2022 ACCESS TO MEDICINE INDEX

Special Report Progress Analysis

SPECIAL REPORT: PROGRESS ANALYSIS

The 2022 Index report marks the eighth edition of the Access to Medicine Index, which was first published in 2008. For over a decade, the Index has provided insights into how 20 of the world's largest pharmaceutical companies perform on access to medicine in low- and middle-income countries (LMICs). The methodology for the 2022 Index has a high level of continuity with the previous Index, allowing for a detailed longitudinal analysis of where progress has been made – and where it has not.

This Special Report explores the extent to which the industry is making progress on improving access to medicine, and progress towards the UN Sustainable Development Goal 3 (SDG3) for 2030, despite the challenge of the COVID-19 pandemic.

The analysis presented here compares data from the 2022 Access to Medicine Index with data from the 2021 Index, and where possible, previous editions of the Index. Although the methodology was updated with a new robust framework after the publication of the 2018 Index, comparisons have been drawn where viable and meaningful.

access to medicine FOUNDATION

GOVERNANCE OF ACCESS

Progress seen at board level as companies increasingly integrate strategies to address access to medicine

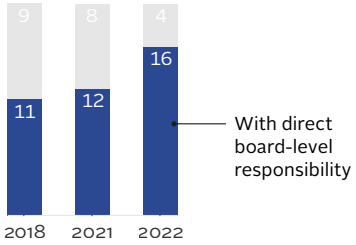
This section looks at where there has been a shift from indirect to direct top-level accountability for access to medicine and whether the companies are increasingly embedding an access-to-medicine mindset in their business operations. Additionally, this section considers changes in how companies ensure compliance with codes of conduct and incentivise good ethical conduct by sales agents.

Governance structures and incentives

Since 2018, the number of companies with either a board member or a board-level committee responsible and accountable for access to medicine activities has increased from 11 in 2018, to 12 in 2021, and 16 in 2022, with Eisai, Bristol Myers Squibb, Merck and Sanofi now also providing evidence of direct board-level accountability for access-to-medicine activities.

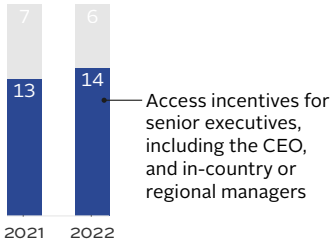
In 2019, the Foundation published an independent ten-year analysis titled, "Are pharmaceutical companies making progress when it comes to global health?", which identified a shift from indirect board-level responsibility for access to medicine towards assigning direct responsibility to a named board member. As the data from the 2021 and 2022 Indexes shows, there has been noticeable progress.

FIGURE 22 **Progress in number of companies with direct board-level responsibility for access to medicine**



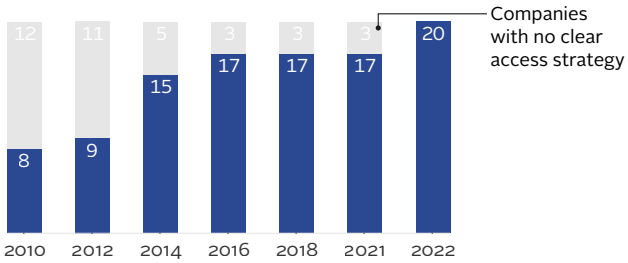
In 2021, 13 companies provided evidence of access-related incentives for senior executives, including the CEO, and regional or in-country management. In 2022, one more company, Gilead, provided evidence of incentives for senior management, indicating only a slight improvement in the companies' top-level incentivisation of access-related targets and goals.

FIGURE 23 **Small increase in the number of companies with access incentives for senior management**



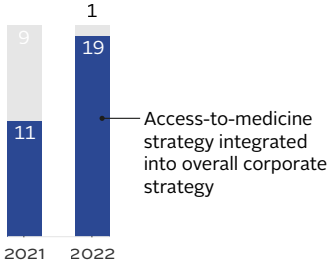
The 2022 Index finds that three companies have newly implemented an access-to-medicine strategy, meaning all 20 companies now have an access-to-medicine strategy in place to expand access to their products for people living in LMICs. These companies are AbbVie, Astellas and Daiichi Sankyo. Previously, these companies had only general commitments to improve access to medicine rather than a clear, intergrated access-to-medicine strategy.

