Medicines Horizon Scanning Annual Report 2025

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Date: October 2026

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How to cite this document

Nesworthy, J., Khan, S., Hussain. A., & Norman, G. Medicines Horizon Scanning Annual Report 2025. NIHR Innovation Observatory; Newcastle upon Tyne, 2026. DOI: 10.6084/m9.figshare.34754613

Acknowledgements and disclaimers

This study/project is funded by the National Institute for Health and Care Research (NIHR) [NIHR IO/project reference HSRIC-2016-10009]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

We would like to thank Alex Inskip for assistance in retrieving and organising the data into a spreadsheet suitable for analysis.

Conflicts of interest

There are no conflicts of interest

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Background

The Innovation Observatory (IO) is a national horizon scanning research centre funded by the National Institute for Health and Care Research (NIHR) hosted at Newcastle University. The IO focuses on identifying emerging health innovations that are in the pipeline and providing early awareness signals and access to timely intelligence to the health and care ecosystem in the UK to support decision making around healthcare innovation. The IO also proactively advances cutting edge horizon scanning research methods and tools that allow more effective and efficient identification of emerging health innovations, enable efficiency in the innovation, regulation and market access pathway along with current and future trends thus playing a vital role in supporting getting the right innovation to patients at the right time.

Within the IO, one of the most established areas of research has been the Medicines Programme that identifies innovative medicines that meet the needs of the NHS and are likely to be available for patient access in the UK or EU in the next few years. Innovative medicines comprise of new medicinal products that are not yet licensed for any indication along with, already licensed medicinal products that are now in clinical development for new indications.

Over the past year, the Medicines Horizon Scanning (MHS) team has identified and sifted through nearly 5,000 clinical trials to identify those in remit for us to monitor and track through well-established horizon scanning processes. This provided the basis for a signal of upcoming availability for over 150 medicinal innovations to the National Institute for Health and Care Excellence (NICE) and supported ad hoc scans to stakeholders such the NHS and IRLSS group.

Aim

This report provides an overview of the MHS team's horizon scanning activity in 2025. It provides: a summary of the horizon scanning strategy devised to identify newly created or updated[a] records within 2025; an overview of the landscape of clinical trials in remit, the therapeutic areas of the indications based on NICE categories,[1,2] drug designations, industry sponsors; and gives some high-level conclusions drawing on the themes and patterns identified.

Methods

Medicines Innovation Database

The IO has developed a bespoke, comprehensive database, the Medicines Innovation Database (MInD) that serves as a repository of intelligence collected from:

- Hard data sources (clinical trial registries, regulatory authorities)
- Soft intel (news/media)
- Pharma intel (company website, press releases, direct engagement with companies)

The MInD consists of unique records [innovative medicine(s) + target indication] that provide a clear and complete picture of the clinical/innovation profile and regulatory status of each

[a] An update constitutes addition of a newly identified clinical trial relevant to a record present on MInD

medicine in clinical development. The information collated on MInD helps provide the most reliable and accurate intelligence for medicines in development for national stakeholders to inform timely assessment and facilitate decision making.

Scope

Medicinal products in clinical development that fall within the scope of the MHS team at the IO need to fulfil the following criteria:

- Medicinal products and therapeutic vaccines (vaccine used during disease state)
- Interventional trials
- Phase I/II to III trials
- Trial locations in Europe, US, Canada, Australia, Japan, Singapore

Search Strategy

The MInD was queried to identify newly created records and updated records from 1st January – 31st December 2025. Most of the new records were created from clinical trials sifts. A small number were created from new records identified from UK PharmaScan, news articles or information provided by pharmaceutical companies during pipeline meetings.

Results

Our analysis showed that from a total of 1,685 technology records, 1,356 new records were created and 329 were updated in 2025 on MinD.

We consider these new and updated records in relation to the indications for which they are in development; the types of technologies under development; the regulatory status of the technologies and specific populations involved.

Indications

i. Cancer vs non-cancer indications

Of the 1,685 records created and updated on MInD in 2025, there were 640 (38%) cancer records, and 1,045 (62%) non-cancer records. Figure 1 shows the number of records with indications classified as cancer by NICE condition categories.[3] The most frequent cancer categories were blood and bone marrow cancers (n=167, 26%), multiple cancers (n=97, 15%), lung cancer (n=80, 13%), breast cancer (n=40, 6%) and prostate cancer (n=36, 6%).

