The BioCentury-BayHelix

EAST-WEST BIOPHARMA SUMMIT

Organized by BioCentury and BayHelix in collaboration with McKinsey & Company

Taking innovation global: BioCentury's East-West Scene Setter survey, 2022

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#BioCenturyEastWest

Paving the path to global impact will take perseverance

BioCentury's East-West Scene Setter survey says the road to global medicines is entering tough terrain

- The biopharma industry is going to need to revert to type, knuckle down and demonstrate the perseverance that was the hallmark of its foundation to maximize the impact of the innovations that are ushering in the next era of therapies.
- The mission to create medicines for patients globally faces an uphill struggle. That is not only because the recent era of free money is over, but because the industry – against the backdrop of geopolitical unrest – faces new and escalating challenges in cross-border interactions.
- Surveyed biotechs in the West and East see harder times ahead for developing, testing and commercializing their products in other regions – from manufacturing to gaining regulatory approval to selling their drugs.
- It's not all dour, however. Dealmaking might be the panacea; both West and East, there's optimism this will get easier.
- Cross-border investment appears to be the big unknown, with companies in the West and East opposed in their predictions.

BioCentury East-West Survey details

- BioCentury surveyed the East-West biotech community on how they envisage cross-border dynamics unfolding, and the impact for creating global businesses to treat patients across the world.
- It asked their predictions for the environment in the next five years for:
  - Accessing capital
  - Partnering
  - Developing therapies
  - Commercializing products
- 49 biotech leaders responded: 34 from the West, 15 from Asia
  - Western execs from: U.S., Canada, Europe, Australia
  - Asian execs from: China, Japan, S. Korea, Taiwan
- The survey ran from Sept. 27 to Oct. 22, 2022
- Quotes are from write-in comments and in-person interviews

"To be the company we want to be, we need to be global."

Asia-based exec

“I’m certain there are other opportunities to bridge the East and West together and create more meaningful partnerships than just extracting from one territory to another, to more collaborative objectives.”

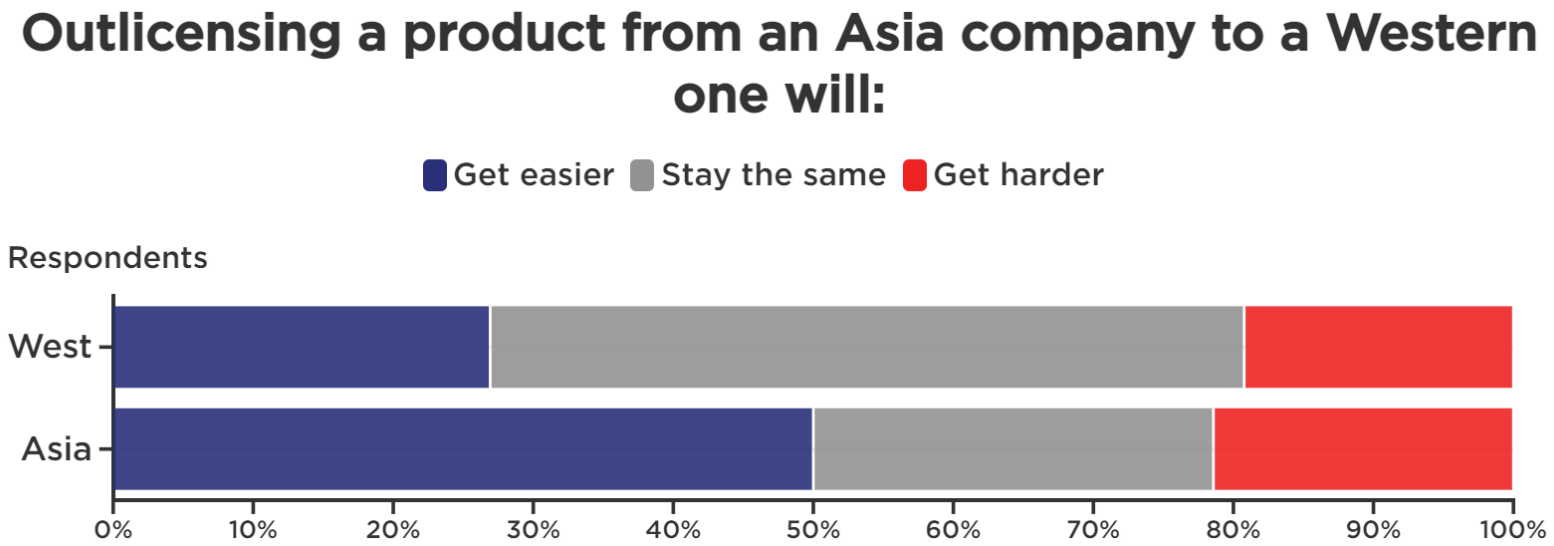
Asia-based executive

Biotechs will continue to find deals and money

The consensus view is that companies in East and West will continue to partner and find ways to enter deals with global players, with a two-way street increasingly opening up. Views differ, however, on the prospects for cross-border financing.

Deal-making will be a two-way street

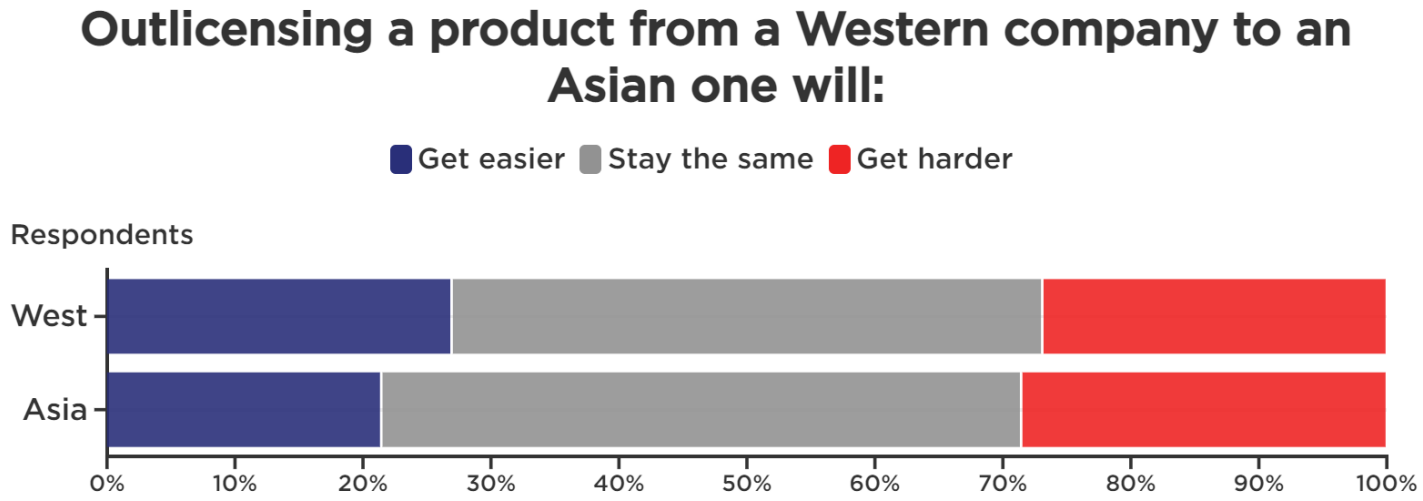
After years of West to East deal flow, Asia companies are capturing value for their innovations



