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Approval of new drugs – comparison of Switzerland with US and EU

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Overview

- Time until access to new drugs

- Differences between approved label and trial populations

Time until access to new drugs



Glaus CEG, Serra-Burriel M, Dusetzina SB, Vokinger KN. Time from approval to reimbursement of new drugs: A comparative analysis between the United States, England, Germany, France, and Switzerland. Annals of Internal Medicine 2024.

Time until access to new drugs

- Three key periods
  - Clinical development duration: Time from human testing to submission to the regulatory authorities
  - Regulatory review duration: Time from submission to approval decision
  - Reimbursement review duration: Time from approval decision to reimbursement decision

- Research questions: Duration of the three key periods in Switzerland, EU countries (Germany, France) and the USA? Trends over time?

Hediger S, Glaus CEG, Dusetzina SB, Rohr UP, Hwang TJ, Vokinger KN. Expedited approval and duration of clinical development, regulatory and reimbursement review of new drugs in the US and European countries. JAMA Health Forum 2026.

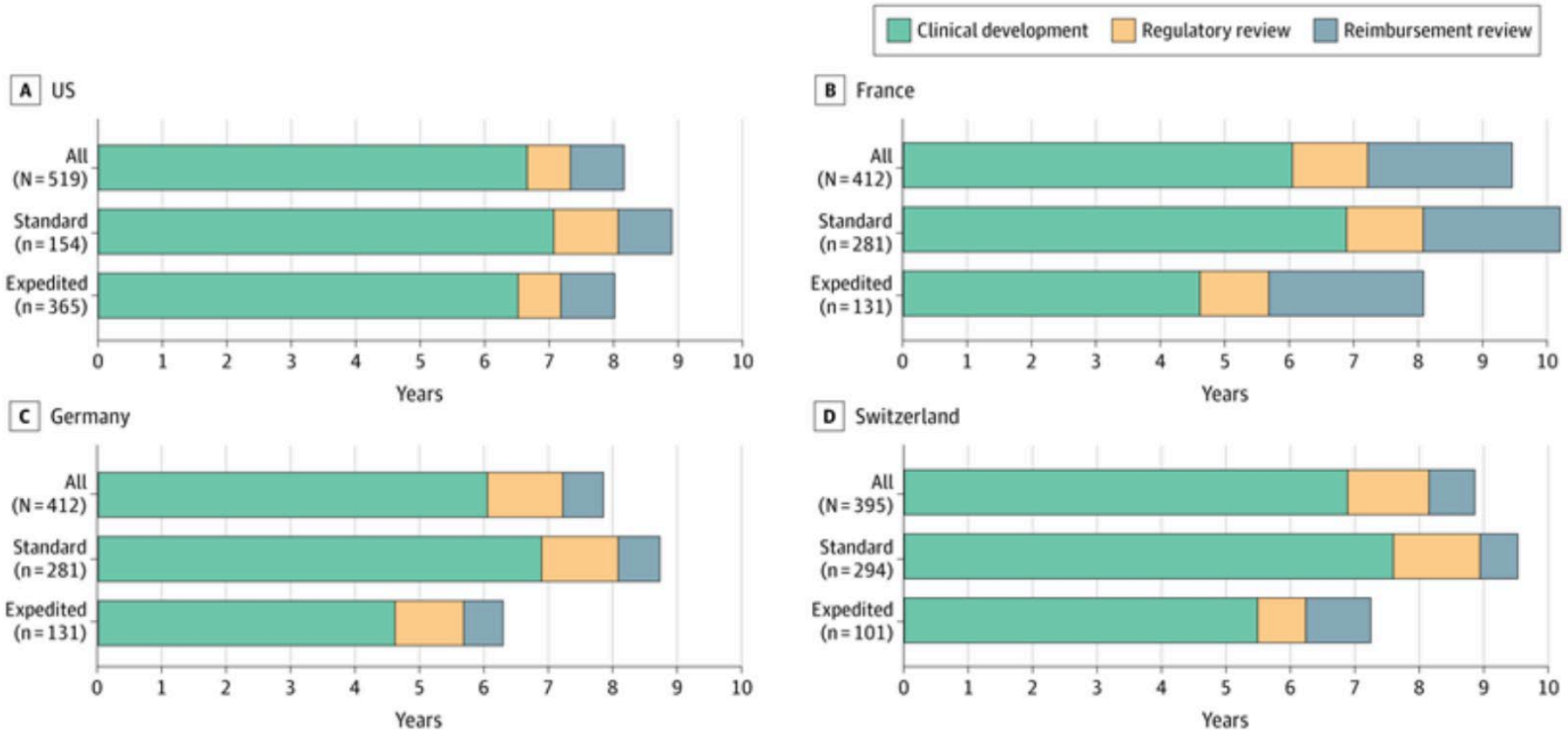
Time until access to new drugs

- Study cohort: New drugs approved 2014–2024 (Swissmedic, EMA, FDA)
    - Switzerland: 395 medicinal products
    - Germany: 412 medicinal products
    - France: 412 medicinal products
    - USA: 519 medicinal products
    - Important: different cohorts depending on the country

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Time until access to new drugs

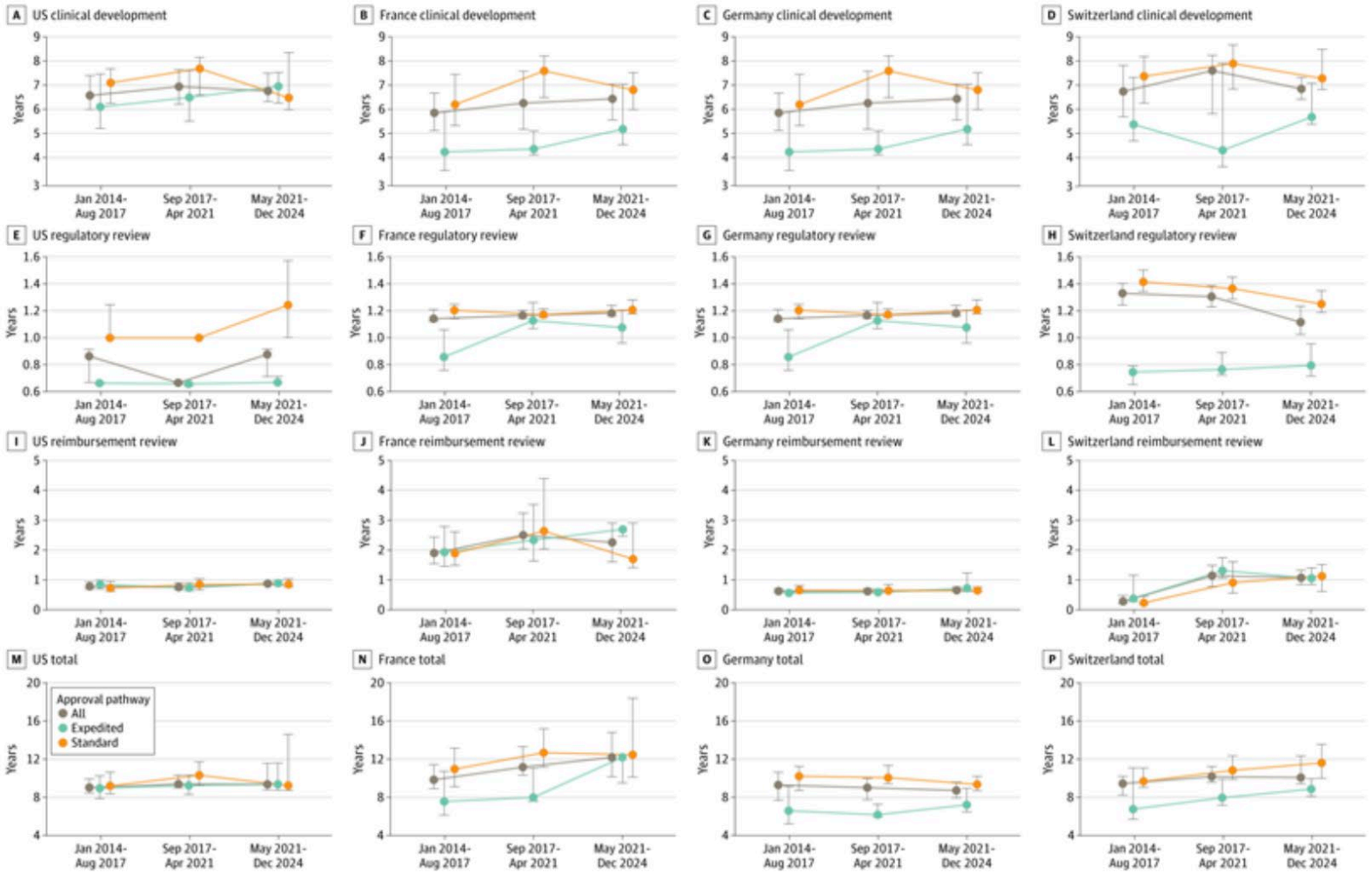
Figure 1. Bar Graphs for Duration for Clinical Development, Regulatory Review, and Reimbursement Review