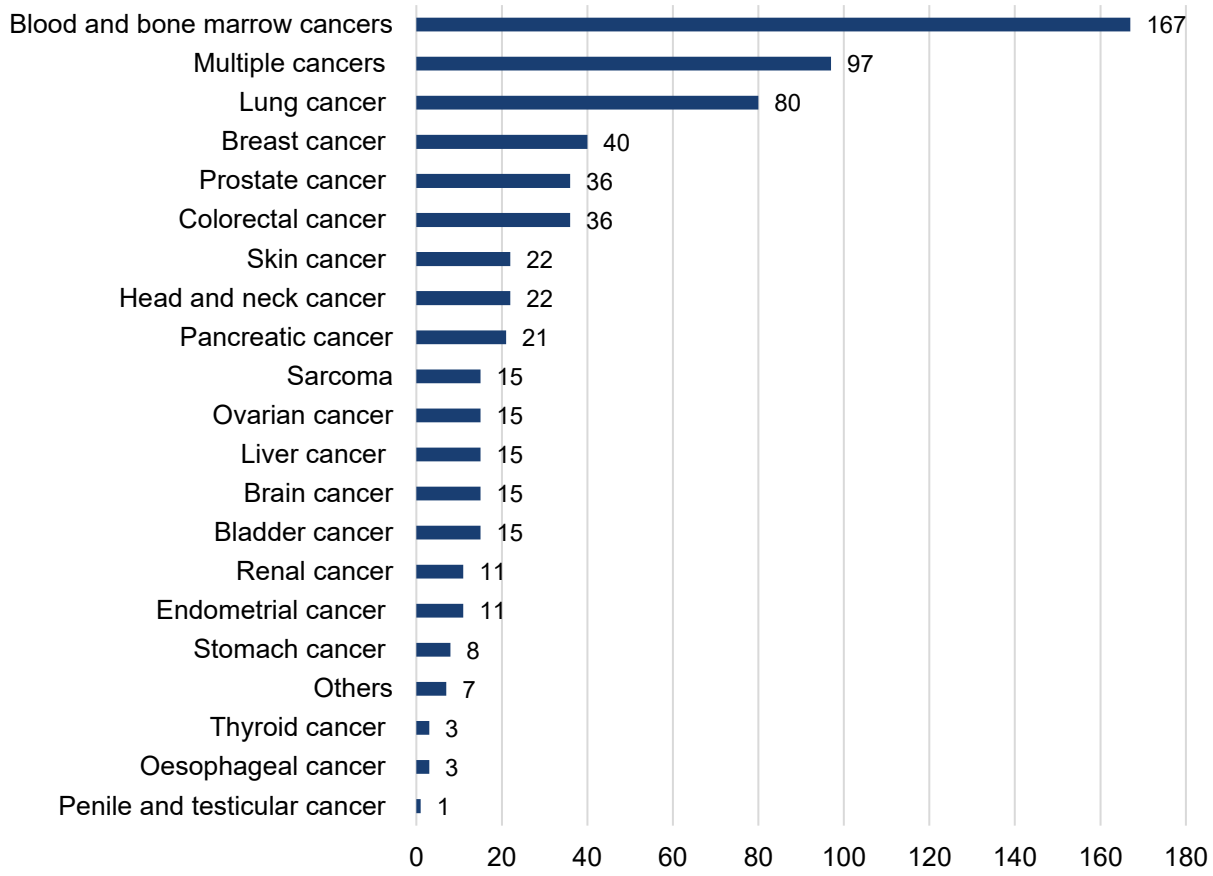

Figure 1. Number of cancer records by NICE condition categories[b]

Figure 2 shows the number of records with indications classified as non-cancer by NICE.[2] The most common non-cancer categories in these records were neurological conditions (n=141, 13%), diabetes and other endocrinal, nutritional and metabolic conditions (n=128, 12%), blood and immune system conditions (n=113, 11%), skin conditions (n=99, 9%) and infections (n=87, 8%).

[b] Within the figure we have included an 'Other' category which represents indications that do not fit into a NICE category

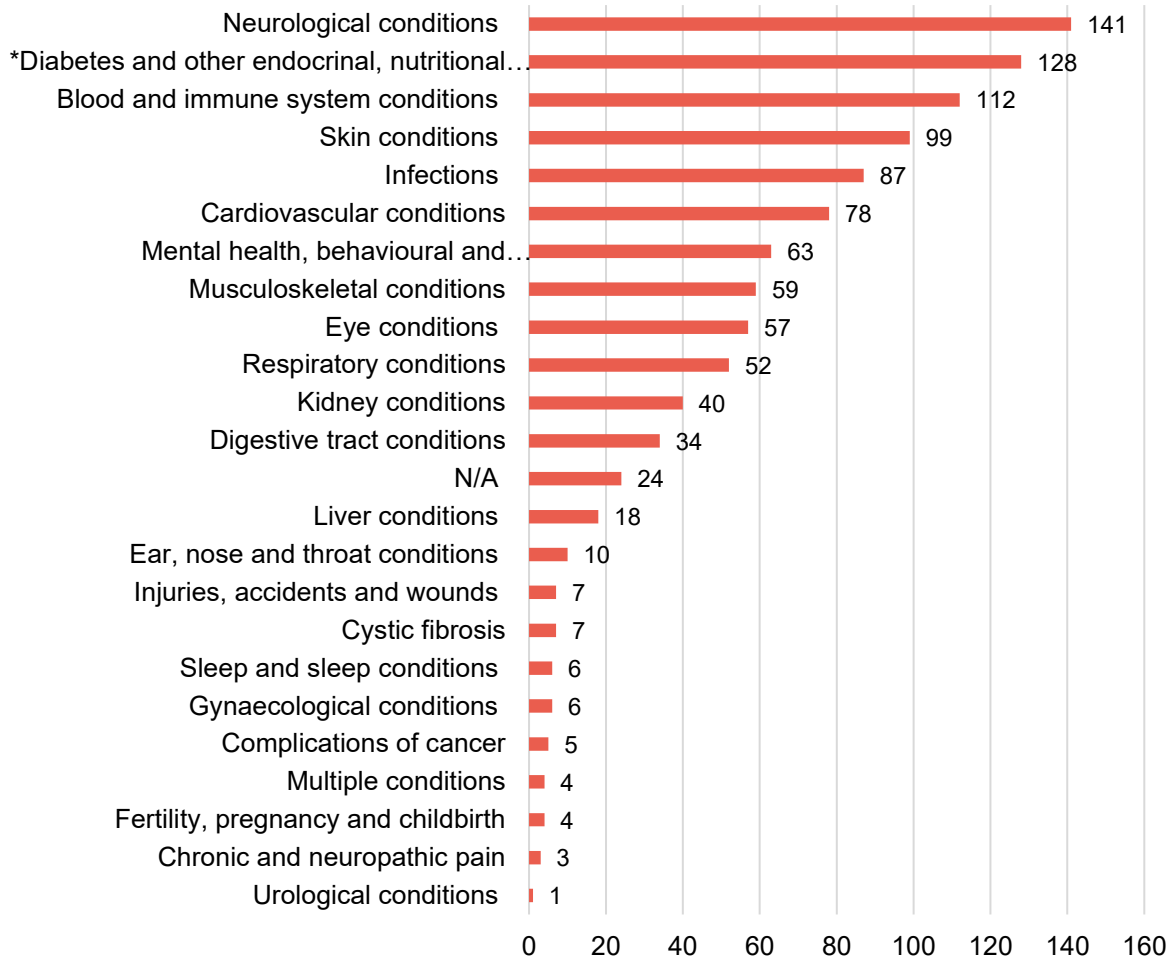

*Figure 2. Number of records by NICE non-cancer condition categories[c] *Diabetes and other endocrinal, nutritional and metabolic conditions.*

[c] The category of N/A includes conditions that do not fit well into the other indication categories e.g. anaesthesia

ii. Indication for female population group

We identified 101 (6% of total) records created and updated with indications specifically affecting the female population. Of these records, 80 (79%) were for indications classified as cancer, and 21 (21%) for non-cancer indications by NICE condition categories. The most common cancer categories in these records were breast cancer (n=40, 50%), ovarian cancer (n=15, 19%) and endometrial cancer (n=11, 14%). Neurological conditions (n=6, 29%) and gynaecological conditions (n=5, 24%) were the most frequent non-cancer indications, as shown in Figure 3.

