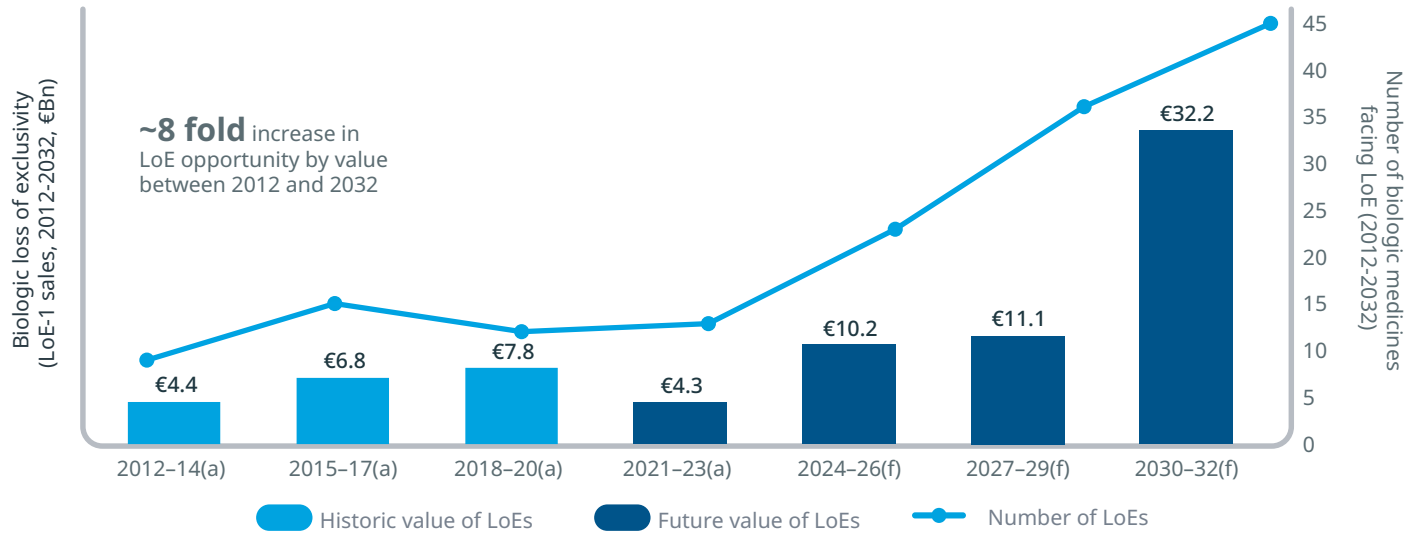
Addressing Biosimilar Clinical Trial Challenges with the IQVIA Biosimilar Site Network

With an estimated value of $25.1 billion in 2022, the global biosimilars market is forecast to increase to $1.3 trillion by 2032, a compound annual growth rate of 17.6%.[1] Since their debut two decades ago – with Omnitrope® (somatropin) approved by the European Medicines agency in 2006[2] and Zarxio® (filgrastim-sndz) approved by the U.S. Food and Drug Administration in March 2015[3] – biosimilars have played an essential role in achieving healthcare savings and expanding patient access. For example, in Europe, by the end of 2022, cumulative savings at list prices from biosimilar competition amounted to more than €30 billion.[4]

After several years of increases in the number and value of loss of exclusivity (LoE) events for biologics, fewer opportunities for biosimilars emerged in 2021 to 2023. In that period, €4.3 billion worth of biologics were faced with off-patent competition, a reduction of 45% compared to the prior three years. Over the short term, however, potential opportunities for savings are predicted to increase rapidly. In Europe, some 110 biologics are expected to lose intellectual property (IP) protection by the end of 2032, with LoE opportunities peaking at around €30 billion between 2030 and 2032 *(Figure 1)*. Overall, an eight-fold rise in the LoE by value is anticipated in the period from 2012 to 2032.