- Half (50%) of Asia companies expect licensing to Western companies to get easier, and they outweigh the naysayers by more than 2:1
- Western players are slightly less bullish (27% say it'll get easier), but they still outnumber the 19% who believe it will get harder

East-West Biopharma Summit Scene Setter 2022; n=26, 14

And the West to East deals will remain robust

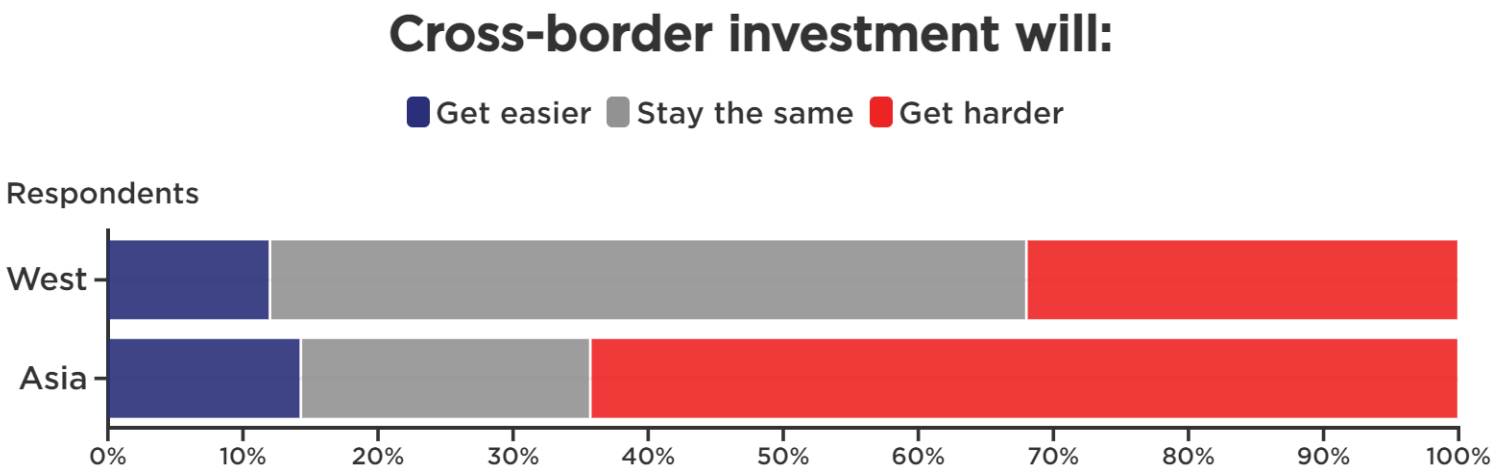


- Opportunities for Western companies to license products from Asian biotechs will stay the same or get better, according to more than 70% of respondents, regardless of location.

East-West Biopharma Summit Scene Setter 2022; n=26, 14

The outlook for investments depends on where you are

Does negative news flow impact Asia more? Or are Western companies ignoring the signs?



"Many VCs have withdrawn from the Hong Kong market – so the capital market is very tough for biotech companies in China. It's very unfortunate because we are trying to develop a drug for the whole of mankind. The political system is trying to make it this side vs that side which is not right."

Asia-based exec

- While most companies in the west expect stasis (56%), Asia-based companies are more grim. Almost two-thirds (64%) see it getting harder. About the same amount say it will get easier.

East-West Biopharma Summit Scene Setter 2022; n=25, 14

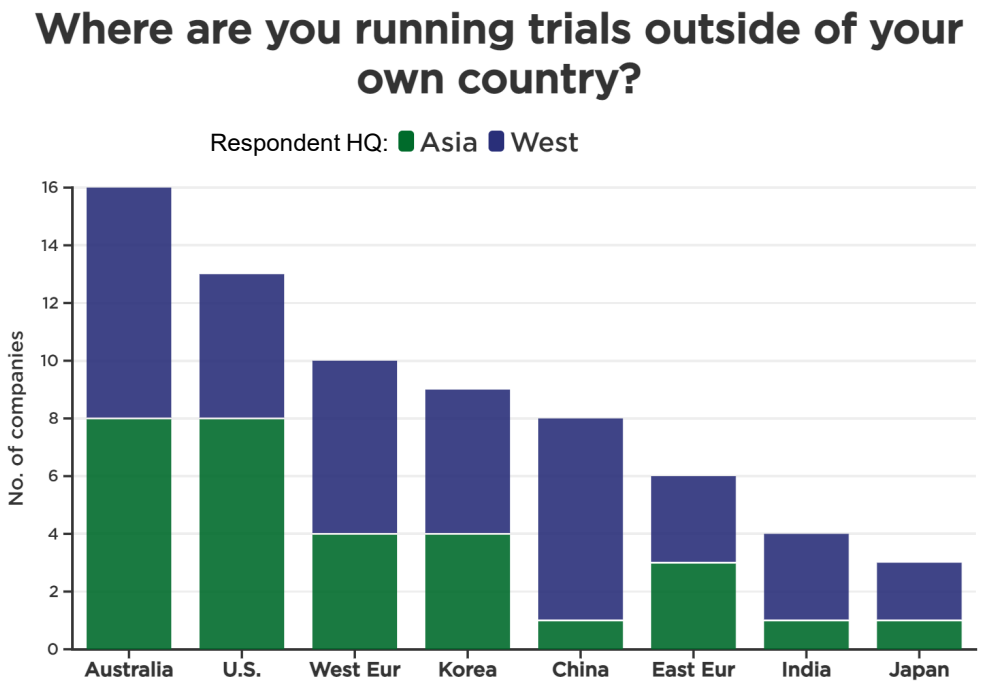
“We expect things to get harder as trade barriers rise, regulators change goalposts, companies on-shore activities.”