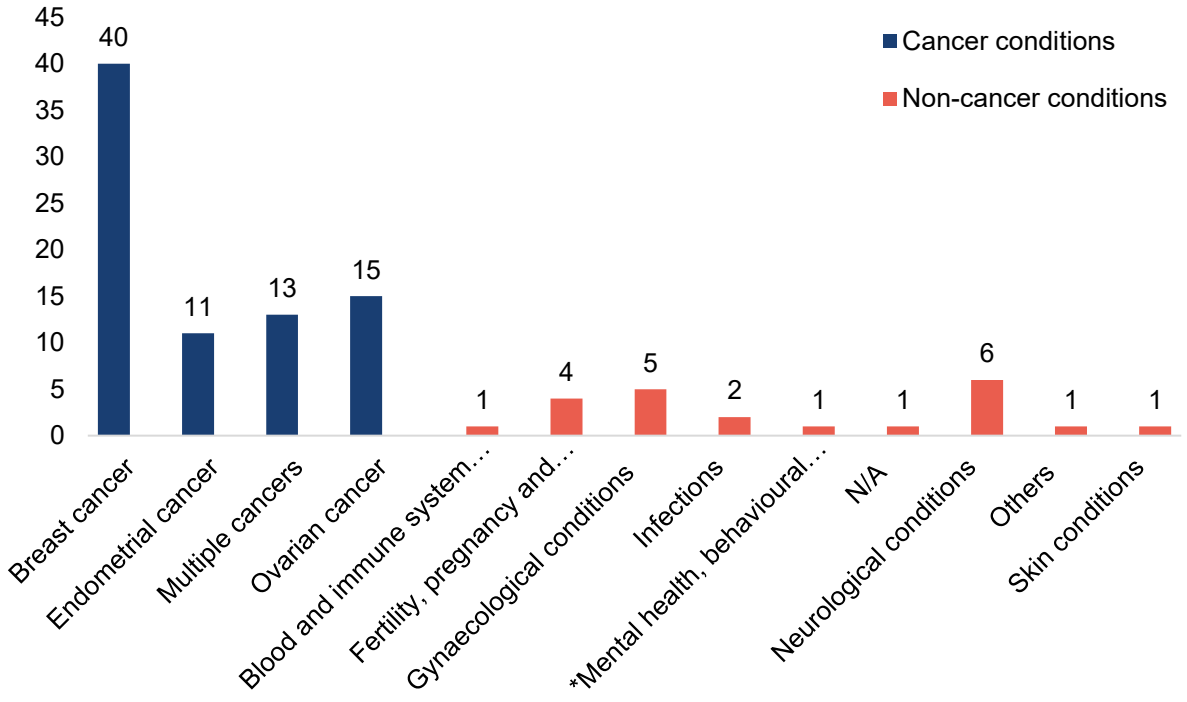

Figure 3. Number of records with indications affecting the female population classified by NICE condition categories[d,e] **Mental health, behavioural and neurodevelopmental conditions.*

[d] The category of N/A includes conditions that do not fit well into the other indication categories e.g. anaesthesia

[e] Within the figure we have included an 'Other' category which represents indications that do not fit into a NICE category

iii. Indications for paediatric population

289 (17% of total) records were created and updated on MInD for use in the paediatric population (below 18 years) in 2025. These records both those which were specifically for the paediatric population and those with both paediatric and adult indications. Of these records, 31 (11%) were in development for cancer indications, and 258 (89%) for non-cancer indications classified by NICE condition categories.

Of the 31 cancer records, blood and bone marrow cancer indications (n=15, 48%) were the most common. This was followed by sarcoma (n=5, 16%), as shown in Figure 4.