Hediger S, Glaus CEG, Dusetzina SB, Rohr UP, Hwang TJ, Vokinger KN. Clinical development, regulatory and reimbursement review of new drugs in the US and European countries. JAMA Health Forum 2026.

Time until access to new drugs

Figure 2. Dot and Whisker Plots of Duration for Clinical Development, Regulatory Review, and Reimbursement Review Over Time



Hediger S, Glaus CEG, Dusetzina SB, Rohr UP, Hwang TJ, Vokinger KN. Clinical development, regulatory and reimbursement review of new drugs in the US and European countries. JAMA Health Forum 2026.

Time until access to new drugs

- Trends over time: Slight increase with exception of Germany
    - Median total time Switzerland: 9.42 years (2014–2017) → 10.05 years (2021–2024)
    - Median total time Germany: 9.27 years (2014–2017) → 8.7 years (2021–2024)
    - Median total time France: 9.82 years (2014–2017) → 12.18 years (2021–2024)
    - Median total time USA: 9 years (2014–2017) → 9.35 years (2021–2024)
    - → Gap between “expedited” and “standard” medicinal products decreases over time

Hediger S, Glaus CEG, Dusetzina SB, Rohr UP, Hwang TJ, Vokinger KN. Clinical development, regulatory and reimbursement review of new drugs in the US and European countries. JAMA Health Forum 2026.

Time until access to new drugs

- Research question: What is the regulatory review duration for new medicinal products 2011–2020 in the USA, EU and CH, and how large are submission gaps between regulatory authorities?

- Study cohort: 241 medicinal products

- Median regulatory review duration
  - Clock stop taken into account
    - 39 weeks FDA (fastest medicinal product group: oncology products)
    - 44 weeks EMA (fastest medicinal product group: anti-infective drugs)
    - 44 weeks Swissmedic (fastest medicinal product group: oncology products)

Vokinger KN, Serra-Burriel M, Glaus CEG, Rohr UP, Hwang TJ, Dalla Torre di Sanguinetto S, Kesselheim AS. Regulatory review duration and differences in submission times of drugs in the US and Europe (2011-2020), Annals of Internal Medicine 2024.

Differences between approved label and trial populations

- Research question: What are the differences in terms of populations between trial and approved label populations?

- Study cohort: New drugs approved 2012–2023 → 263 medicinal products (278 indications)

- 5 categories: age, disease subtype, disease severity, prior therapy, patient fitness

Vokinger KN, Serra-Burriel M, Glaus CEG, Welti L, Ross JS, Kesselheim AS. Differences between trial populations and approved label populations of new drugs in the US and Europe (2012-2023), Annals of Internal Medicine 2025.