West-based survey respondent

Running trials, gaining approval and selling drugs tell a different story

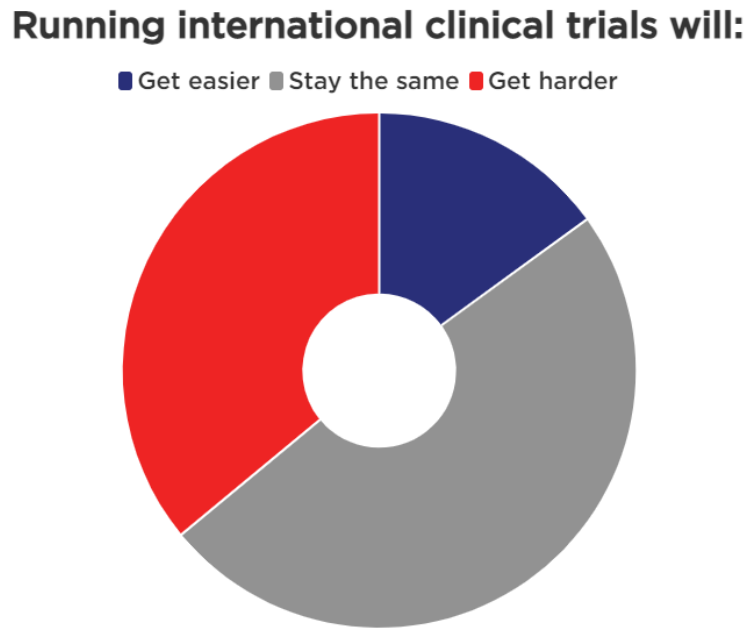
Along the continuum of running trials, manufacturing product, gaining approval and selling drugs across East-West borders, respondents see increasingly difficult times ahead

The first step is not the hurdle. Most are upbeat on global trials



- Australia the top spot for non-domestic trials. Equally popular among East and West

> *"It's a big lesson that we learned."*
>
> Asia-based exec, on multi-regional clinical trials

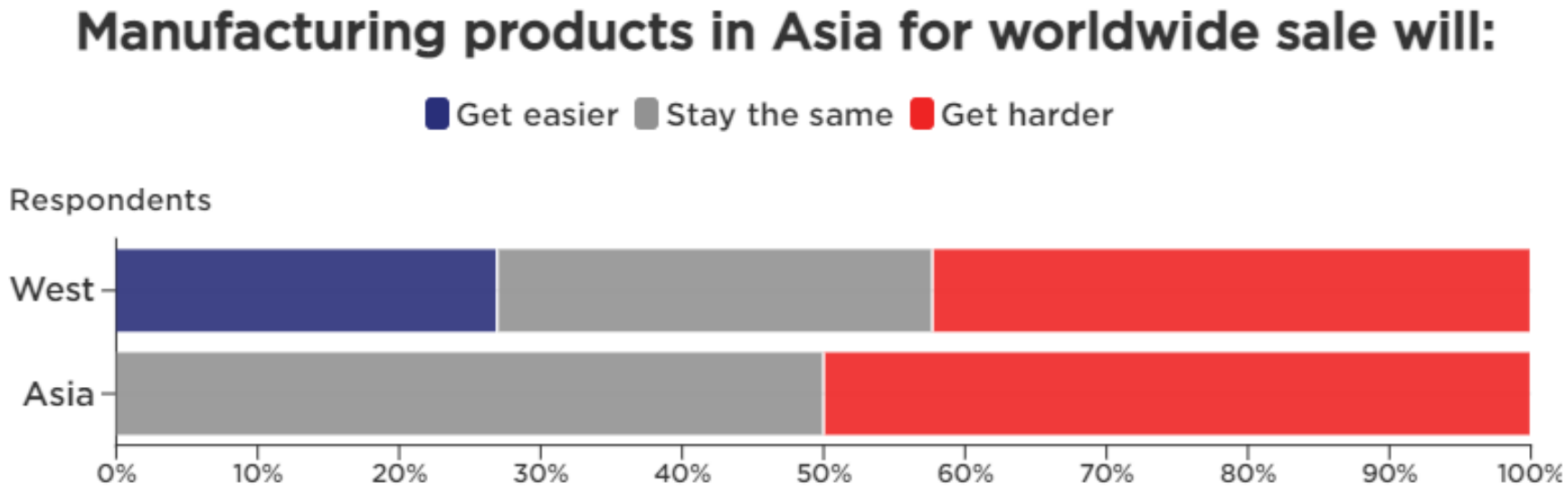


- 64% say running international trials will get easier or stay the same

East-West Biopharma Summit Scene Setter 2022; n=35, 39

But overall, a dim outlook on manufacturing in Asia

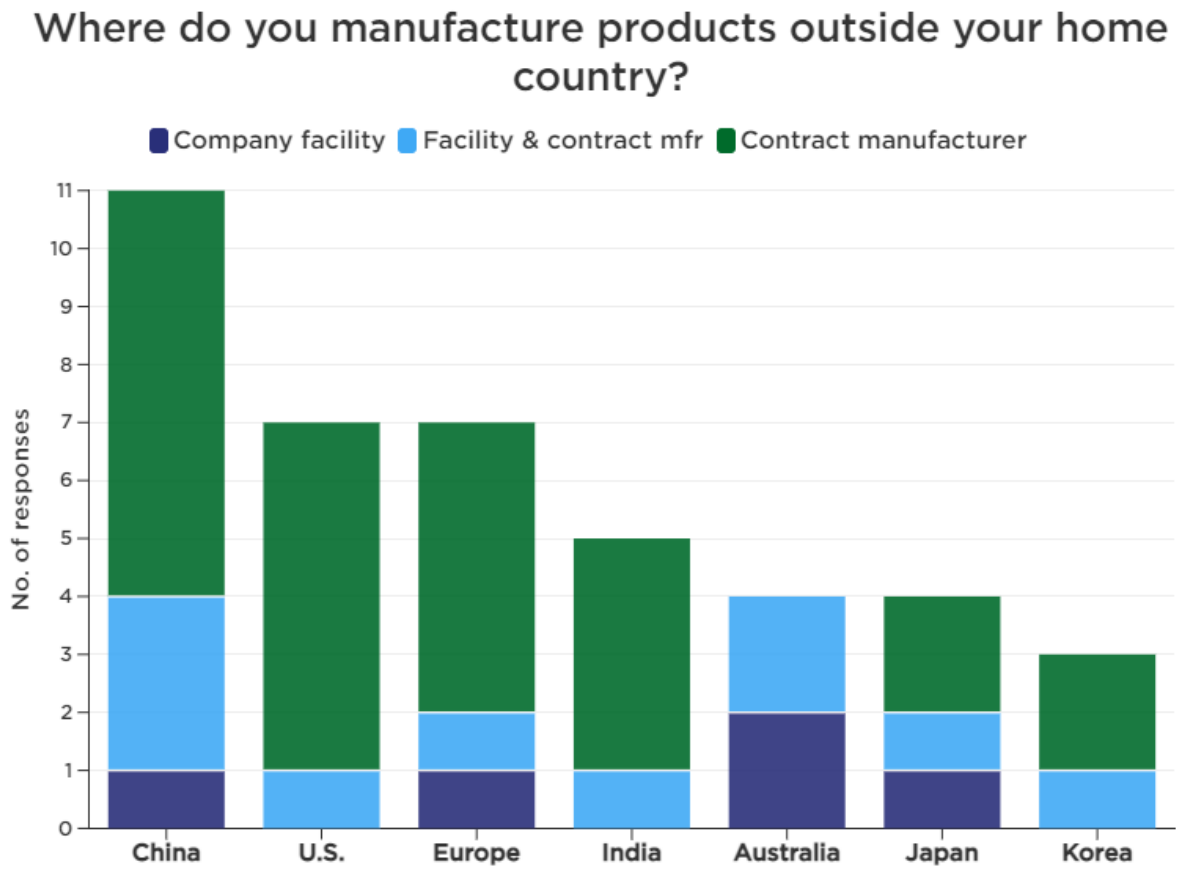
Though Western biotechs are more bullish than local ones



