White Paper

Landscape of Clinical Trials in asthma and Chronic Obstructive Pulmonary Disease (COPD) in India

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Executive summary

Chronic respiratory diseases account for 4% of all diseases and 8.3% of chronic diseases worldwide (WHO report 2007). Major preventable chronic respiratory diseases include asthma and respiratory allergies, chronic obstructive pulmonary disease (COPD), and occupational lung diseases, among others. It is estimated that out of the four major groups of noncommunicable diseases, respiratory diseases has the second-highest predicted economic burden for 2011-2025: a cost of US$ 1.59 trillion [The global asthma report 2018].

Chronic respiratory diseases account for 4% of all diseases and 8.3% of chronic diseases worldwide. India shares a large part of the global disease burden and has well-resourced clinical research sites, which potentially allows their successful participation in chronic respiratory disease clinical trials. The aim of this paper is to evaluate the potential of India as an attractive clinical trial destination for respiratory diseases, with a focus on asthma and COPD, by assessing the views of leading investigators regarding the standard practices across India for the diagnosis, treatment and long-term management of patients, as well as their preparedness for participation in clinical trials.

The various data sources, such as the Burden of Obstructive Lung Disease Initiative Survey (BOLD), The Indian Study on Epidemiology of Asthma, Respiratory Symptoms and Chronic Bronchitis in adults (INSEARCH), and the International Study of Asthma and Allergy in Childhood (ISAAC), point toward the increasing chronic respiratory disease burden in India (www.thelancet.com/lancetgh Vol 6 December, 2018).

To understand the potential of Indian investigators and sites to conduct respiratory clinical trials on the Indian subcontinent, with a focus on asthma and COPD, IQVIA conducted an Advisory Board meeting involving six leading Pulmonologists and renowned Chest physicians across India on November 29, 2022.

Disease epidemiology and prevalence of asthma and COPD in India

Asthma is a chronic inflammatory disorder of the bronchial airway. It is characterized by hyperresponsiveness of airways, which leads to recurrent episodes of wheezing, breathlessness, chest tightness and coughing, mostly at night and early morning. The worldwide prevalence of asthma is 1-18% of the population in different countries. Agarwal et al. noted in their study that the prevalence of asthma in children and adults (cumulative) in India is at least 2%. (Agarwal et al. 2015 April); Elsewhere, Ghosal et al. have indicated that the prevalence may vary from 2.05% to 3.5%.

THE MAIN OBJECTIVES OF IQVIA'S ADVISORY BOARD MEETING WERE TO:

- Understand epidemiology of asthma and COPD in India
- Understand disease management and standard of care vis-a-vis global practices
- Discuss anticipated challenges and favorable factors for conducting respiratory trials in India

Table 1: Summary of the main clinical phenotypes of asthma

SL.NO	ASTHMA PHENOTYPE	CHARACTERISTICS
1.	Allergic asthma	Past or family history of allergies Sputum reveals eosinophilic airway inflammation Response to Inhaled corticosteroid treatment (ICS)
2.	Non-allergic asthma	Sputum may show neutrophils, eosinophils and few inflammatory cells Low response to ICS
3.	Adult-onset asthma	Non-allergic Refractory to ICS or may need very high doses of corticosteroids Includes occupational asthma
4.	Asthma with persistent airflow limitation	Long-standing asthma patients may develop airflow limitation that is partially or completely irreversible
5.	Asthma with obesity	Obese patients with prominent respiratory symptoms and little eosinophilic inflammation

According to the advisory board panelists' experience in India, asthma is seen equally in both urban and rural populations. The major risk factors associated with asthma include allergies, pollution, advancing age, smoking, household/environmental tobacco smoke exposure, and asthma in a first-degree relative (genetics). In rural populations the use of unclean cooking fuels (biomass fuels) is a contributing factor.

Chronic Obstructive Pulmonary disease is a heterogeneous lung condition characterized by chronic respiratory symptoms (dyspnea, cough, sputum) due to airway abnormalities that cause progressive persistent airflow obstruction. Worldwide, COPD affects 65 million people, kills more than 3 million people every year and has a prevalence of 4-10%.

