications

13,710

substantial modifications

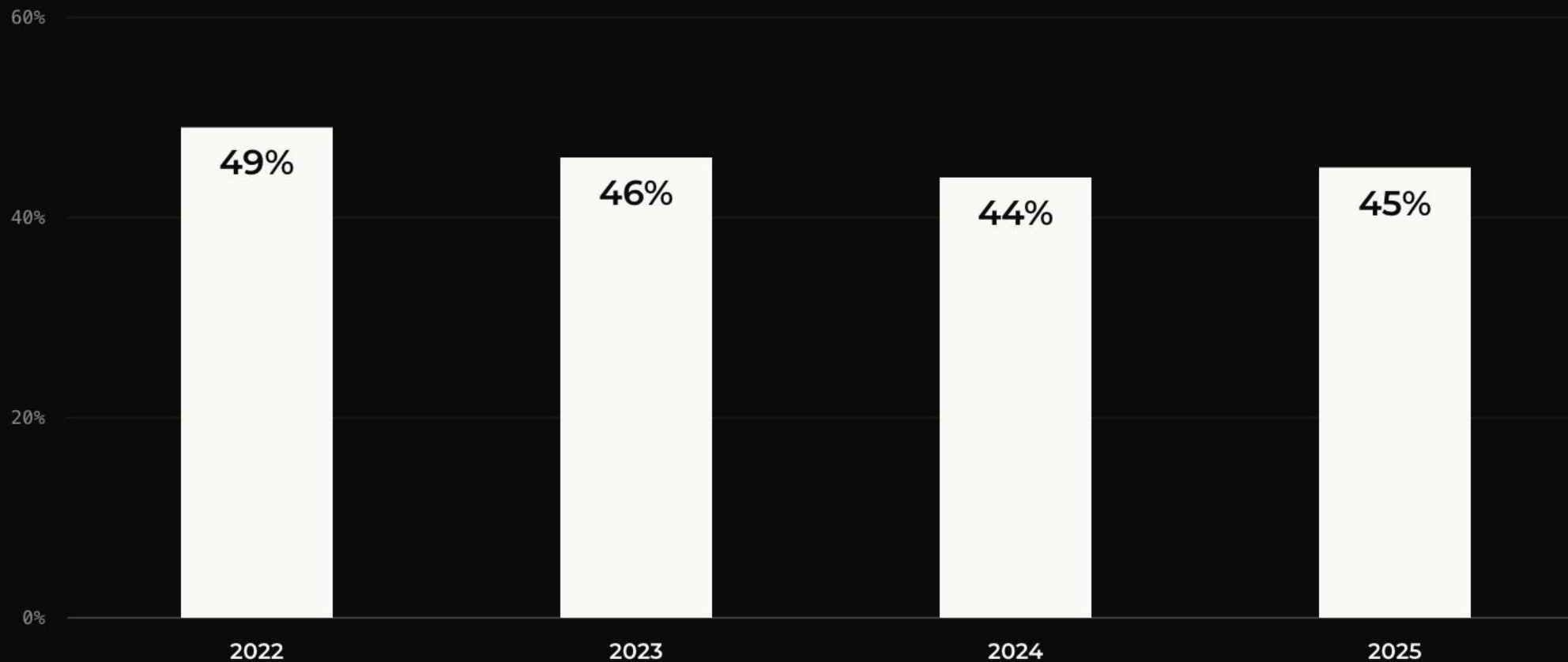
975

applications to add Member States

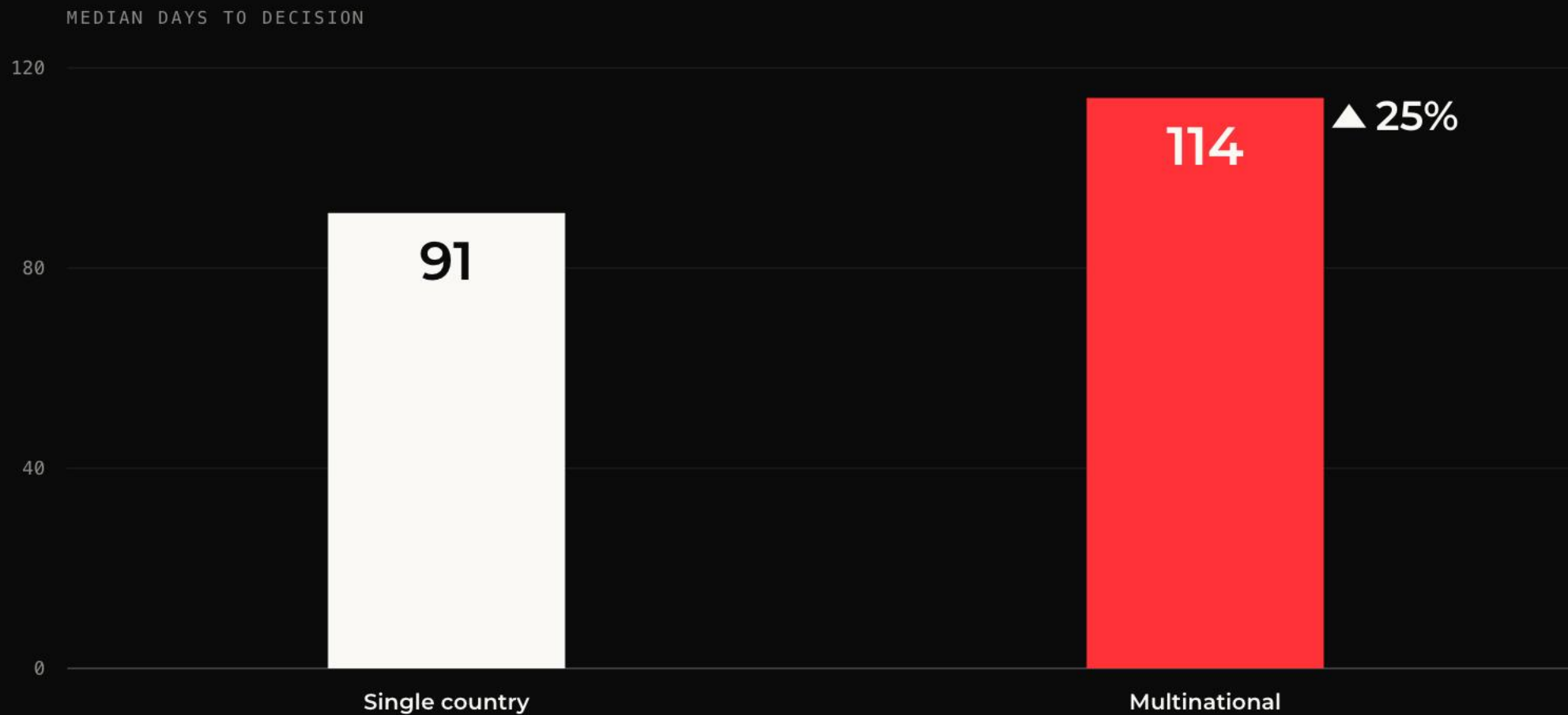
Source: Yendou Country & Site allocation decision intelligence · ACT EU monitoring reports, 2025: 2,831 new applications, 13,710 substantial modifications, 975 additional Member State applications · one square = 100 applications

Fewer than half of new applications are multinational, a share that has not grown