- Almost half, regardless of location, believe it will get harder to manufacture products in Asia for worldwide sale
- Asia-based companies are even more pessimistic – none believe it will get easier
- In contrast, more than one quarter (28%) of Western biotechs expect a smoother path ahead

East-West Biopharma Summit Scene Setter 2022; n=26, 14

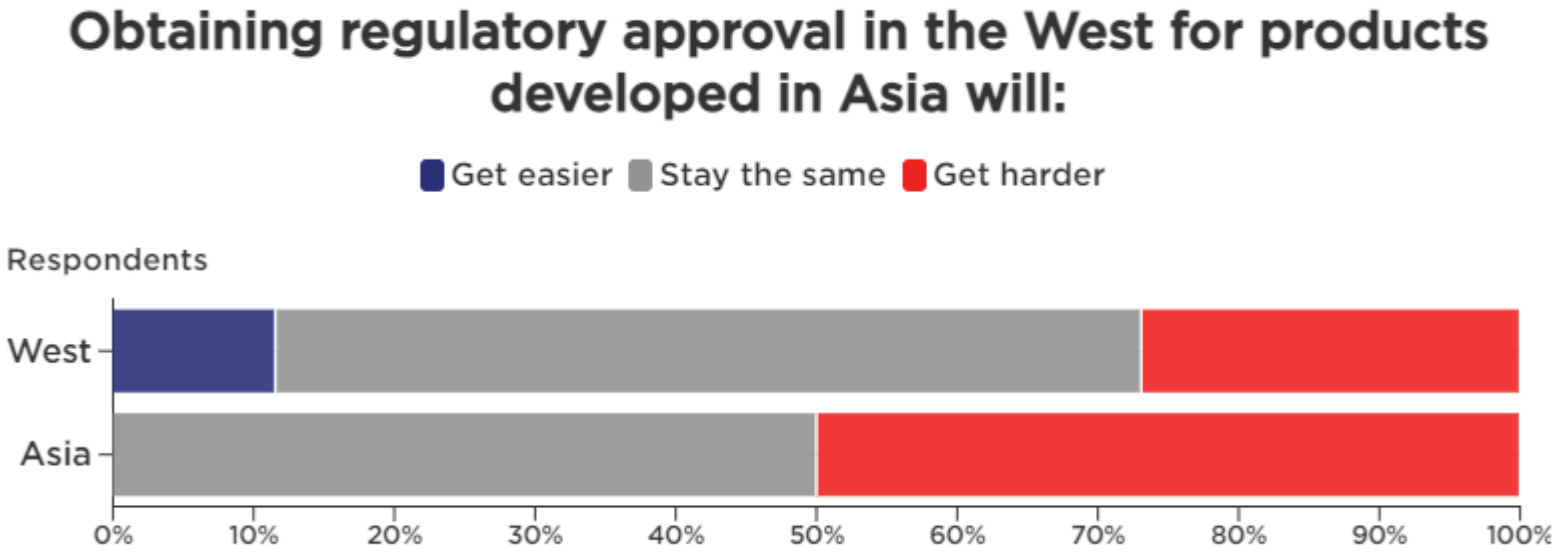
Yet companies depend on Asia for manufacturing



- China dominates for non-domestic manufacturing
- Two-thirds of respondents manufacture cross-border in Asia
  - 46% of Western biotechs
- Few Asia companies manufacture in the West (3 out of 14)

East-West Biopharma Summit Scene Setter 2022; n=38

Asia companies see a hard road ahead to FDA approval



- Half of Asia-based respondents believe it will get harder to gain regulatory approval in the West for products developed in Asia – None believe it will get easier
- Companies in the West are more optimistic for their Asia peers. 12% think it will get easier, and 27% say it will get harder for Asia products to gain FDA or EMA approval

East-West Biopharma Summit Scene Setter 2022; n=26, 14

Potato, pot-ah-to: differing takes on regulatory landscape

"Drug regulations will continue to be harmonized across major markets.There will be fewer and fewer drugs developed just for one market, regardless of the size of that specific market."