FIGURE 24 **Clear signs of progress as all 20 companies now have an access-to-medicine strategy**



Nineteen of the 20 companies have integrated their access-to-medicine strategy into their overall corporate strategy, with Gilead having a business rationale for its access-to-medicine strategy that is focused on partnerships to enhance access. This is in stark contrast to the 2021 Index, where just 11 companies had integrated strategies.

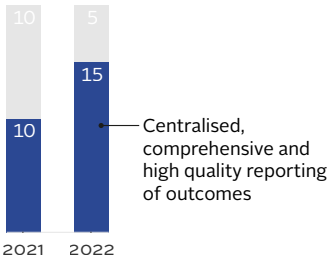
FIGURE 25 **Significant increase in number of companies that have integrated their access-to-medicine strategies into their overall corporate strategy**



While all pharmaceutical companies included in the analysis have set targets and goals related to their access-to-medicine initiatives, companies vary considerably in terms of the quantity and quality of outcome reporting.

For example, several companies report outcomes using centralised, easy-to-digest dashboards detailing how and when short-, medium- and long-term results were achieved for all activities. Other companies do not have such transparent practices; for example, they may share this information via multiple documents or external websites, or only report on certain products or therapeutic areas, making it difficult to gain a complete picture of the company's activities and hold them accountable.

FIGURE 26 **More companies are increasing transparency about their access-to-medicine activities**

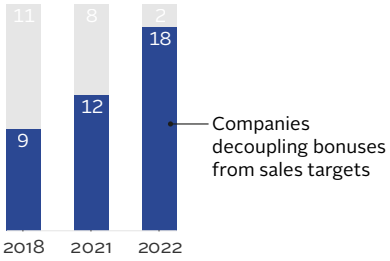


Ethical marketing and compliance

With respect to risk management of unethical marketing and other practices, the 2022 Index has determined that companies are making strides. AbbVie, Bristol Myers Squibb, Boehringer Ingelheim, Daiichi Sankyo, Gilead and Sanofi newly demonstrate that sales agents' incentives are not based solely on sales volume.

The number of companies decoupling sales agents' rewards from sales targets has steadily increased over time. Compensation for sales representatives is becoming increasingly tied to qualitative performance indicators, such as technical knowledge or compliance adherence.

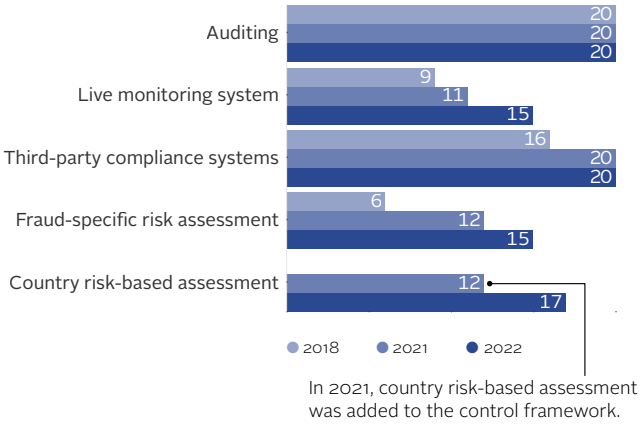
FIGURE 27 **Companies are making progress on decoupling agents' rewards from sales targets**



The Foundation's ten-year progress report, published in 2019, found that all 20 companies had auditing controls in place since the 2016 Index. In the 2022 Index, this remains the case.

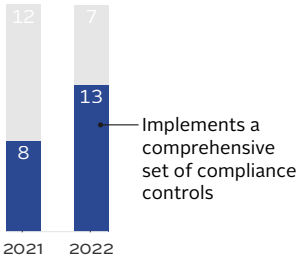
In 2018, the Index began analysing whether companies had additional controls in place to ensure compliance with each country's regulatory and anti-corruption laws. This included fraud-specific risk assessments, a continuous monitoring system for compliance and processes to ensure third-party compliance.

FIGURE 28 **Some signs of progress in applying specific compliance controls**



Of the five controls measured by the Index in 2021, only eight companies demonstrated evidence of applying all of them. In 2022, five additional companies have implemented all controls, meaning there are 13 companies that have a strong – i.e., comprehensive – internal control framework for ensuring compliance. The five additional companies are Bayer, Bristol Myers Squibb, Eisai, Merck and Pfizer.