Rigorous estimates of the current prevalence of COPD in India are not well understood; however, data indicate that prevalence may vary from 3% to 8% [Ghosal et al. 2016]. (Ghosal et al. Lung India. 2016 Nov-Dec; 33(6): 611-619, doi: 10.4103/0970-2113.192878). The Advisory Board Panelists conveyed that, overall, India is becoming increasingly urbanized and consequently has increasing risk factors for chronic respiratory disorders, which is leading to more COPD patients.

The age-specific prevalence of COPD increases rapidly after the age of 30 years, with a greater increase in men than in women, reaching the highest prevalence among men in the 80 years or older age group (37.8%) and among women in the 75-79 years age group (19.7%) [India State-Level Disease Burden Initiative CRD Collaborators 2018]. Variance among countries and between different groups in the prevalence of this disease is often directly related to smoking prevalence, although environmental pollution has a greater role in many countries. (Sarah de Oliveira Rodrigues et al. Pharmaceuticals. 2021,14,979, https://doi.org/10.3390/ph14100979). The epidemiological report for India cites air pollution as the leading risk factor for COPD in 2016, more responsible than smoking for the COPD burden. The panelists concurred with these reported findings and confirmed that, in India, there is increased association between chronic respiratory diseases like COPD and non-smoking related factors, such as outdoor air pollution from particulate matter, indoor air pollution from biomass fuels, occupational exposure to crop dust, dust from mines, chemicals, poor socio-economic status, poor nutrition, overcrowding, and residence in urban slums [India State-Level Disease Burden Initiative CRD Collaborators 2018].

Table 2: Risk factors for Chronic Respiratory disorders in India

SL.NO	RISK FACTORS
1.	Air pollution
2.	Aging
3.	Tobacco smoking
4.	Overcrowding
5.	Biomass fuels
6.	Poor nutrition
7.	Occupational (mine dust, crop dust, cotton dust), chemicals
8.	Residence in urban slums
9.	Genetics
10.	Betel nut and tobacco chewing

Additionally, the panelists also attributed a major portion (approximately 10%) of COPD in India to post-tuberculosis COPD.

Diagnosis and disease management: Current guidelines and usual physician practice in India

The standard guidelines play an important role in guiding health care providers and patients by providing evidence-based recommendations for disease management. International guidelines — the National Heart, Lung, and Blood Institute (NHLBI) guidelines 2020 and Global Initiative for Asthma (GINA) guidelines 2022 for asthma, Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines 2019 (updated 2023) for COPD — provide recommendations for the diagnosis and management of these diseases. In India, the two National Associations — the Indian Chest Society (ICS) and the National College of Chest Physicians (NCCP) — reviewed these guidelines and came up with their joint recommendations, which forms the country-specific guidance for Indian Healthcare professionals. [Agarwal et al. 2015]. The Panelists also confirmed that the Indian guidelines are in line with International guidelines and have similar recommendations for diagnosis and disease management.

The diagnosis of asthma is largely based on clinical assessment. Various guidelines recommend a careful medical history, physical examination and pulmonary function tests, and additional tests are sometimes suggested to ensure a correct diagnosis of asthma. Spirometry is the gold standard for confirming the diagnosis, assessing the severity of airflow limitation and monitoring asthma control.

Spirometry should be performed using equipment and techniques that meet standards developed by the American Thoracic Society (ATS)/European Respiratory Society (ERS). The ICS-NCCP recommendations also state that normal spirometry does not exclude asthma: however, the demonstration of obstruction and/or bronchodilator reversibility supports a clinical diagnosis of asthma. Therefore, pulmonary function testing by spirometry should be used in diagnosis, classification, and severity assessment of asthma. The GOLD 2019 (updated 2023) guidelines for COPD also recommend the use of Spirometry to make a diagnosis. The presence of post-bronchodilator FEV1/FVC < 0.70 confirms the presence of persistent airflow limitations.

The panelist unanimously agreed with the recommendations and confirmed the practice of using spirometry and peak flow meter measures in their clinical set ups. Some secondary and tertiary centers use additional methods, such as diffusing capacity of the lungs for carbon monoxide (DLCO), body plethysmography, cardiopulmonary exercise testing (CPET), six-minute walk test, forced oscillation (FOT) and CT scans, based upon disease severity on a case-by-case basis.