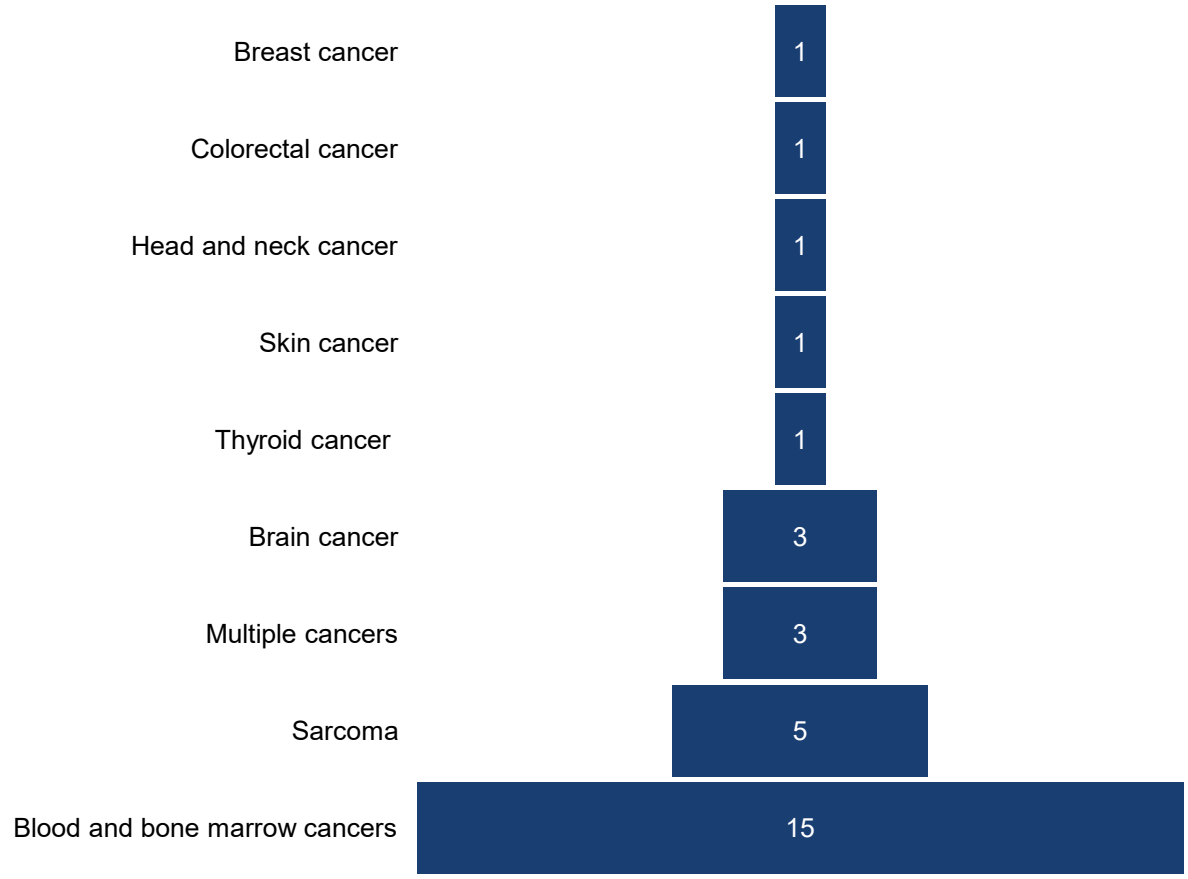

Figure 4. Number of records with cancer indications for the paediatric population classified by NICE condition categories.

In the non-cancer category, infections (n=38, 15%) were the most common. This was followed by blood and immune system conditions (n=36, 14%), diabetes and other endocrinal, nutritional and metabolic conditions (n=33, 13%), and skin conditions (29, 11%) as shown in Figure 5.

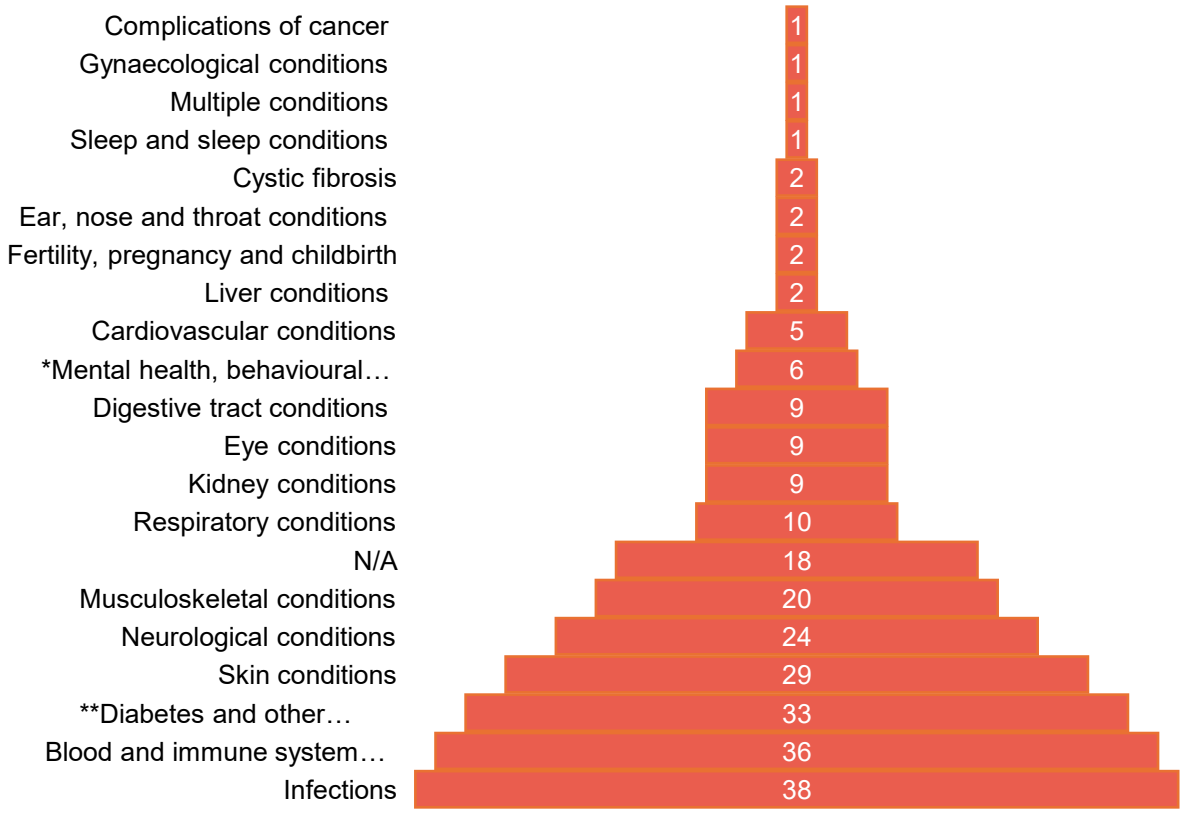

*Figure 5. Number of records with non-cancer indications for the paediatric population classified by NICE condition categories[f] *Mental health, behavioural and neurodevelopmental conditions, **Diabetes and other endocrinal, nutritional and metabolic conditions.*

Interventions

i. Monotherapies vs Combination therapies

Out of the 1,685 newly created and updated records in 2025, 1,222 (73%) had monotherapy interventions while 463 (27%) had combination therapies. Of the 640 cancer records, there were more combination therapies (n=367, 57%) for cancer indications compared to monotherapies (n=273, 43%). The reverse was the case in non-cancer categories where monotherapy interventions (n=949, 91%) appeared much more frequently than combination therapies (n=96, 9%) (figure 6).