SHARE OF NEW APPLICATIONS THAT ARE MULTINATIONAL

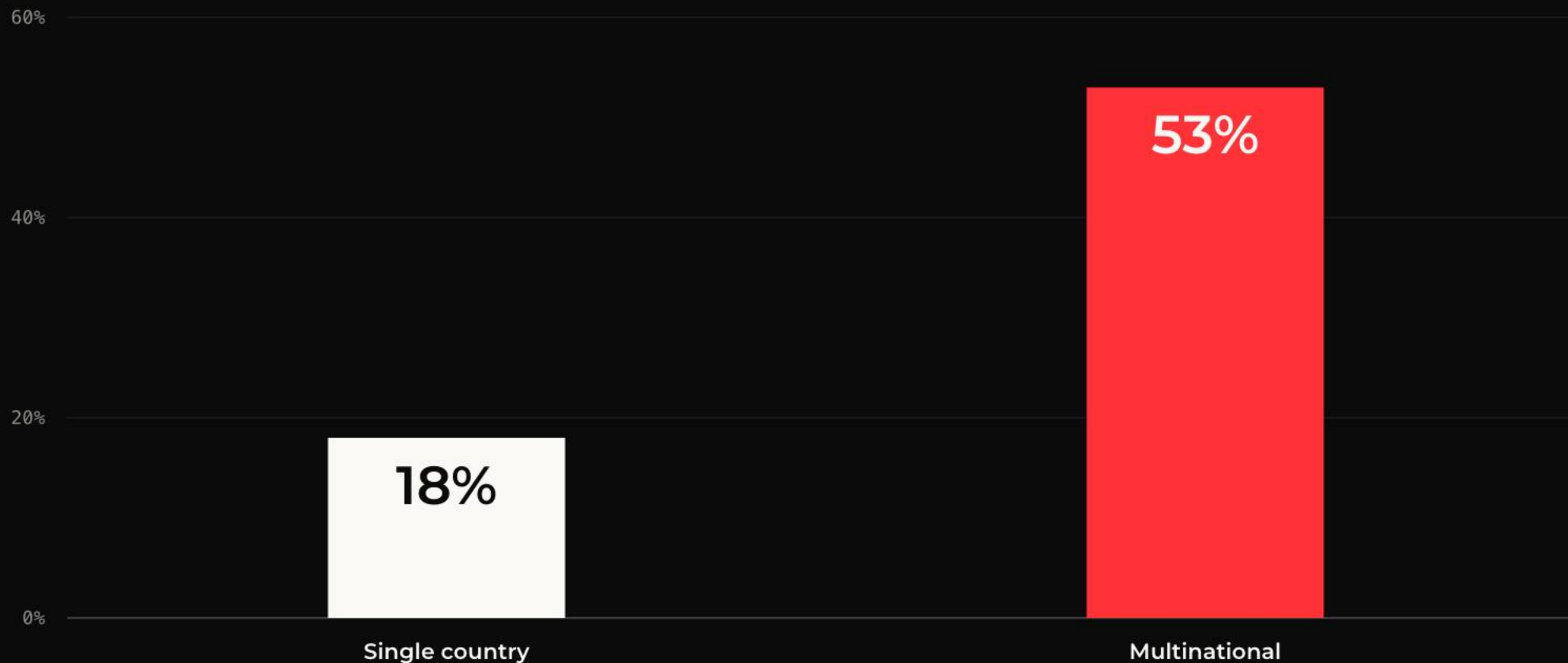


Multinational applications take 25% longer to authorise

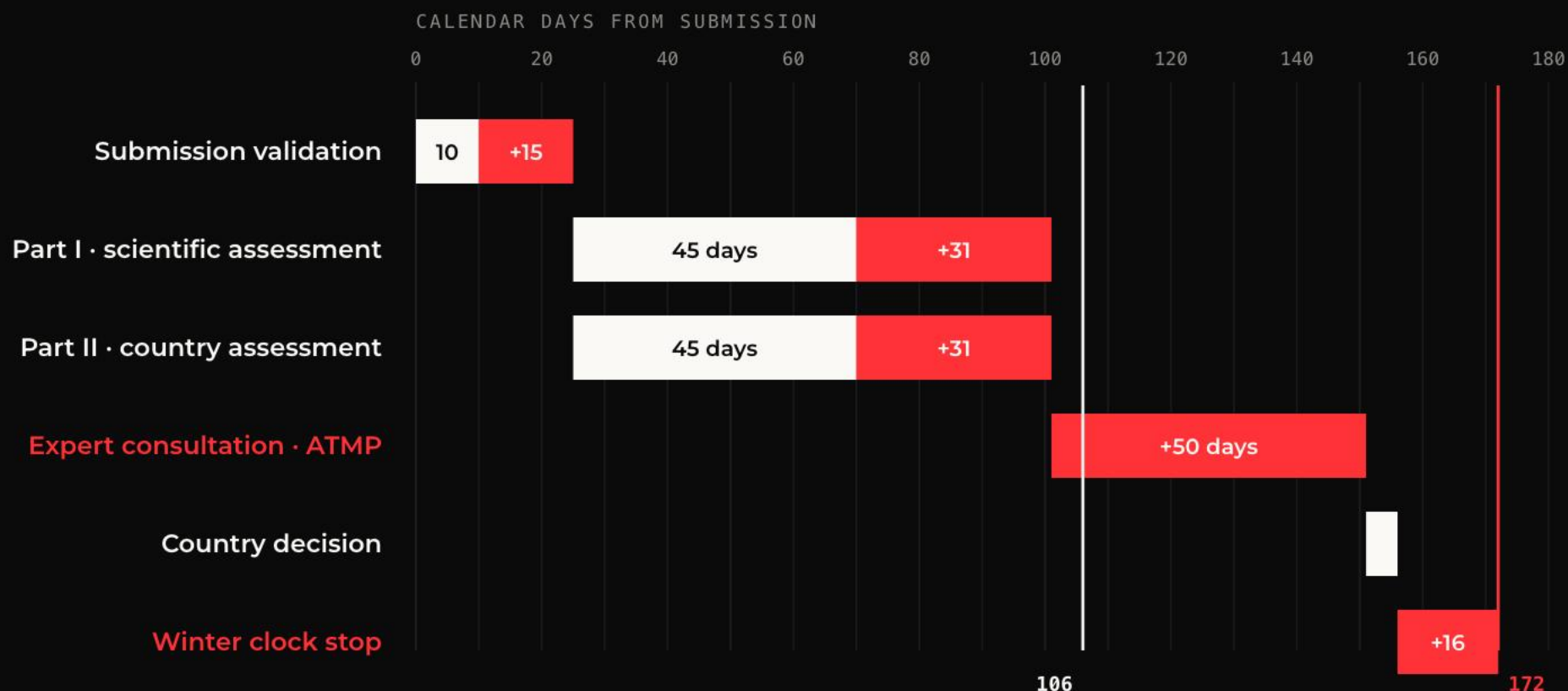


Multinational applications are three times as likely to receive conditions

CONDITIONAL DECISION IN AT LEAST ONE COUNTRY

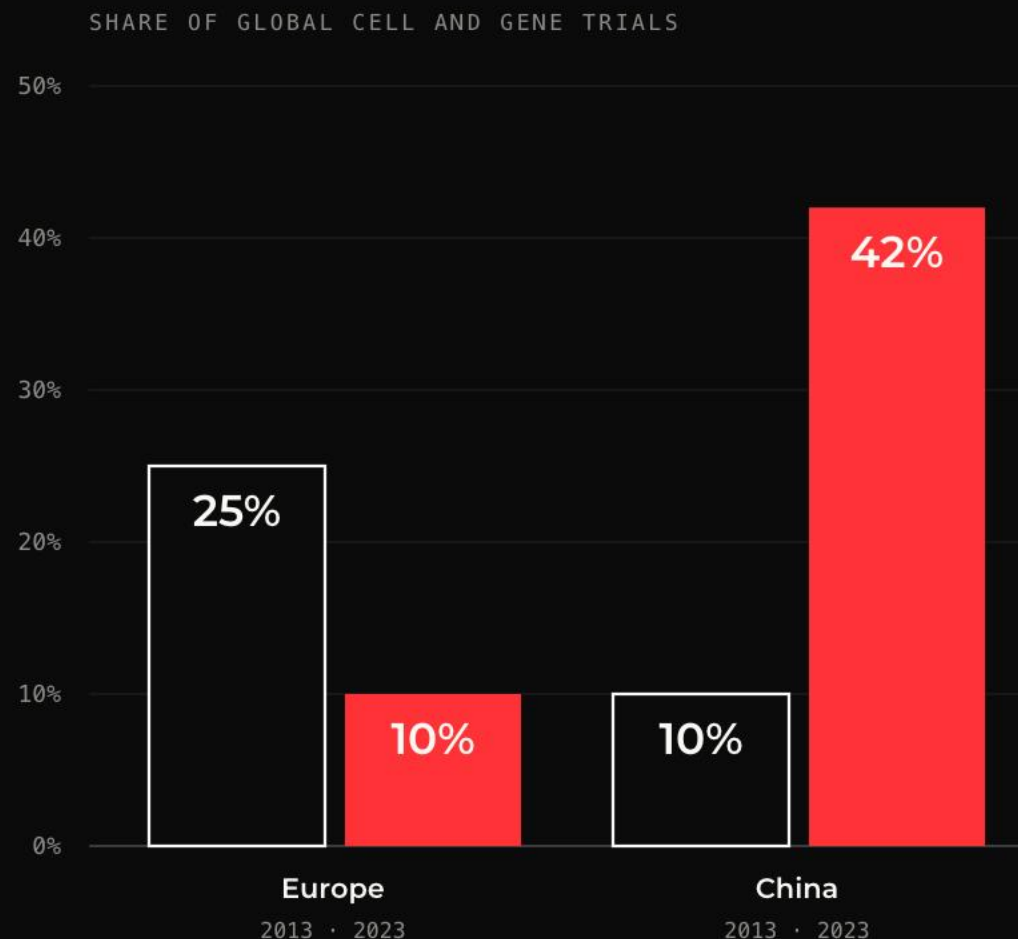


For advanced therapies, the Regulation allows a further 50 days



Source: Yendou Country & Site allocation decision intelligence · Regulation (EU) 536/2014, Article 6(7): extension of the assessment for consultation with experts on advanced therapy products

Europe's share of cell and gene therapy trials fell from 25% to 10%



DECEMBER 2025

The Commission has proposed removing the extension.

Eleven years after introducing it.

ACT IV · THE DESIGN

The question is not whether to regulate. It is how.

Regulation decides where medicine is developed. Australia and the US show what a well-designed process does.