Management of the disease

Pharmacotherapy is the mainstay of treatment for these diseases. The panelists widely support inhalational therapy as the first choice for asthma patients.

Asthma medications commonly used in India, as per the discussion, are listed in Table 3.

Table 3: Pharmacotherapy in asthma patients

CONTROLLER DRUGS (These achieve and maintain control of persistent asthma)	RELIEVER DRUGS (Treat acute symptoms and exacerbation)
Anti-inflammatory drugs • Inhaled corticosteroids-drug of choice • Cromolyn sodium • Nedocromil	Anti-cholinergic
Immunomodulation	Short-Acting Beta-Agonists (SABA)
Leukotriene modifiers	Systemic Corticosteroids
Long-Acting Beta-Agonists (LABA)	
Methyl-Xanthines	
Long-Acting Muscarinic Antagonist (LAMA)	

The panelists confirmed that in India, several formulations of ICS (fluticasone, mometasone, budesonide beclomethasone) are currently available in India. The two most commonly used LABA are salmeterol and formoterol. LABA monotherapy is not recommended in the management of stable asthma, but the addition of LABA to ICS is the preferred choice when symptoms are uncontrolled despite ICS monotherapy in moderate doses. Monotherapy with a Leukotriene Receptor Antagonist (LTRA) might be an alternative to ICS in patients with mild asthma if they are unwilling to use ICS or if they are not suitable for ICS therapy. LTRA is beneficial as an added drug if the patient is not responding to an ICS-LABA combination.

Chronic Obstructive Pulmonary Disease

The global initiative for Chronic Obstructive Pulmonary Disease guidelines are followed across Indian hospitals for the treatment of COPD. While non-pharmacological methods, such as smoking cessation and avoidance of trigger factors, are recommended to improve COPD symptoms, the mainstay of therapy is Pharmacotherapy.

Newer therapies — monoclonal antibodies, biologics, tyrosine kinase inhibitors and Janus kinase inhibitors — are also being explored in asthma. Currently in the United States, tezepelumab (an anti-thymic stromal lymphopoietin monoclonal antibody) is used along with other medications to prevent wheezing, difficulty breathing, chest tightness, and coughing caused by asthma in adults and children 12 years and older whose asthma is not controlled with their current asthma medication. In India, tezepelumab is currently not used.

The goal of therapy is to reduce symptoms, reduce frequency and severity of exacerbations and improve exercise tolerance as well as overall health status. Additionally, pulmonary rehabilitation with its core components of exercise and education is encouraged. As per the panelists, the most commonly used drugs are salmeterol/formoterol (LABA) and fluticasone/mometasone/budesonide (ICS). Combination therapy (LABA+ICS) is most preferred therapy.

Table 4: Standard of care in COPD

SL.NO.	STANDARD OF CARE IN COPD
1.	Beta-2 adrenergic agonists • Short-acting B2 agonists (SABA) • Long-acting B2 agonists (LABA)
2.	Anticholinergic drugs • Short-acting muscarinic antagonist (SAMA) • Long-acting muscarinic antagonist (LAMA)
3.	Combination therapies: • SABA+SAMA • LABA+LAMA
4.	Methylxanthines
5.	Combination therapies: LABA+inhaled corticosteroids
6.	Triple therapy (LABA+LAMA+ICS)
7.	Phosphodiesterase-4 Inhibitors
8.	Mucolytic agents

Triple inhaled therapy of LABA+LAMA+ICS improves lung function, symptoms, and health status, and reduces exacerbations compared to LABA+ICS, LABA+LAMA, or LAMA mono therapy. For triple therapy, budesonide/glycopyrronium/formoterol is generally prescribed.

For COPD exacerbations, GOLD guidelines are also followed. Commonly prescribed treatment includes nebulized bronchodilators, systemic steroids, anti-inflammatory agents, antibiotics, oxygen ventilation (NIV, BiPAP) and an increased dosage of current therapy.