[f] The category of N/A includes conditions that do not fit well into the other indication categories e.g. anaesthesia

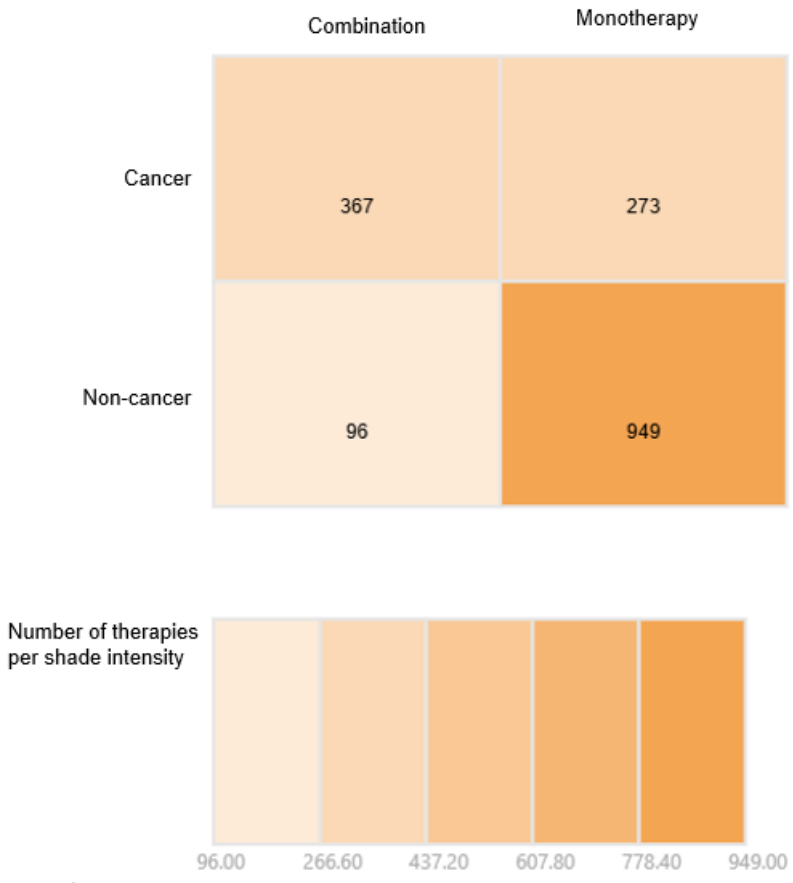

Figure 6. Number of monotherapy and combination therapies in cancer and non-cancer categories.

ii. Advanced therapy medicinal products

Advanced therapy medicinal products (ATMPs) are defined by the European Medicines Agency as medicines for human use that are based on genes, tissues or cells and include three categories: gene therapy, somatic-cell therapy, and tissue-engineered medicines.[4] Of the 1,685 newly created and updated records in 2025, 67 (4%) records had ATMP interventions. Out of these records, 26 (39%) had ATMP interventions in development for cancer related indications, while 41 (61%) records had ATMP interventions in development for non-cancer conditions. In the cancer category, blood and bone marrow cancers had the highest number of ATMPs in development (n=10, 38%). This NICE condition category includes some indications like multiple myeloma, lymphomas and leukaemia. In the non-cancer category, blood and immune system conditions (n=7, 17%), eye conditions (n=7, 17%), and musculoskeletal conditions (n-7, 17%) had the highest number of ATMPs in development, as shown in Figure 7. An analysis of the ATMP types showed that there were 44 (66%) cell

therapies, 20 (30%) gene therapies and 4 tissue engineered therapies records with ATMPs, and 3 (4%) tissue-engineered therapies as shown in Figure 8.

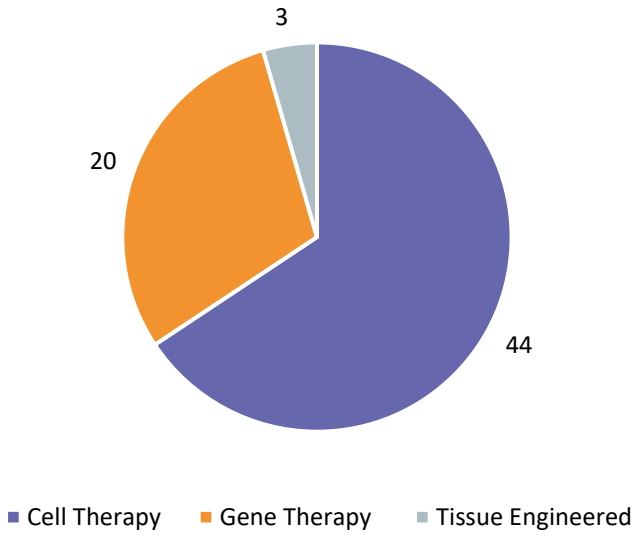

Figure 7. Number of ATMPs in each category.