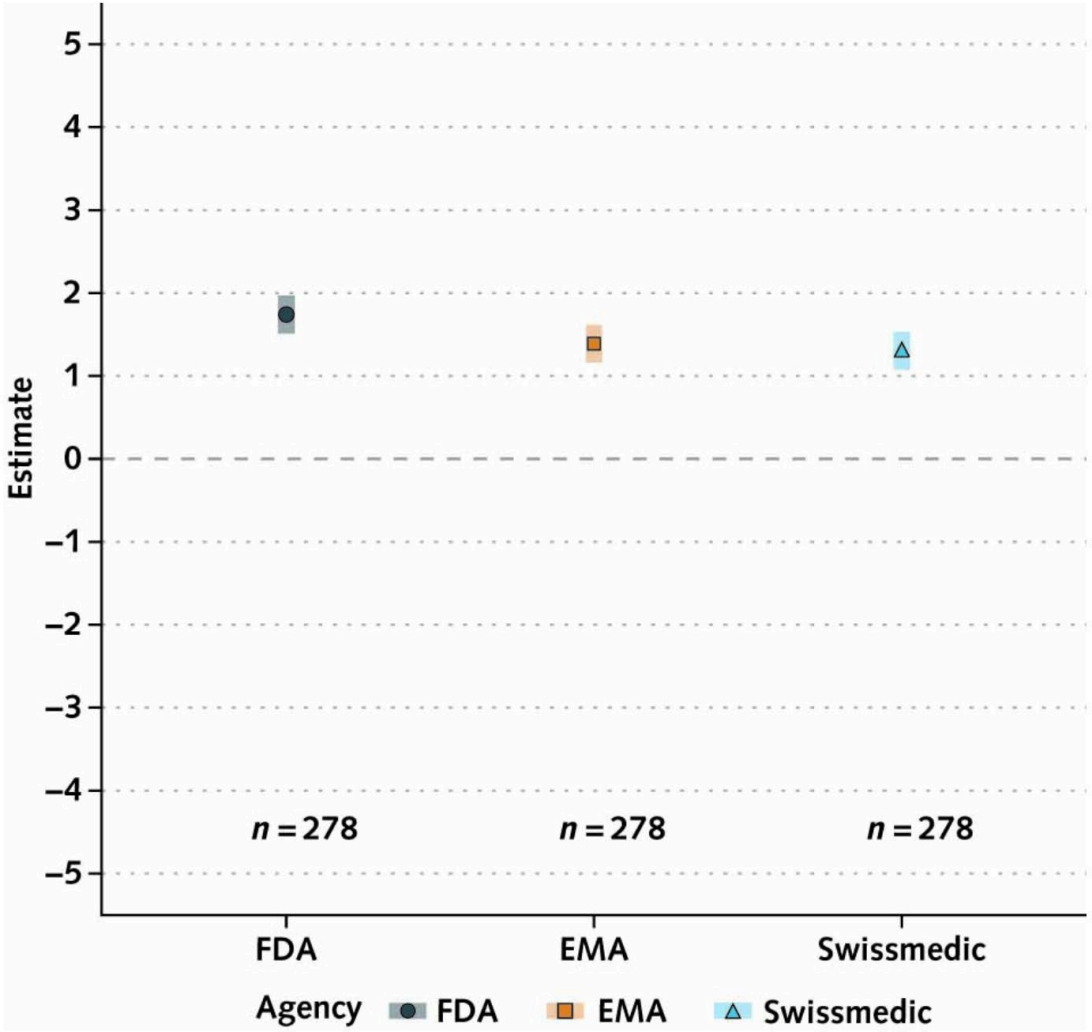
Differences between approved label and trial populations