FIGURE 29 **Progress in implementing a comprehensive set of compliance controls to prevent corrupt and non-compliant activity**



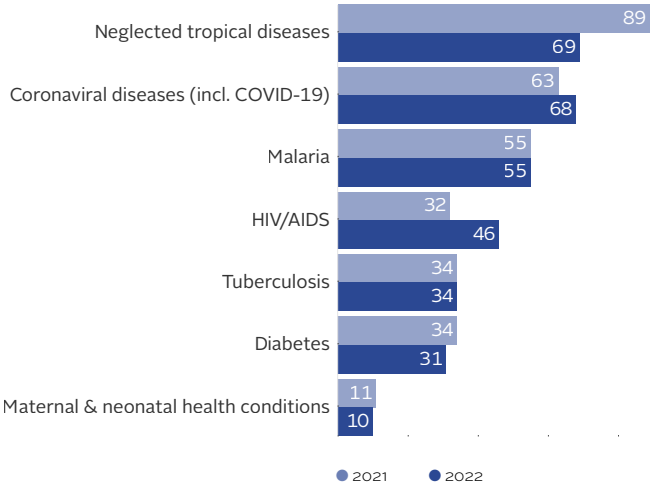
RESEARCH & DEVELOPMENT

Companies make progress in access planning but little change in makeup of R&D pipelines

Breakdown of the pipeline

The total number of projects targeting specific disease classifications has remained relatively stable since the 2021 Index, with a slight decrease in the number of R&D projects in the pipeline targeting diseases in scope; 1,060 projects in 2022 compared with 1,073 projects in 2021. A total of 62 products received regulatory approval,* 479 new projects were added to the pipeline and 466 projects were removed during the period of analysis.** Notably, there has been a decrease in the number of projects targeting neglected tropical diseases (NTDs). Despite 20 new NTD projects being added to the pipeline, the total number of NTD projects fell from 89 in the previous Index to 69 in the 2022 Index. The decrease in the number of active projects is mostly a result of some discovery-phase projects being discontinued and some projects leaving the pipeline after successfully reaching product approval and launch.

FIGURE 30 **HIV/AIDS and COVID-19 draw more R&D attention, number of projects targeting NTDs decreases**

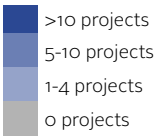


Among R&D projects to address priority diseases, a small number of diseases dominate the pipeline

Of the 1,060 projects in the pipeline, one third target a disease identified as a priority R&D treatment gap, as defined by global health organisations (see Appendix VI) – a figure consistent with the findings of the previous Index.

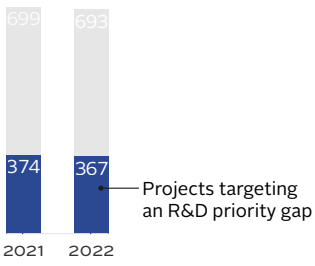
However, although there are 64 priority diseases, over half of these projects (202) focus on four priority diseases: coronaviral diseases, HIV/AIDS, malaria, and tuberculosis. Many diseases with urgent requirements for R&D are not being addressed by research-based pharmaceutical companies. This figure remains consistent with the 2021 pipeline, where 199 projects targeted these four diseases. This is a long-term trend that was also identified by the Foundation's 10-year progress report in 2019, which found that, in general, companies' R&D activities are concentrated on a few diseases.

FIGURE 31 **R&D activity for NTDs such as leishmaniasis, onchocerciasis and Chagas disease decreases**



Neglected tropical disease	2021	2022
Buruli ulcer	0	0
Chagas disease	27	21
Dengue and chikungunya	12	11
Dracunculiasis	0	0
Echinococcosis	0	0
Food-borne trematodiases	1	0
Human African trypanosomiasis	7	7
Leishmaniasis	28	15
Leprosy	2	1
Lymphatic filiariasis	5	1
Mycetoma	1	1
Onchocerciasis	11	4
Rabies	3	3
Scabies and other ectoparasites	0	0
Schistosomiasis	18	16
Snakebite envenoming	0	0
Soil-transmitted helminthiasis	4	3
Taeniasis/cysticercosis	0	0
Trachoma	0	0
Yaws	0	0

FIGURE 32 **Limited change in companies' focus on R&D for priority diseases**



*This includes products that received emergency use authorisation or conditional marketing approval during the period of analysis (1 June 2020 - 31 May 2022).