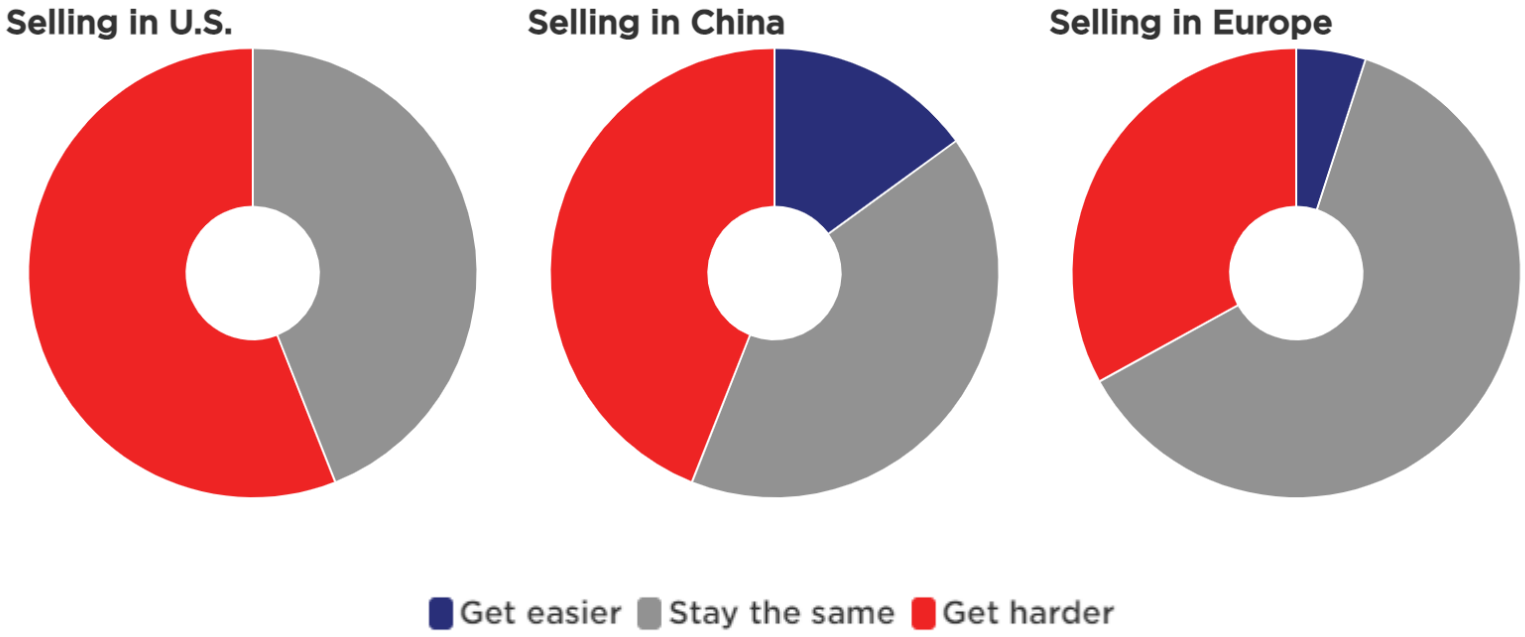
West-based survey respondent

"I think the FDA should more readily accept data from China, assuming the trial was done correctly. Rejecting data due to racial make up of China vs. U.S. is overblown, especially for cancer drugs. Some degree of protectionism by the U.S. in my view."

West-based survey respondent

Selling medicines in the U.S. will get harder

Survey respondents aren't much more enthusiastic about Europe or China



"Increasing payer control will make selling medicines in the U.S. to prescribers and patients more difficult than in the past."

West-based survey respondent

- More than half the group – regardless of location -- see the U.S. market as getting harder to penetrate. No one thinks it will get easier

East-West Biopharma Summit Scene Setter 2022; n=39

How has the international commercialization landscape changed in the past 5 years? Would you develop any of your programs differently given these changes

"Fast growth of China in innovative drugs. However, ***given the 'unpredictability' of Chinese government as well as China-US struggle, I would not make it a priority to take advantage of the growth of Chinese Pharma/Biotech industry."***

Asia-based survey respondent

"Continuing huge discrepancy between prices of innovative and rare disease drugs in the U.S. and the rest of world. This drives decisions to develop and commercialize products for the U.S. market's idiosyncrasies instead of [for] maximum impact on patients and societies. At some point, ***we must return to developing new drugs for the diseases afflicting the largest populations."***

West-based survey respondent

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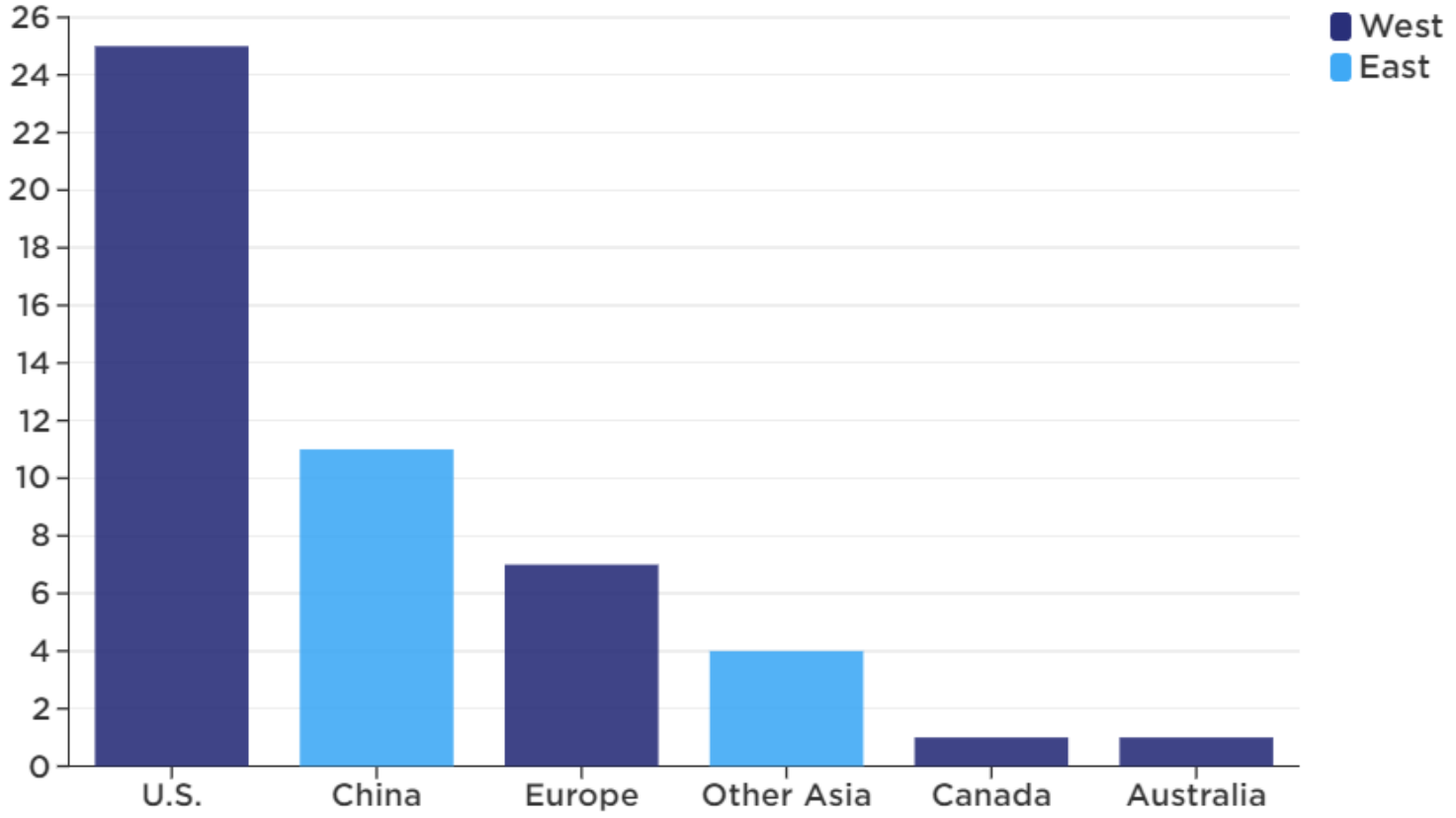
Respondent demographics