Figure 1: Opportunity forecast for biosimilar competition in Europe[4]

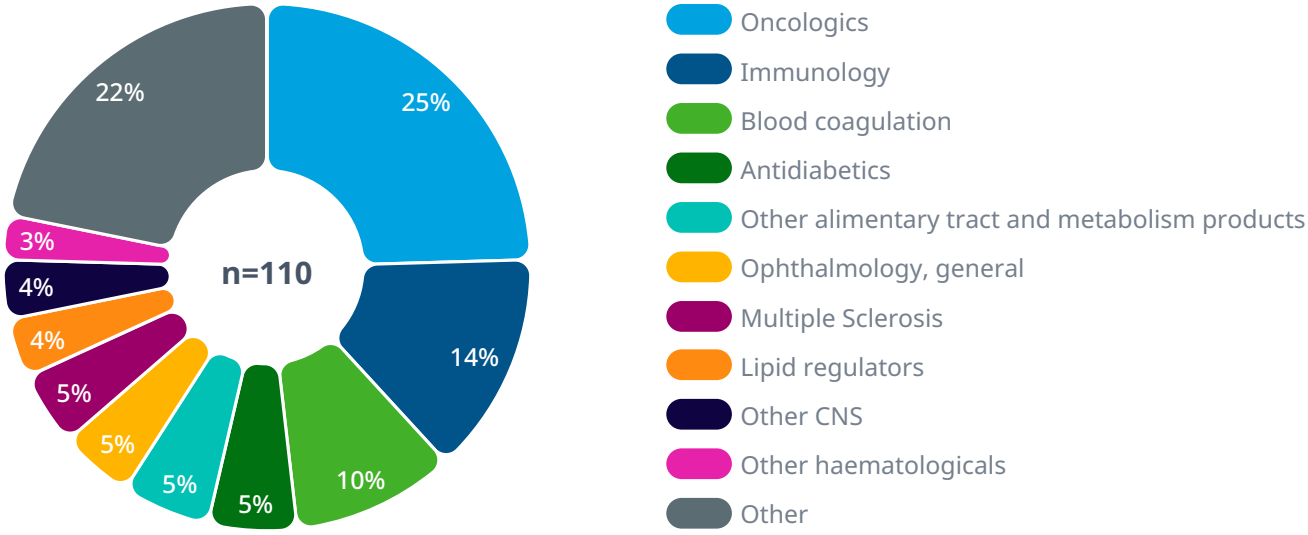


Source: IQVIA Ark Intelligence; IQVIA Forecast Link; IQVIA MIDAS Q4 2022.
Notes: (a) represents actual sales and (f) represents forecast sales. The IP profile of individual biologics is subject to change as new patents and/or patent extensions become available during a product lifecycle. The data shown in this chart is accurate as of July 2023.

During the next decade, the highest level of biologic LoEs are forecast to occur in the oncology sector (25%), followed by immune system therapies (14%) and treatments for blood disorders (10%), as shown in Figure 2.

However, among biosimilars, the average number of candidates per originator biologic molecule is expected to fall from 4.3 in the short term (defined as 2023 to 2027) to 1.2 in the long term (2028 to 2032).

Figure 2: Biologic medicines LoE by therapeutic area (2023-2032)[4]



Source: IQVIA Ark Intelligence; IQVIA Forecast Link; IQVIA MIDAS. Other= therapeutic areas with <3 products.

IQVIA Biosimilar Site Network offers solutions to sponsor challenges

The falling number of biosimilars per originator biologic reflects the fact that while the biosimilar market opportunity is expanding, sponsors face multiple challenges, including the costly and time-consuming nature of clinical development of biosimilars. There remains intense competition for patients and sites, and successful biosimilar launches typically rely on being among the first three companies to launch. To address these sponsor challenges, the IQVIA Biosimilar Site Network (BS Network) was established in 2022, focusing particularly on oncology and onco-hematology indications. This initiative reflects the industry pipeline, reimbursement policies across key countries, overall healthcare and regulatory environments, as well as internal and external competition. The network is expanding across Europe, Africa, Asia and Latin America and is composed of healthcare professionals interested in conducting biosimilar studies, and with the appropriate capabilities, experience and facilities, including facilities suitable for PK studies.

The IQVIA BS Network brings together data and biosimilar-specific business intelligence to deliver optimal strategies and solutions. Partnering with IQVIA enables sponsors to access tailor-made strategies and develop biosimilar products more quickly and cost effectively. Activities supported range from clinical and operational planning, to pipeline prioritization and feasibility analyses, to full-service study execution.

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