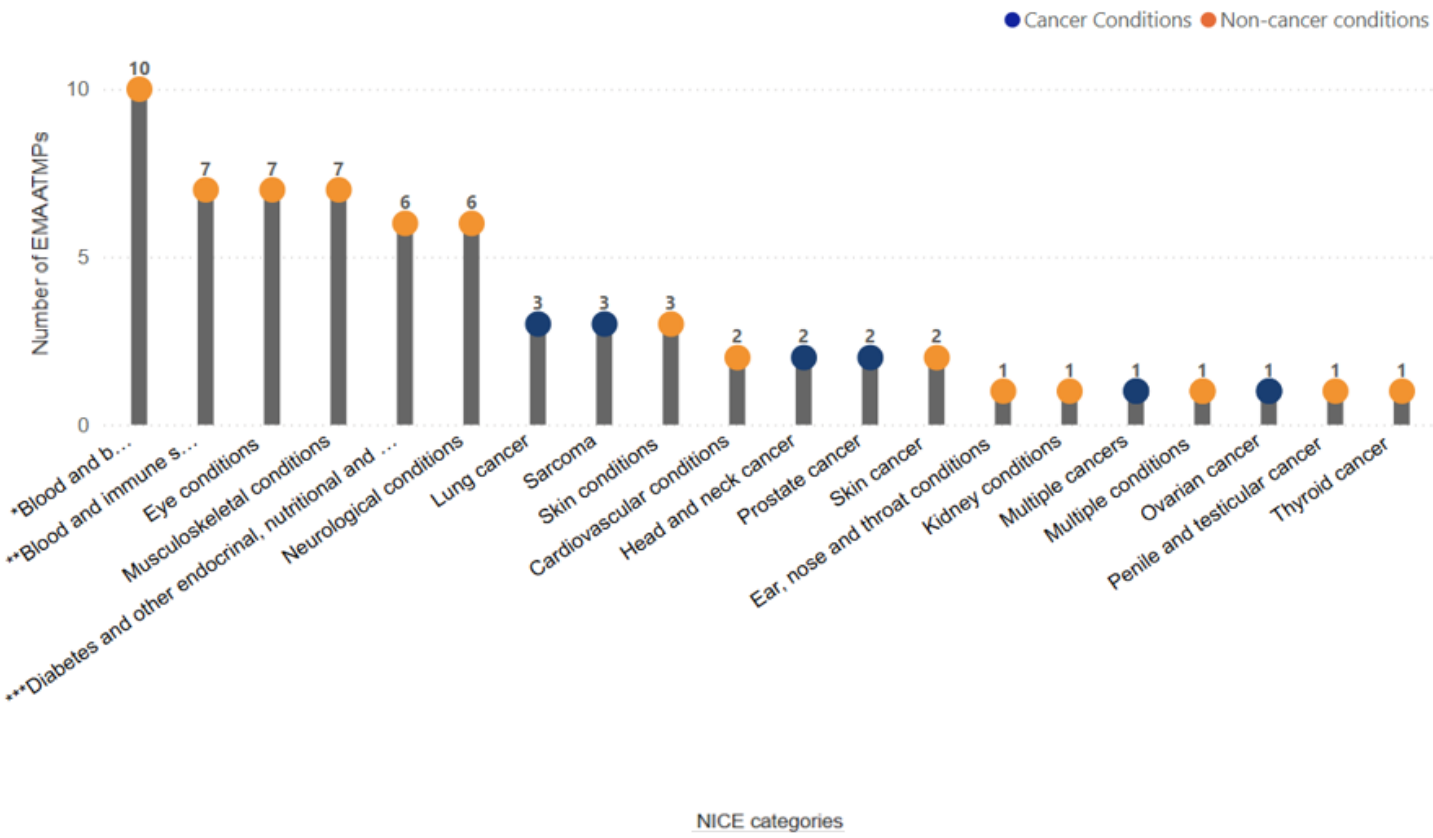

*Figure 8. Number of EMA ATMPs per indication in cancer and non-cancer NICE categories. *Blood and bone marrow cancers, **Blood and immune system conditions, ***Diabetes and other endocrinal, nutritional and metabolic conditions.*

Biosimilars

The NHS definition of a biosimilar is a medicine which has been shown not to have any clinically meaningful differences from the originator medicine in terms of quality, safety and efficacy.[5] Of the 1,685 newly created and updated records in 2025, 9 (0.5%) records had biosimilar interventions. Out of the 9 records, 3 (33%) records had biosimilar interventions in development for cancer related indications, while 6 (67%) records had biosimilar interventions in development for non-cancer conditions. In the cancer category, breast cancer indications had the highest number of records with biosimilars in development (n=2, 22%). Biosimilar interventions in development for musculoskeletal conditions appeared most frequently in the non-cancer records (n=3, 33%) out of the 9 newly added and updated records in the biosimilars category. Ocrelizumab biosimilar (n=2, 22%) and Infliximab biosimilar (n=2, 33%) were found to be the most common reference products in the 9 biosimilar records we added and updated on MInD in 2025.

1. Regulatory information

i. Orphan drugs

Orphan drugs as defined by the EMA are medicines that must meet the following criteria: [6]

- it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating.
- the prevalence of the condition in the EU must not be more than 5 in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development.
- no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorised, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In 2025, we added and updated 78 records with at least one intervention that had an EMA orphan designation (5% of the total records). 15 (19%) of the records had interventions in development for cancer indications, while most of the other records had non-cancer indications (n=63, 81%). Blood and bone marrow cancers were the most common indications seen in the cancer category (n=6, 40%). In the non-cancer category, diabetes and other endocrinal, nutritional and metabolic conditions were the most occurring indications (n=11, 17%), as shown in Figure 10.