Survey participants span the globe

34 from West, 15 from East

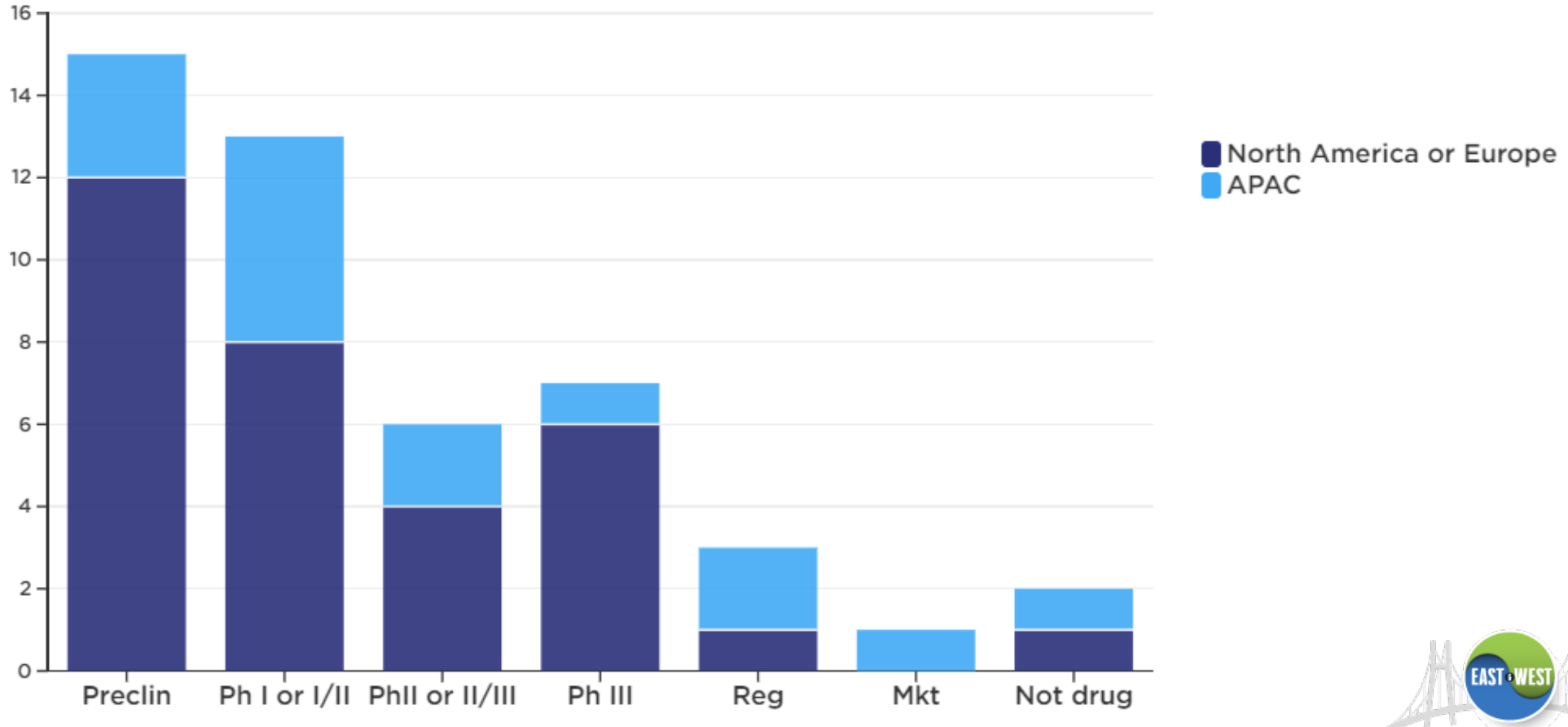
Where are your company's headquarters?



Respondents are primarily in early development

Under half are in clinical POC or pivotal trials

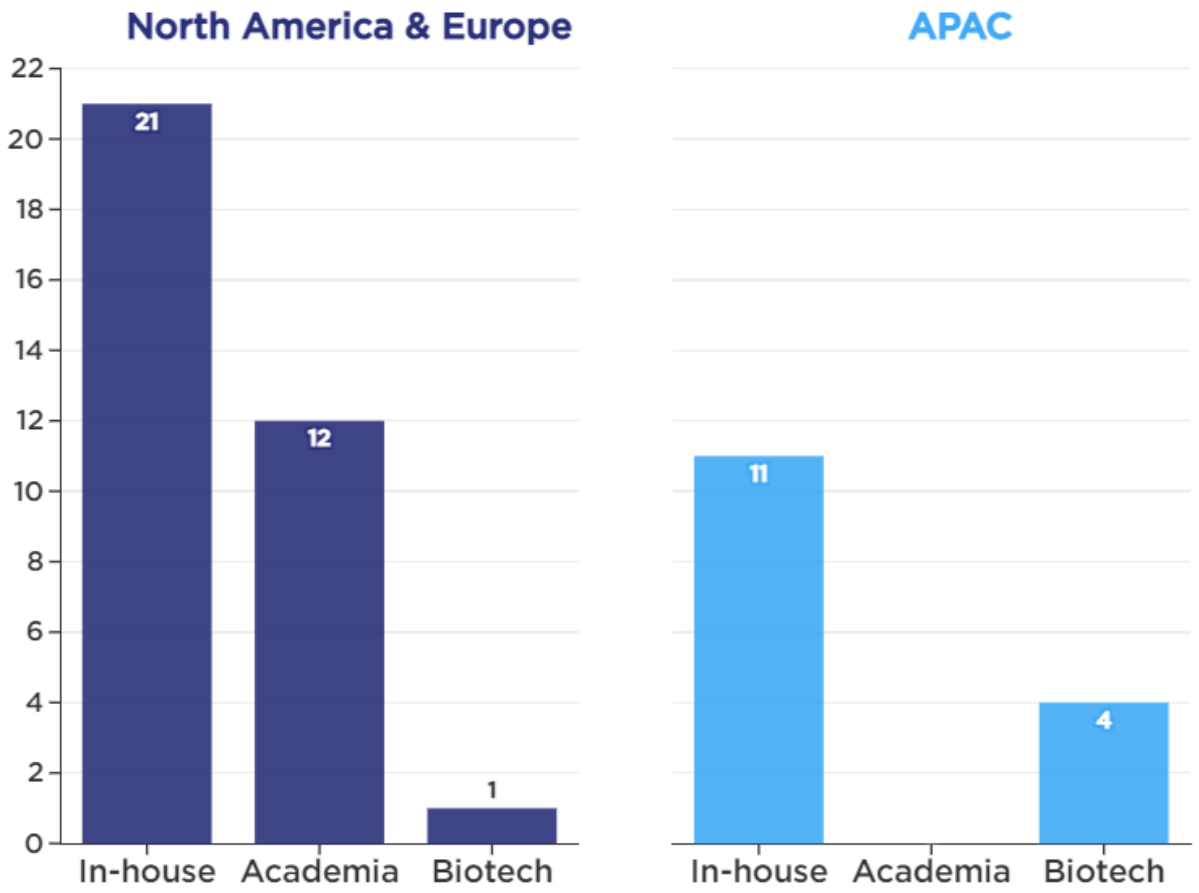
What is the development phase of your lead program?