**Period of analysis 1 June 2022 - 31 May 2022

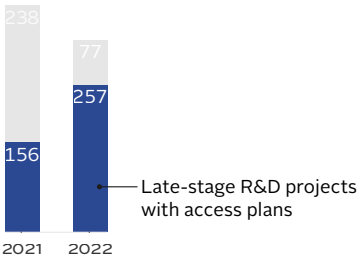
Companies begin to look ahead but with a narrow lens

While the ten-year progress report published by the Foundation in 2019 found that the proportion of late-stage R&D projects with access plans had remained largely unchanged over the previous decade, in 2022 the number of late-stage projects with access plans has increased markedly. In the 2021 Index, 40% of late-stage projects analysed had plans for access in place during the R&D stage. This year, 77% of late-stage projects have access plans in place.

This improvement corroborates a Key Finding from the 2021 Index, which identified an industry shift towards systematic access planning during late-stage R&D so that new products quickly reach the people who need them in LMICs. The significant increase between the 2021 and 2022 Indexes may indicate that companies' commitments to systematically implementing access planning during R&D are now leading to tangible results.

However, an in-depth analysis of the quality and breadth of these plans concludes that the majority of these plans focus on a select number of countries in scope, thus leaving these important product developments out of reach for most. Furthermore, most of these plans focus solely on registering the product in at least one country in scope of the Index with few provisions for affordability to ensure the product will be accessible for all.

FIGURE 33 **More late-stage R&D projects have access plans compared to previous years**



PRODUCT DELIVERY

Progress in access strategies and voluntary licensing, but overall picture mixed

Each product should have an access strategy to ensure it is widely available and affordable in LMICs. Equitable pricing and non-exclusive voluntary licensing (NEVL) are two important mechanisms that companies can use as part of an access strategy to increase access to a product. Furthermore, patent transparency is an important tool to ensure generic manufacturers can quickly enter the market once the original patents on a health product expire.

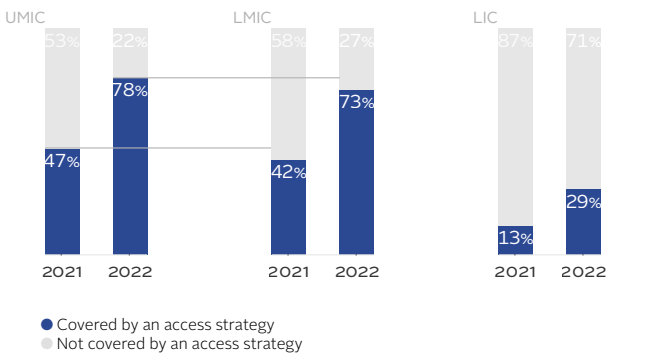
This section shows how companies have developed their access strategies since the 2021 Index. It also looks at how companies have progressed in NEVL and patent transparency over past Indexes.

More products now covered by access strategies

Since the previous Index, there has been a significant increase in the number of products in scope that are now covered by an access strategy. Access strategies can include, for example, pricing strategies, non-pricing initiatives (e.g., patient assistance programmes, non-exclusive voluntary licensing, donations) or a combination of pricing strategies with non-pricing initiatives.

It is important that companies put access strategies in place for both self-administered products and healthcare practitioner (HCP)-administered products. However, as in the 2021 Index, HCP-administered products continue to be covered by fewer access strategies compared to self-administered products in upper-middle income and lower-middle income countries. Access strategies are also far less likely to be used to expand access to products in low-income countries, compared to upper-middle income countries and lower-middle income countries.

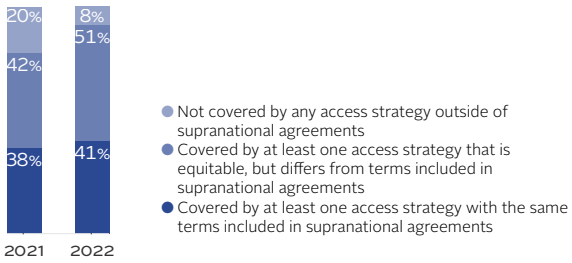
FIGURE 34 **Percentage of products covered by access strategies in upper-middle, lower-middle, and low-income countries**



Compared with the 2021 Index, data analysed in the 2022 Index shows an increase in the number of companies engaging in supranational agreements.