Authority	Approved Label Population	Evaluation	Difference to Trial Population	Category
Active substance: encorafenib				
FDA	Indicated, in combination with binimetinib, for treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutation, as detected by an FDA-approved test. Limitations of use: Not indicated for treatment of patients with wild-type BRAF melanoma. Contraindication: None.	Broader (+1)	Trial only included adult patients.	Age
		Same (0)	–	Disease subtype
		Restrictive (–1)	Trial also included patients with locally advanced disease.	Disease severity
		Broader (+1)	Trial included either naive untreated patients or patients who progressed on first-line immunotherapy.	Prior therapy
		Broader (+1)	Trial included patients with ECOG performance 0 or 1, required adequate bone marrow, organ function, specific laboratory parameters, and adequate cardiac functions. Trial excluded patients with untreated CNS lesions, neuromuscular disorders, uncontrolled arterial hypertension, impaired cardiovascular function or clinically significant cardiovascular diseases, previous or concurrent malignancy, history of Gilbert syndrome, history of allogeneic bone marrow transplantation or organ transplantation, and history or current evidence of retinal vein occlusion or current risk factors.	Patient fitness

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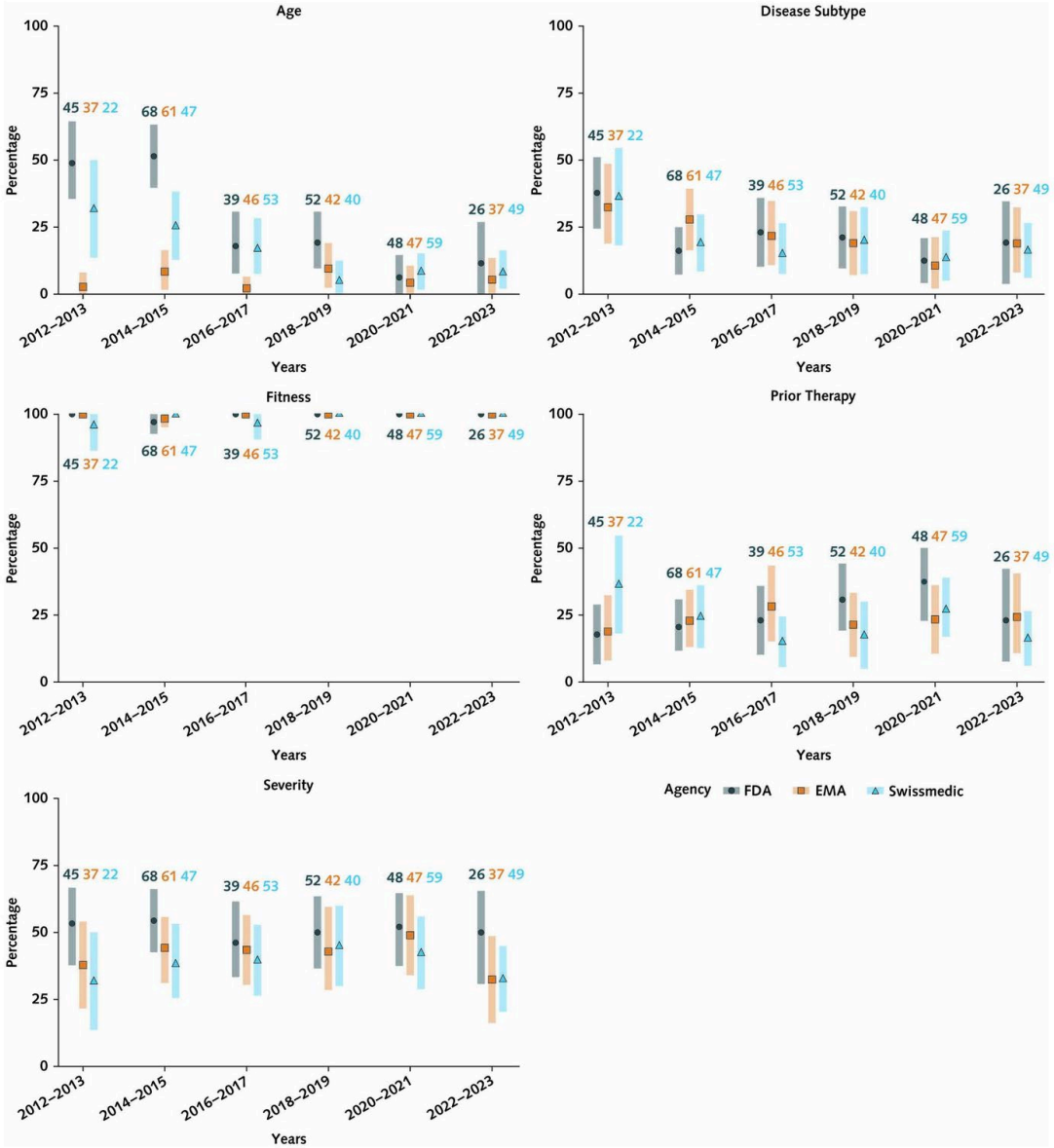
Differences between approved label and trial populations