In-house programs are the key source of assets

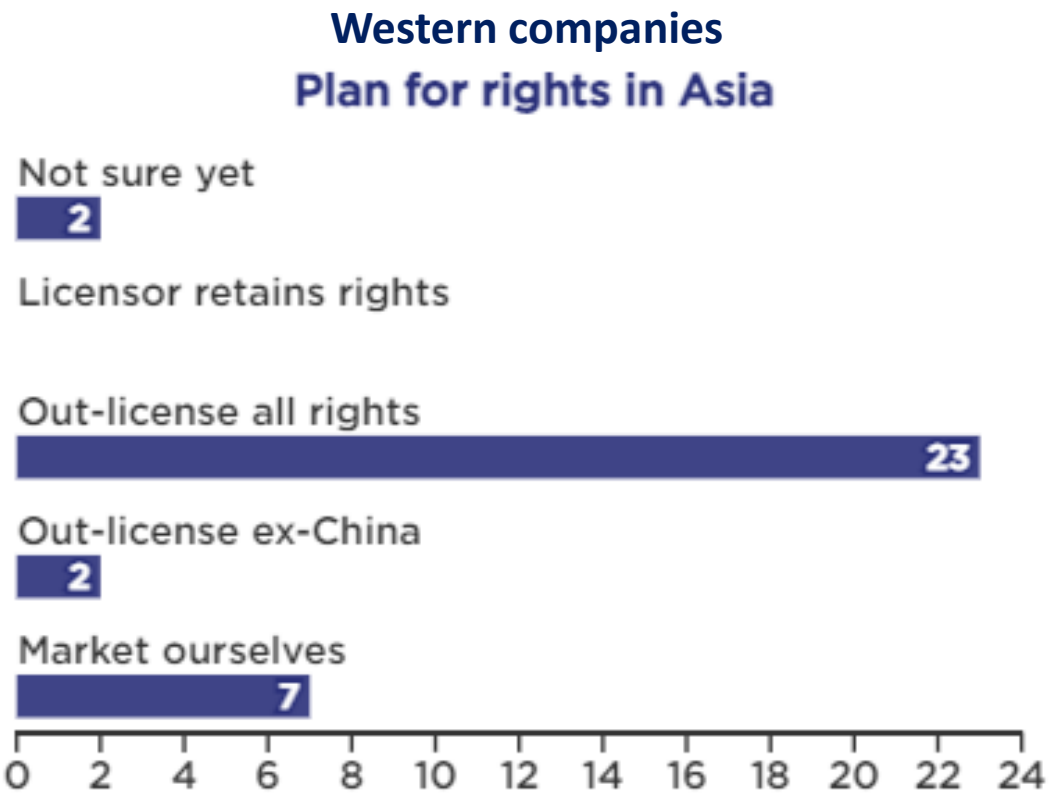
Academia is a major source in the West, but not among APAC respondents

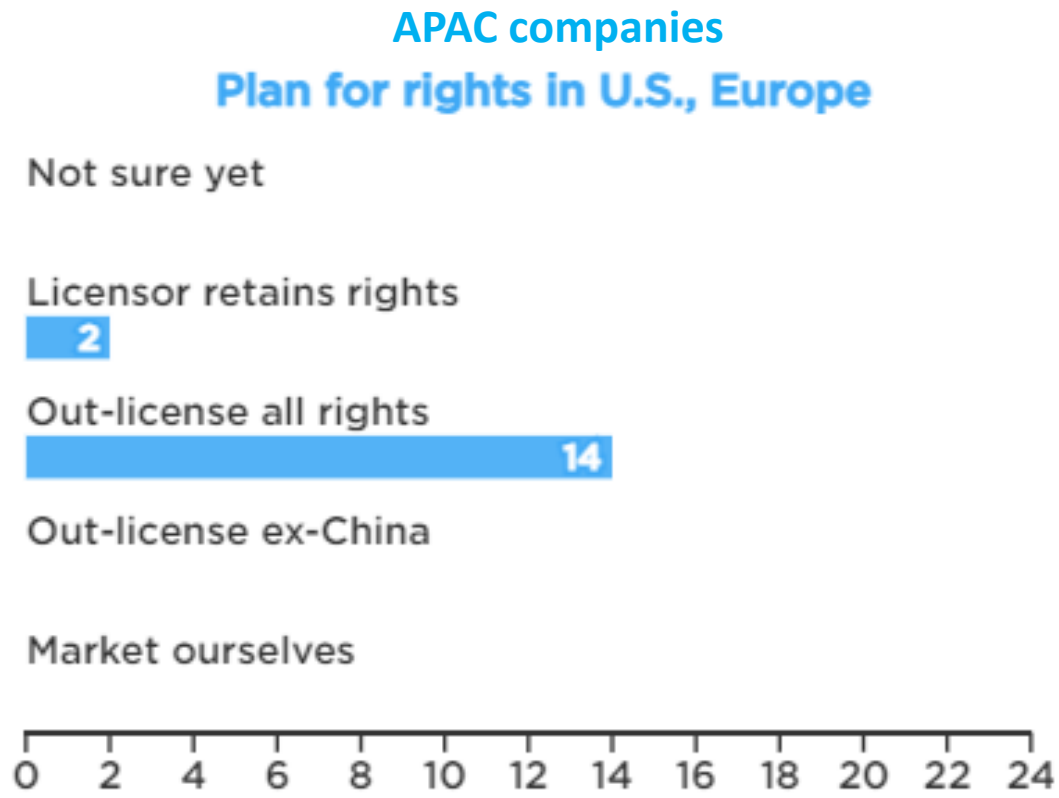
Where did your lead asset originate?