AstraZeneca now supplies products via supranational agreements, and in countries not eligible for international procurement processes. The company, along with Pfizer, also has access strategies that include the same terms as supranational agreements. As the figure shows, this has slightly increased the proportion of the products in scope that are covered by these access strategies. Data analysed in the 2022 Index shows progress in the percentage of products covered by an access strategy in countries outside supranational agreements. A smaller percentage of products are not covered by access strategies in non-eligible countries.

FIGURE 35 **Small increase in number of products included in access strategies outside of supranational agreements**

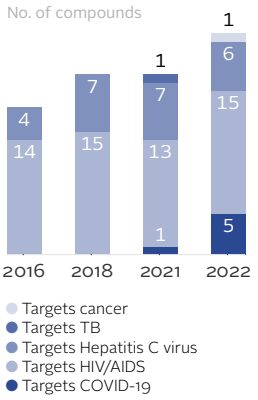


Increase in voluntary licensing is mainly related to COVID-19 products

Engaging in NEVLs is one way that research-based pharmaceutical companies can ensure that key healthcare products, or the compounds vital to making those products, reach more people who need them – particularly those living in LMICs. When companies offer NEVLs, this can facilitate the entrance of generic manufacturers to market, making medicines more affordable and accessible.

AstraZeneca, Eli Lilly and Novartis have entered into new licensing agreements since the previous Index. There are now 27 licenced compounds, which include three new NEVLs for COVID-19 treatments and one private voluntary licence for a COVID-19 vaccine (in addition to the COVID-19 product already covered by a licence in the 2021 Index). Although more companies are getting involved in licensing agreements, the transparency, quality and breadth of these licences vary.

FIGURE 36 **Five products have been newly covered by voluntary licences in the last two years***

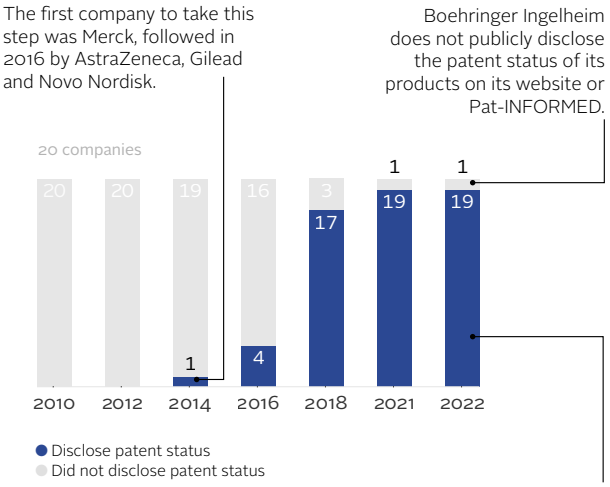


Number of companies disclosing patent status for some of their products remains high

When companies publicly disclose patent status data about their products – i.e., sharing information about where patents are filed – this transparency can bring significant benefits in terms of access to medicine. In particular, it provides greater certainty to generic medicine manufacturers and international drug procurers when planning the manufacture and/or supply of generic products, thereby facilitating increased supply and affordability.

Of the 20 companies, 19 publicly disclose information on the status of patents related to at least some of the prodcuts in their portfolio, the same number as the 2021 Index. Most of the data is shared through the online database Pat-INFORMED – an intitiative coordinated between the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the World Intellectual Property Organization (WIPO) – while a few companies self-publish patent information online.

FIGURE 37 **Number of companies sharing patent status data for some products in their portfolios**



* During the period of analysis for this Index: 1 June 2020 - 31 May 2022.

PRODUCT DELIVERY

Progress in capacity building in R&D and manufacturing, but stagnation in health systems strengthening

Capacity building initiatives focused on health systems strengthening, manufacturing, supply chain and R&D represent additional ways in which pharmaceutical companies can improve access to medicine and address issues in health product availability and accessibility (e.g., appropriate prescription, efficient administration).

