What do we need to change to have smarter, faster, more patient centered trials in Europe?

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- **In 2020 around 19% of global clinical trials were done in Europe, compared with an average of 25.6% in the previous decade**
- **This means the options for European patients to participate in clinical trials and potentially benefit from the latest advances in clinical research are decreasing**
- **To address this concern, the European Federation of Pharmaceutical Industries and Associations (EFPIA) is developing a new clinical trials strategy with the aim to have smarter, faster, more patient centered trials in Europe**

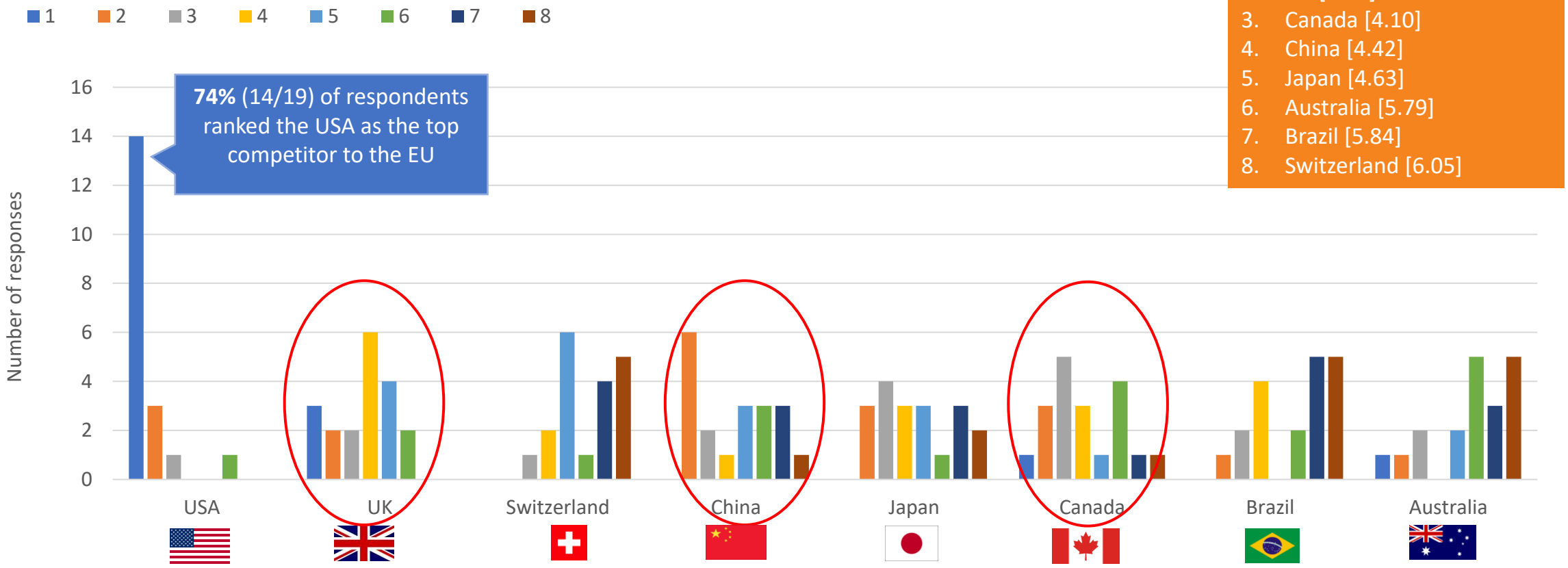
Recently survey of EFPIA member companies was done to:

- **Understand where there are gaps in the current state of clinical research**
- **Identify any barriers limiting or reducing the number of European sites/countries participating in clinical trials**

USA is Europe's main competitor for clinical trials

Based on your site selection process for clinical trials, rank in order of importance
(1 = most important, 8 = least important)

1. US [1.52]
2. UK [3.45]
3. Canada [4.10]
4. China [4.42]
5. Japan [4.63]
6. Australia [5.79]
7. Brazil [5.84]
8. Switzerland [6.05]



Other countries listed as free-text responses included India, Turkey (n=2), Mexico, South Korea (n=3), Colombia, Singapore, Malaysia, Taiwan, Russia, and Argentina.

Reasons for other regions being more attractive for trials

Top three voted reasons:

- Faster and more predictable trial approval by agency
- Quicker patient recruitment once site is approved
- Faster trial and more predictable approval by IRB or Ethics Committees

Additional reasons (free text responses):

- Clear set of country-level rules, ensuring a predictable study approval and site activation process
- Possibilities to engage in a fast and direct communication with the authorities to discuss important study elements
- Well-established medical infrastructure, fast approval timelines, agile regulatory framework, and widely accepted clinical trial data, as well as faster contracting and start up timelines, stability of economy
- More accepting of innovative trial designs (e.g., platform trials, decentralised trials) and greater ease of protocol modifications
- Standard of care for the specific disease/ indication in the countries
- Sites better equipped and resourced for clinical research (availability of qualified staff, facilities able to use modern technology e.g. digital CRFs, e-consent, e-TMFs)
- Access to investigators who are key thought leaders
- Better access to a diverse patient population
- Ease of access to major markets and need for clinical data
- Post Authorisation/launch impact

What changes are required to bring more innovative trials to Europe?

- Resolving the interface between different regulations, ensuring end-to-end connection (Clinical Trial Regulation, Medical Device Regulation, In-vitro Diagnostic Regulation)
- Faster and improved trial approval process, agile regulatory framework
- Harmonisation among Ethics Committees
- Harmonisation among Regulatory Authorities
- Improved environment (including site infrastructure, access to modern technology, key thought leaders, acceptance of innovative trial designs)
- Faster recruitment and access to a diverse patient population