Most plan to partner to commercialize cross-border

Though about 20% of Western companies plan to market in Asia themselves

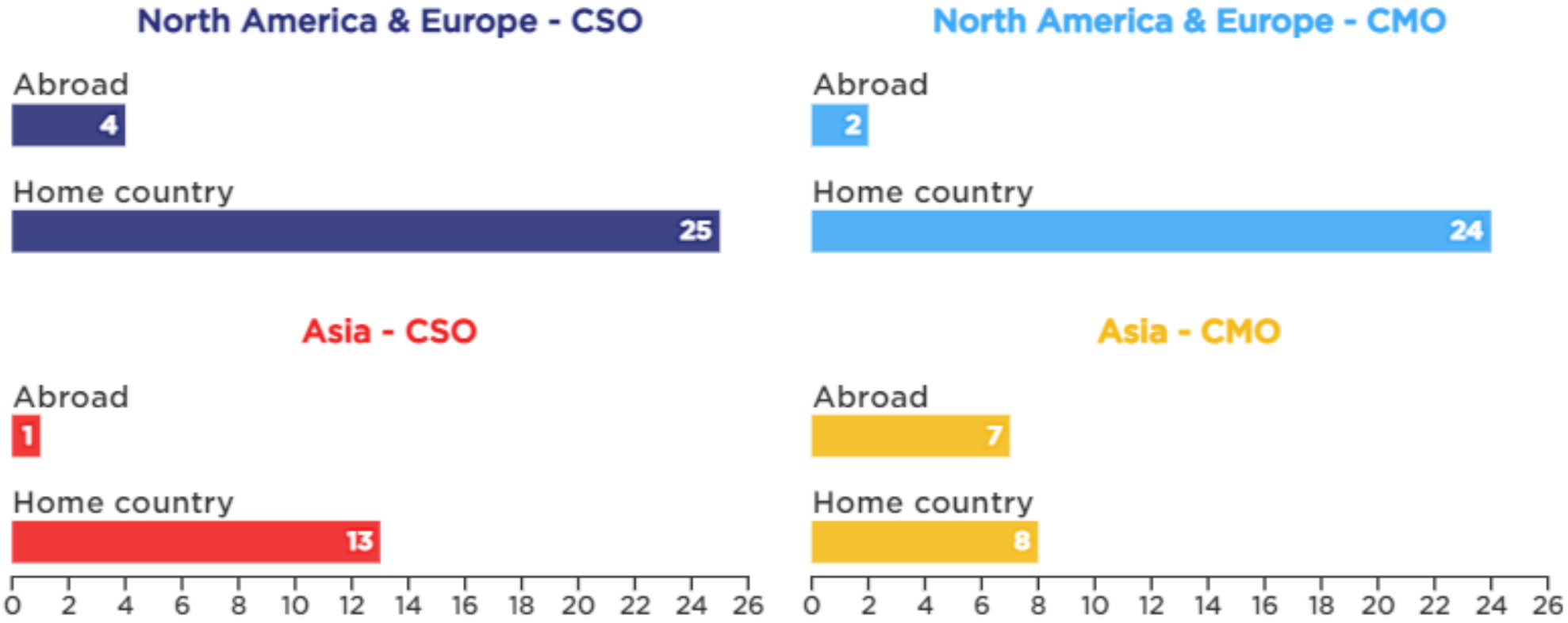




A global trial strategy can mean a CMO based abroad

While CSOs tend to be at HQ, half of Asia companies have CMOs in other countries

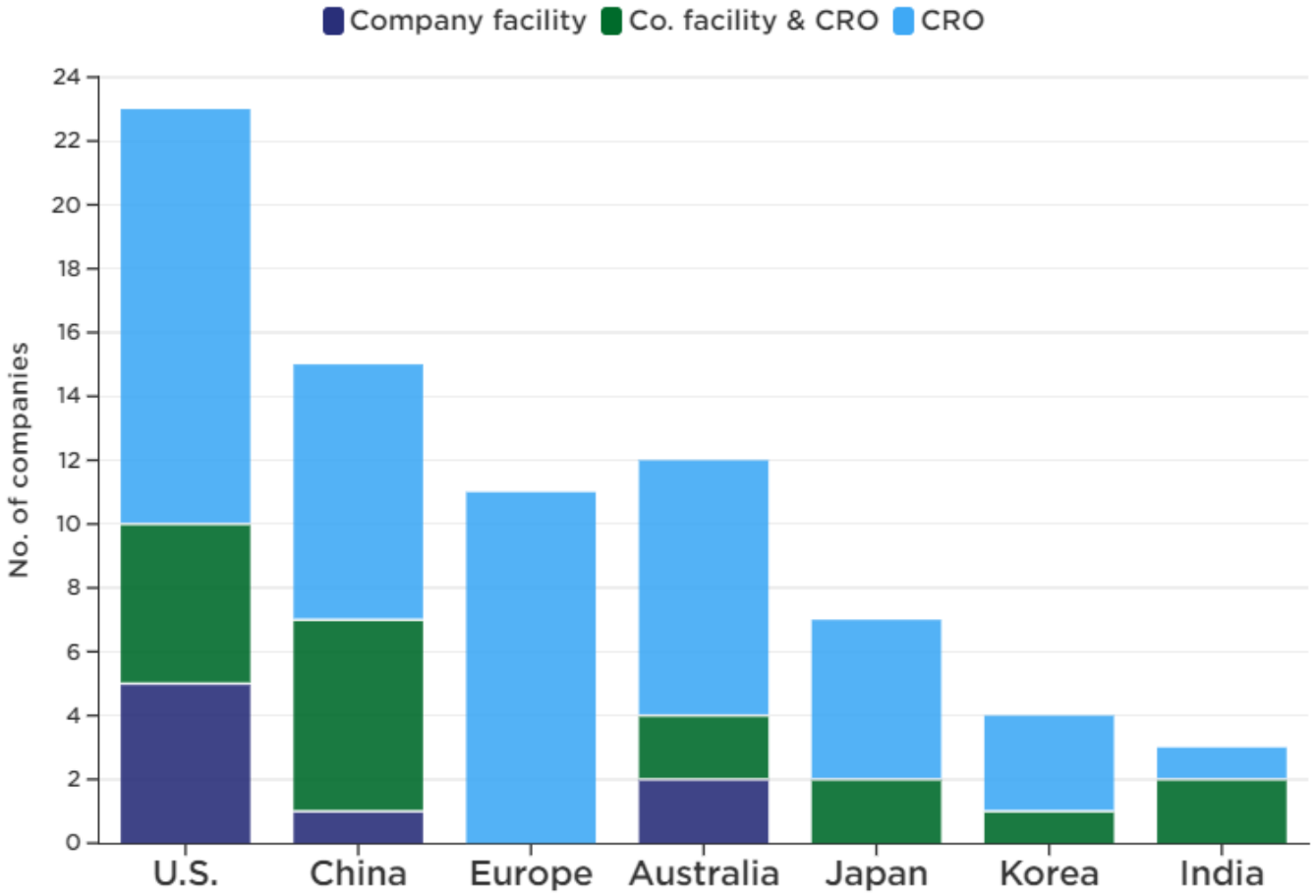
Where are your CSO and CMO located?



Broad footprint of CROs helping globalize R&D

Europe, Australia, Japan compete with U.S. and China for non-domestic R&D

Where do you have R&D sites outside of your HQ country?



Thank You for Joining Us at The BioCentury-BayHelix East-West Biopharma Summit

If you have questions about the event, please contact EastWestSummitHelp@BioCentury.com

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reminder

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https://biocenturyeastwest2022.meeting-mojo.com/