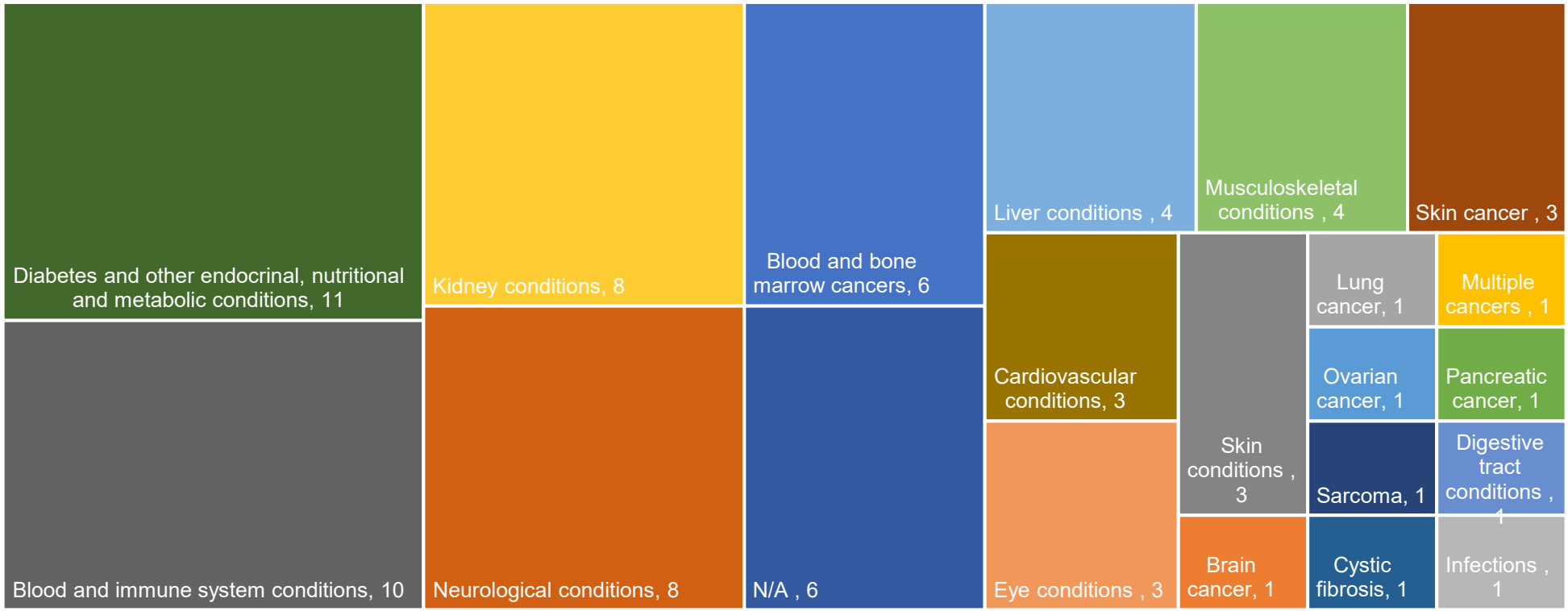

Figure 9. Number of cancer and non-cancer records with at least one orphan drug by NICE condition category.[g]

[g] The category of N/A includes conditions that do not fit well into the other indication categories e.g. anaesthesia

ii. Priority Medicines

Priority Medicines (PRIME) is a voluntary scheme conducted by the EMA to support the development of medicines that address an unmet medical need for which no treatment option exists or where a medicine can offer major therapeutic advantage compared to existing treatments.[7] In 2025 we added and updated 21 records with at least one intervention that had a PRIME designation (1% of the total records). Of these records, 4 (19%) had interventions in development for cancer indications, while most of the other records had non-cancer indications (n=17, 81%). Sarcoma was the most common indication in the cancer category (n=2, 50%). In the non-cancer category, blood and immune system conditions were the most occurring indications (n=5, 24%), as shown in Figure 11.

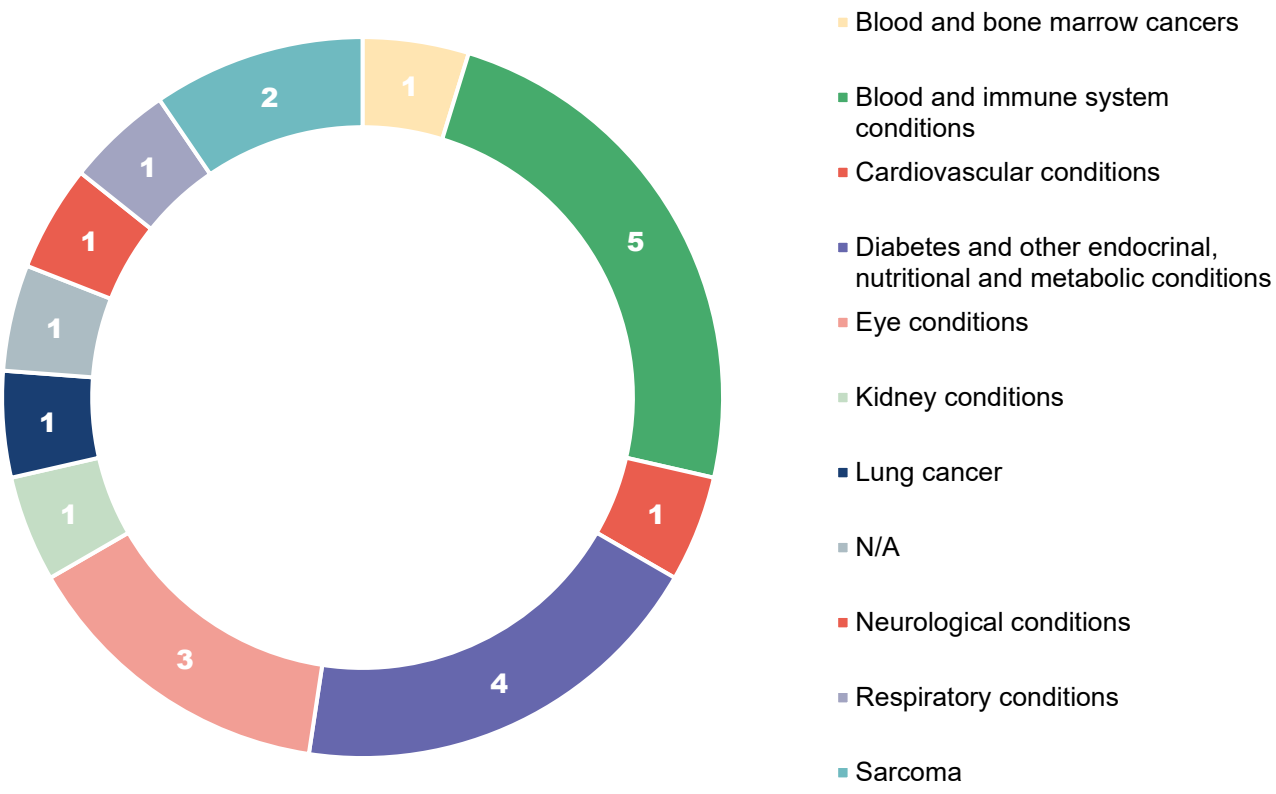

Figure 10. Number of cancer and non-cancer records with at least one PRIME designated drug by NICE condition category[8]

iii. Promising Innovative Medicines

Promising Innovative Medicines (PIM) designation is intended for treatment, diagnosis, or prevention of a life-threatening or seriously debilitating condition that could potentially address an unmet medical need.[8] There were no records in 2025 with interventions that have

[8] The category of N/A includes conditions that do not fit well into the other indication categories e.g. anaesthesia

been assigned a PIM designation by the Medicines and Healthcare products Regulatory Agency (MHRA).

iv. Innovation Licensing and Access Pathway

The MHRA introduced the Innovative Licensing and Access Pathway (ILAP) in January 2021. This initiative aims to accelerate the time to market, ultimately facilitating patient access to medicines. [9] In 2025, we added and updated 2 records (0.1% of the total records) with an ILAP designation. Both these records were non-cancer indications, including diabetes and other endocrinal, nutritional and metabolic conditions (n=1, 50%) and eye conditions (n=1, 50%).