Where regulation is designed for speed, investment follows

40+

trials

in Australia since 2013

2,200+

participants

enrolled across those trials

180+

jobs

about three-quarters in
clinical operations

BeiGene's Australian programme: one allocation decision, a decade of capacity

40+

trials

in Australia since 2013

2,200+

participants

enrolled across those trials

180+

jobs

about three-quarters in
clinical operations

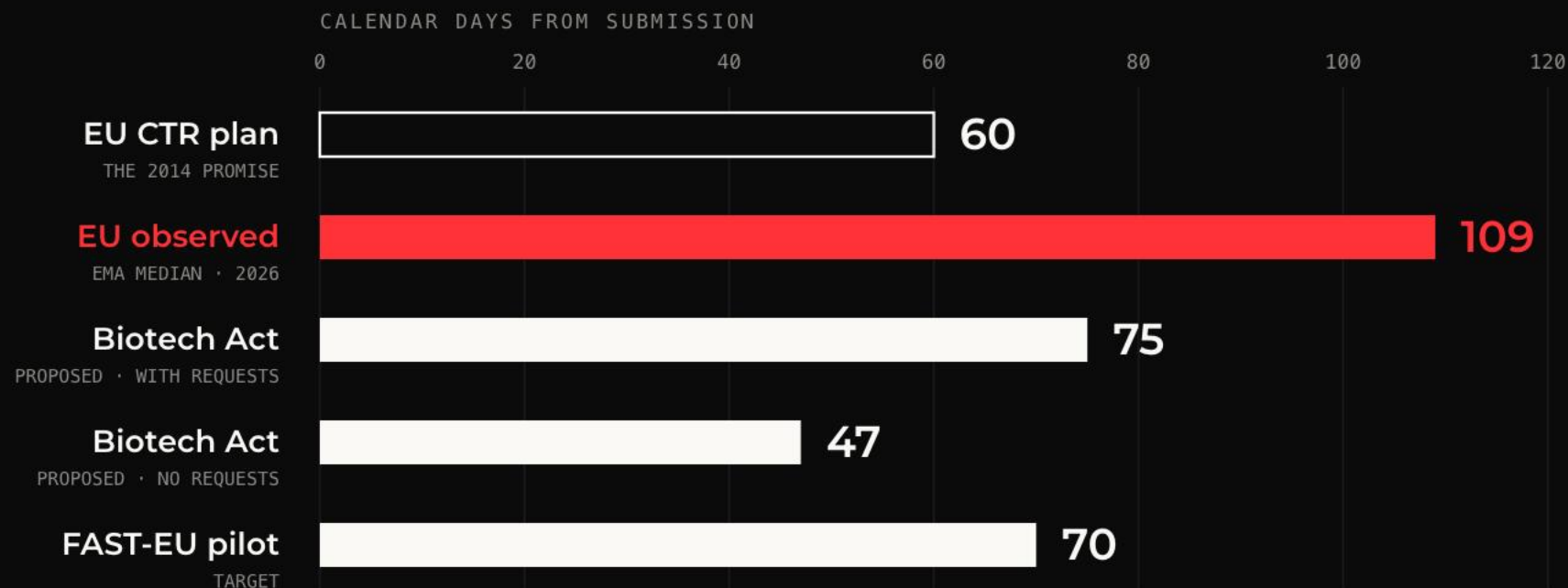
3_{vs 6 to 9}

months

to first patient after approval,
against the US or the EU

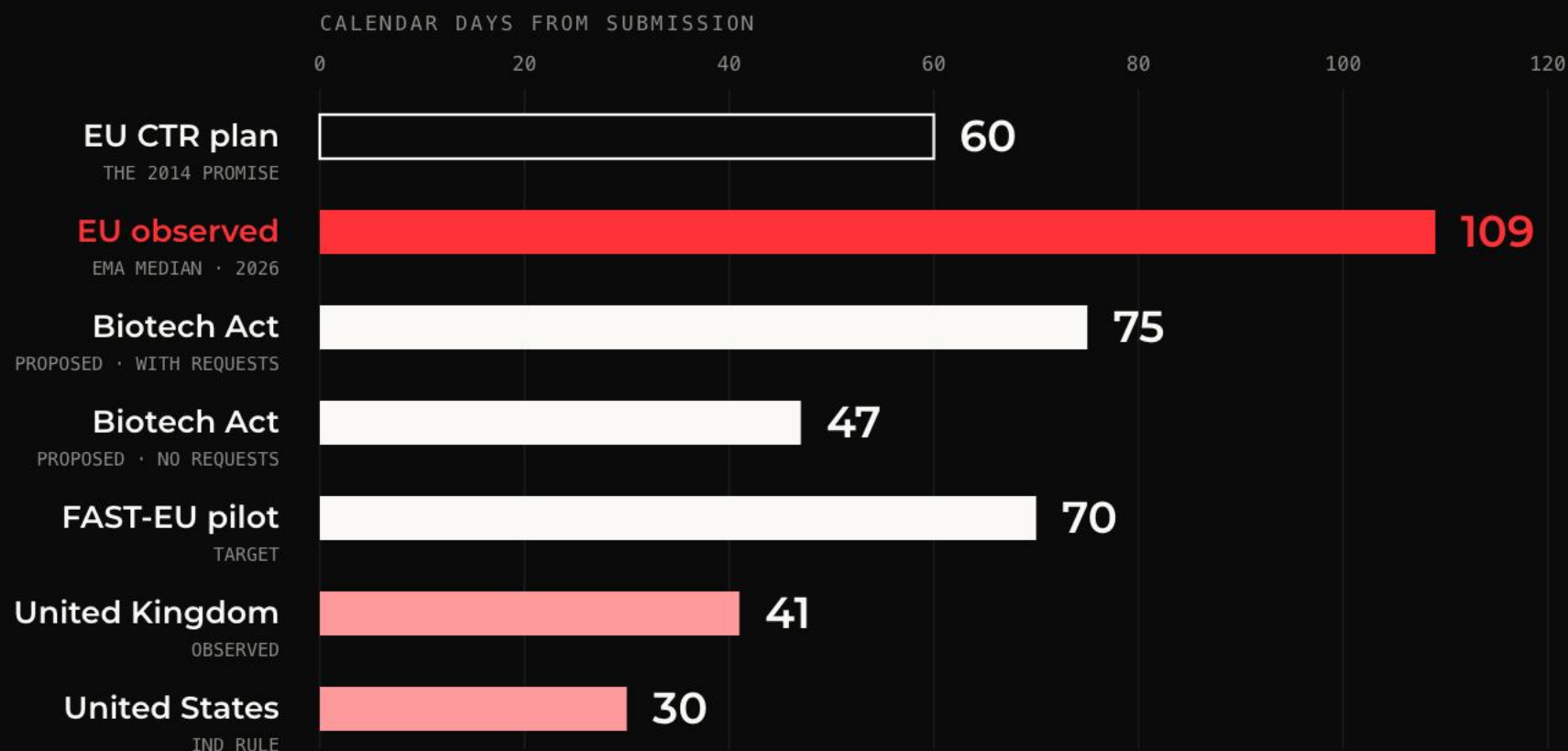
Approval rests with a certified ethics committee and the institution; the TGA is notified. Early-phase programmes that once started in Leuven and Leiden now start in Melbourne and Adelaide.

Brussels now proposes 75 days, and 70 in a pilot



Source: Yendou Country & Site allocation decision intelligence · Regulation 536/2014 · ACT EU Q2 2026 · Biotech Act proposal, 16 Dec 2025 · HMA FAST-EU · MHRA 2025 · 21 CFR 312.40

Even the proposed reforms would leave the EU behind the US and the UK



Source: Yendou Country & Site allocation decision intelligence · Regulation 536/2014 · ACT EU Q2 2026 · Biotech Act proposal, 16 Dec 2025 · HMA FAST-EU · MHRA 2025 · 21 CFR 312.40