Overall improvement in proportion of initiatives meeting all Good Practice Standards

For almost all fields of capacity building, improvement has been seen in the percentage of initiatives included that meet all Good Practice Standards (GPS; see Appendix IV); overall, 21 additional initiatives meet all GPS compared with the previous Index. The most significant improvement was seen in R&D capacity building, with an increase of 34 percentage points. Supply and manufacturing had smaller increases of 18 and 26 percentage points, respectively. For R&D capacity building, 11 more initiatives were included compared with the previous Index. In both supply chain and manufacturing capacity building, 13 new initiatives were included for analysis.

However, the number of high-quality capacity building initiatives focused on health systems strengthening has stayed relatively stable. In the 2021 Index, analysis showed that health systems strengthening initiatives were improving in terms of quality and quantity. In the 2022 Index, while seven new initiatives have been included for analysis, only two more initiatives meet all GPS, thereby reducing the overall percentage of health systems strengthening initiatives that meet all GPS.

Progress in outcome measurement focused on R&D capacity building

Measuring and sharing outcomes can provide valuable insights that can improve ongoing projects and inform future activities. Because of this, measuring capacity building outcomes is one of the GPS for manufacturing, supply and R&D capacity building, and publicly disclosing outcomes is a GPS for health systems strengthening. Outcome measurements across capacity building can include changes in patient health outcomes, quantity of donated equipment, evidence of patient reach or decreased stockouts in pharmacies.

Since the last Index, companies have especially done more to measure outcomes of R&D capacity building. Improvement in outcome measurement was also seen in supply chain capacity building initiatives, but no improvement was seen in measuring outcomes of manufacturing capacity building initiatives.

The Index measures whether companies both measure and publicly disclose outcomes of health systems strengthening initiatives. In the 2022 Index, only a marginal improvement in public disclosure of outcomes was seen across health systems strengthening initiatives.

FIGURE 38 **More supply, manufacturing and R&D capacity building initiatives meet all Good Practice Standards, but improvements in health systems strengthening initiatives have stagnated**

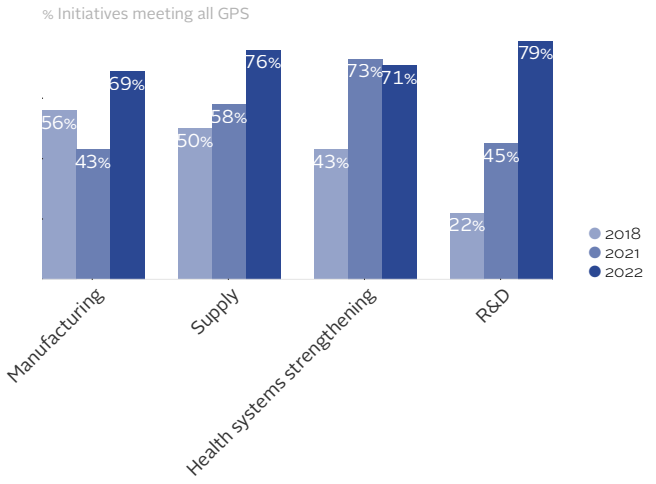


FIGURE 39 **Varied progress in measuring outcomes across capacity building fields**

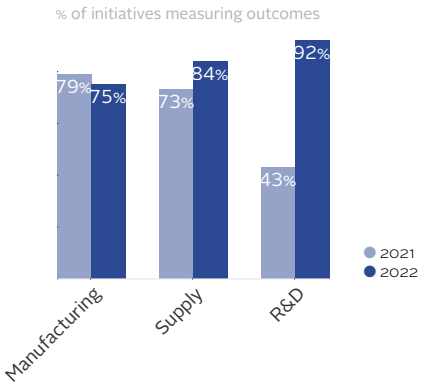


FIGURE 40 **Stagnation in public disclosure of outcomes for health systems strengthening**

Five-fold increase in scaled-up inclusive business models since 2021 Index

Since 2014, when inclusive business models were first assessed in the Index, ten more companies are engaged in inclusive business models, with 16 companies currently engaged in 51 inclusive business models. This change reflects companies' efforts to address unmet health needs of vulnerable groups who may face additional barriers to access. The number of inclusive business models that have scaled up has increased five-fold since 2021, whereas the number of piloted inclusive business models has stayed relatively consistent. Scale-up can involve expanding to new countries, increasing the number of patients served, or expanding the diseases covered.

FIGURE 41 **Use of inclusive business models continues to expand, with an emphasis on scaling up models**