Sponsors

We identified 725 unique companies that were either the sponsors, collaborators or developers of the clinical trials that were newly created and added on MInD in 2025. From the 1,685 newly added or updated records in 2025, the companies with the highest number of records were AstraZeneca UK Ltd (n=66, 9%), Merck Sharp & Dohme Ltd (n=51, 7%), Novartis Pharmaceuticals UK Ltd (n=46, 2%) and Sanofi (n=46, 2%).

Of the 639 newly created and updated cancer records in 2025, AstraZeneca UK Ltd had the highest number (n=43, 7%), this was followed by Merck Sharp & Dohme Ltd (n=38, 6%) and Bristol-Myers Squibb Pharmaceuticals Ltd (n=30, 5%). In the 1,046 non-cancer categories, Sanofi had the highest number of records (n=45, 4%), this was followed by Novartis Pharmaceuticals UK Ltd (n=28, 3%) and AstraZeneca UK Ltd (n=23, 2%) (figure 13).

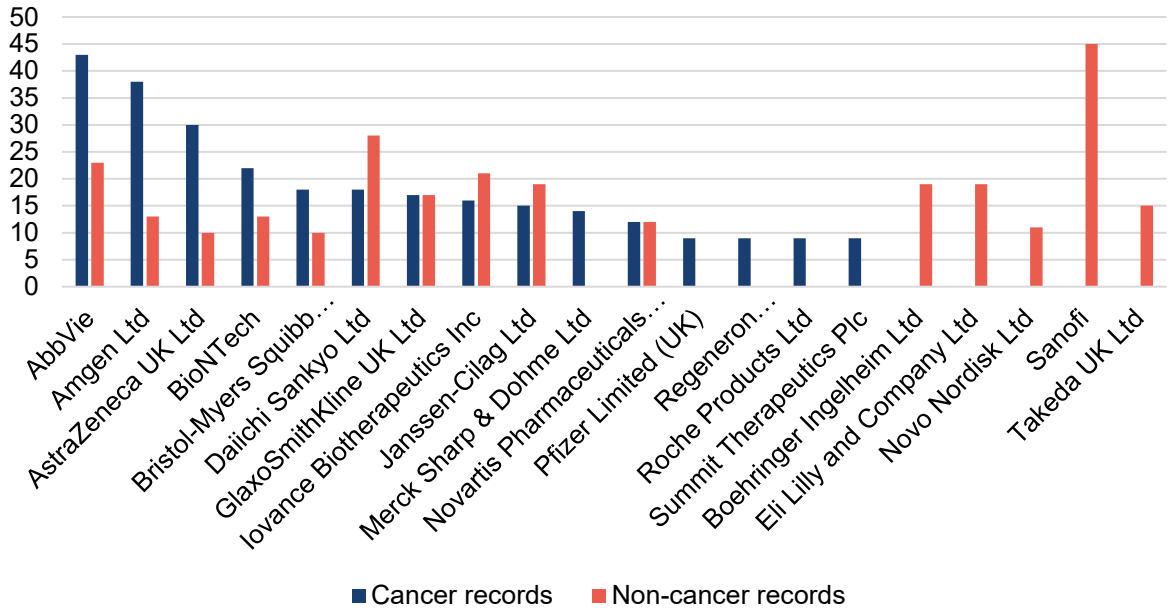

Figure 11. Number of records added/created in 2025 per top 15 commercial sponsors divided into cancer and non-cancer record.

We also identified companies that were developing interventions with EMA orphan and PRIME designations. There were 85 records that had at least one orphan or PRIME designated drug; Novartis Pharmaceuticals UK Ltd had the highest number of these (n=7, 8%), followed by Vertex Pharmaceuticals Inc (n=4, 5%) and Sanofi (n=3, 4%). Of the 2 newly created or updated records in 2025 with MHRA ILAP designations, Spur Therapeutics and Adverum Biotechnologies Inc were developing one interventions each.

Conclusion

This report presents a snapshot of the newly added and updated records on IO's MInD database in 2025. We analysed the technology records base on indications, interventions, regulatory information, and sponsor information. We created 1,356 new records and updated 329 with clinical trials in 2025, giving a total of 1,685. Cancer records made up 38% of these records and 62% was made up of non-cancer records. 73% of the total records were found to be for monotherapy interventions with the rest being combination therapies. We also identified the total number of interventions in development for use in the female population, these records represented 6% of the total records with breast cancer being the most common indication. In children aged below 18 years, 17% of the total records were identified to be in development for use in this population. Blood and bone marrow cancers, and infections were found to be the most frequent indications among the newly created and updated records in 2025 for this population.

When analysing the total number of designations or awards for interventions added or updated in 2025, we identified 78 records with at least one EMA orphan drug, 21 records with at least one PRIME designation drug and 2 records that had interventions with ILAP designations. AstraZeneca UK Ltd was the commercial sponsor that had the most records overall in 2025, and in cancer indications. For non-cancer indications, Sanofi and Novartis Pharmaceuticals UK Ltd had the highest number of newly created or updated records in 2025.

Future work

This report is the sixth annual report produced by IO. We aim to produce reports every year to present a snapshot of innovation in the sphere of clinical development for medicines in the previous year. Going forward IO will also work to develop reporting on classes of drugs (to capture development of new molecular targets); clinical development in specific indications identified as areas of unmet need. We will also consider developments in the horizon scanning landscape over time, allowing the detection of trends in medicines development.

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