ACT V · THE STAKES

The stakes

Industry trials contribute €21.7 billion a year to the EEA economy

€21.7bn

annual gross value added by industry trials across the EEA

Industry trials employ 45,000 people directly in the EEA

45,000

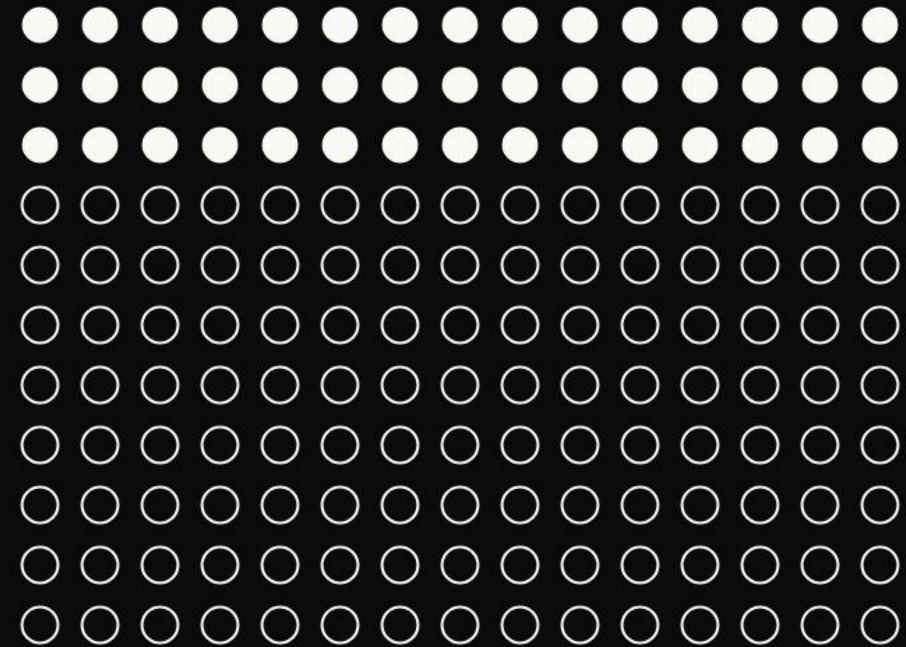
direct clinical research roles



and support 165,000 jobs across the wider economy

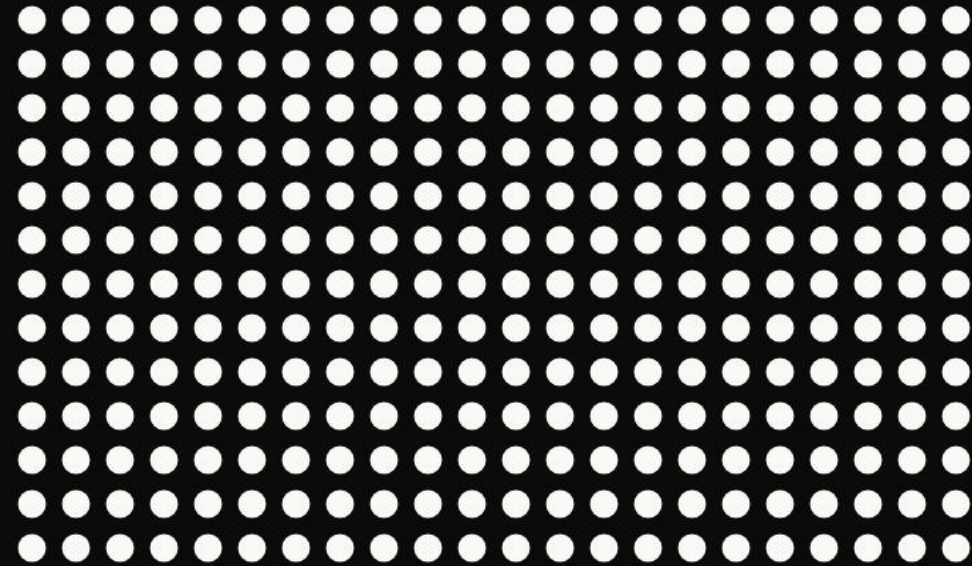
165,000

jobs including the supply chain and
induced effects



In 2018, 286,000 patients enrolled in commercial trials involving the EEA