- Composite score



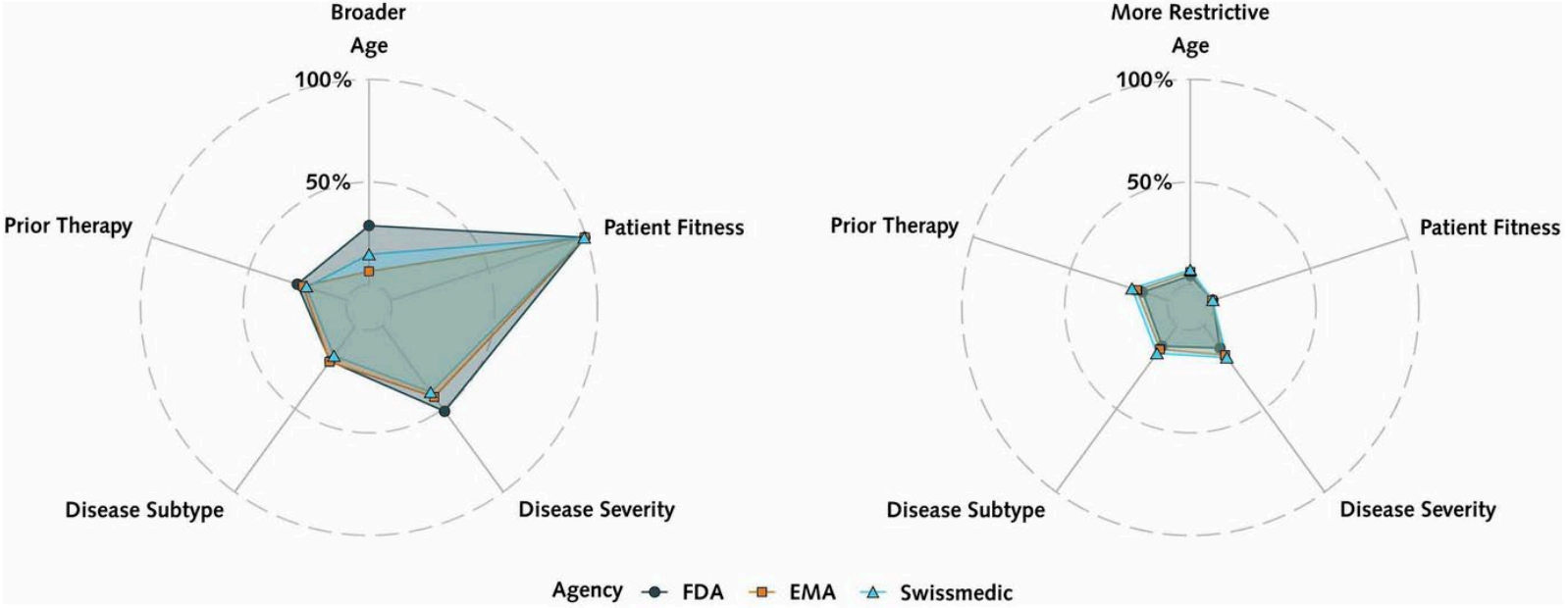
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Differences between approved label and trial populations



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Differences between approved label and trial populations



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Conclusion

- Time until access to new drugs
  - Marginal increase, but closing gap between expedited and standard approvals
  - “submission gap”
  - Project Orbis

- Differences between approved label and trial populations
  - Swissmedic and EMA similar
  - Swissmedic closest to clinical trial populations

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