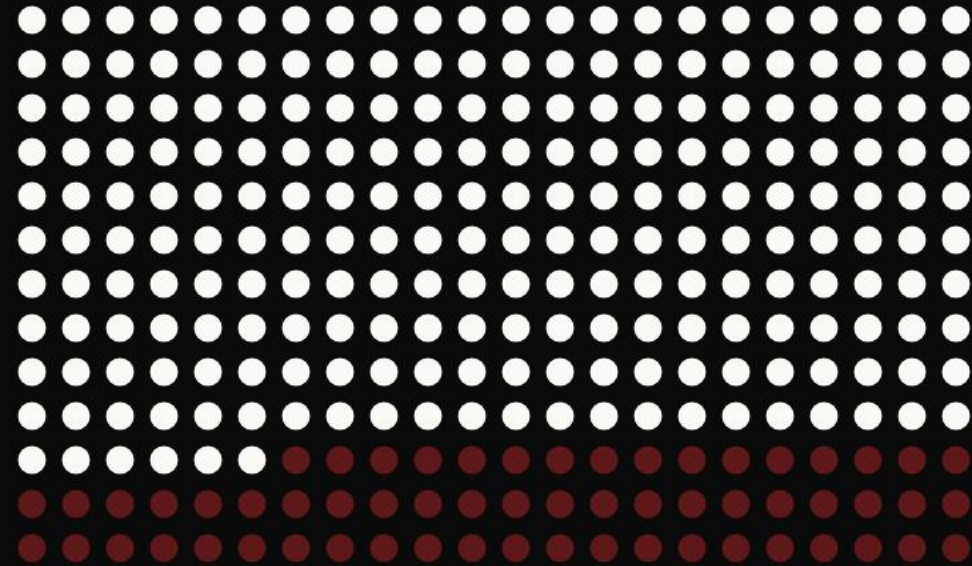
286k



By 2023, 60,000 fewer patients had a place in a trial

226k

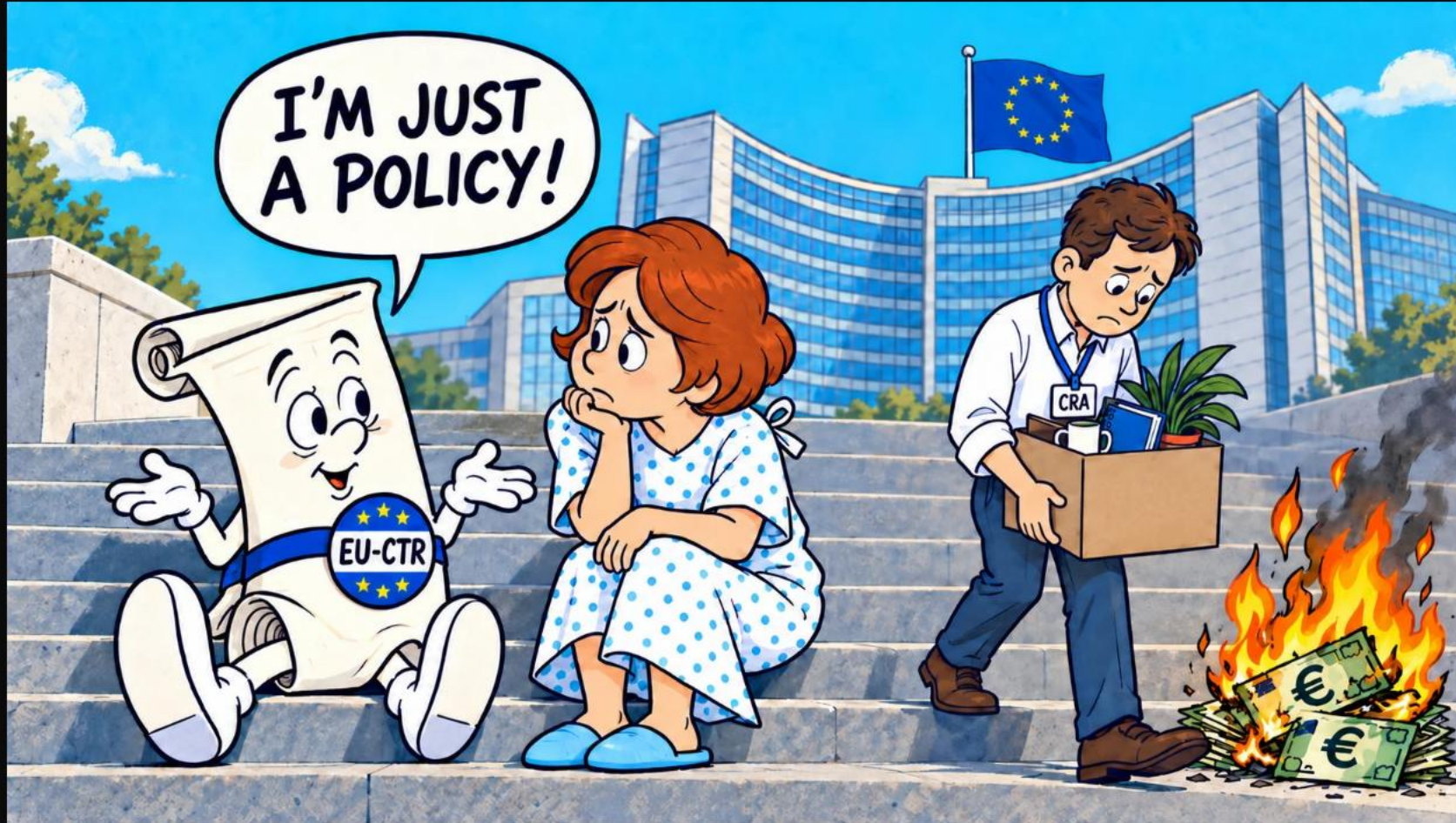
▼21% · 60,000 fewer patients a year



**Did the EU CTR accelerate timelines
and make Europe more attractive?**

Did the EU CTR accelerate timelines
and make Europe more attractive?

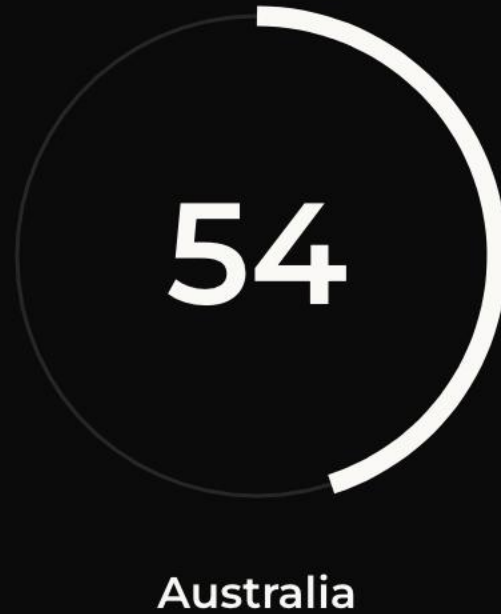
No.



We answer
to them.

Who do they
answer to?

DAYS FROM SUBMISSION TO A DECISION



ZINA SARIF · FOUNDER AND CEO, YENDOU

SCAN FOR THE TALK
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