Opportunities and challenges for clinical trials in asthma and COPD in India

The panelists shared their experiences in the conduct of clinical trials involving asthma and COPD patients. They discussed the patient pool and standard of care, investigator and site experience and preparedness, and use of spirometry.

Investigator experience and resources

All of the panelists were experienced in conducting clinical trials. The usual sites for clinical trials are large, multispecialty hospitals with adequate medical and emergency facilities. All the centers have a well-established local laboratory facility, investigational product storage facilities, and calibrated spirometers. They were well-versed with Good Clinical Practices (GCP) and had site coordinators and technicians to support clinical trials. All sites were experienced with electronic data capture and patient diaries. Hospitals from Tier-2 and Tier-3 cities also actively participate and provide good-quality data with high numbers of patient enrollments in clinical trials.

Patient pool

India has 18% of the global population and an increasing burden of chronic respiratory diseases. Experienced investigators enroll two-thirds of study patients from their existing database and the remaining third are new patients. New investigators indicate that around 50% of patients from their databases are willing to participate when eligible. Patients are referred by general physicians and internal medicine specialists. Most of the centers also get patients from surrounding rural areas whose disease is inadequately controlled by their local physicians.

The trust that patients have in their treating physicians is the primary reason for their willingness to participate in clinical trials.

Standard of care and protocol compliance

As discussed above, physicians in India follow the global standard of care practices as per GINA and GOLD guidelines for asthma and COPD, respectively. Some challenges faced by tertiary care units include the late referral of patients from remote areas, which delays their treatment, use of alternate forms of medicine, and some taboo and misconceptions about using inhalational drugs, such as dependency on inhaled therapy. These challenges are addressed with proper training and counseling of these patients. As awareness about clinical trials has increased, such challenges have recently become easier to overcome.

In most patients, the compliance for inhalational therapy is generally good because they have a great faith in their physicians. Other factors that contribute to patient compliance are awareness, education, and literacy. It is imperative that site staff train patients on the dose inhalational technique as well as the spirometry technique. The panelists agreed that with appropriate training and assessment, the results of spirometry are consistent and patient compliance with protocol is improved. The compliance of patients in a trial can also be increased by implementing dose counting and assigning staff exclusively for checking and fulfilling all trial-related procedures.

Spacer devices for metered dose inhalers are commonly recommended, and some investigators found it challenging when study designs do not allow use of these devices in COPD trials. Additional training and motivation of participants is needed for assuring compliance in such cases.

Use of electronic records, case report forms and patient diaries

Most sites are now experienced with electronic case report forms and electronic patient diaries. They are supportive of electronic medical records and believe that EMRs are very helpful for creating a patient pool that can be used for future clinical trials. However, they discouraged regular monotonous reminders to patients through mobile SMS or social media, as they feel patients in India need a more personal approach instead of a regular burst of messages.

Regulatory environment

The current regulatory environment in India is supportive of conducting clinical trials. The revised regulatory document in India, New Drug and Clinical Trial Rules 2019, is very clear about the process of application and timelines. There are clear guidelines for the registration of ethics committees, and all the sites have access to a registered ethics committee.

Placebo control in respiratory clinical trials

Investigators on the panel unanimously agreed that recruitment is not difficult when study designs prescribe placebo in addition to standard of care (SOC). However, in studies where placebo is prescribed for long periods in absence of SOC, it is sometimes challenging to obtain regulatory or ethics committee approvals.Study designs should include appropriate justification for using placebos as well as protocol for use of rescue medication.

Spirometry

The panelists discussed the spirometry service line in detail with respect to the spirometer used, its technical standards, the over-reading (data QA) services, timelines, and the connected devices digital platform. The panelists also discussed use of spirometry in clinical trials, 24-hour spirometry, home spirometry, acoustics, role of artificial intelligence, and spirometry reference equations.

The panelists overwhelmingly opined that with the introduction of the 2019 American Thoracic Society/ European Respiratory Society (ATS/ERS) guidelines (acceptability, usability criteria) and individual grading of FEV1 and FVC, more data will be usable (especially from patients with severe obstruction, chronic cough). The group said technicians need to be trained on the ATS/ERS 2019 guidelines and stated that most patients can blow into a spirometry device for 15 seconds.

TThe experts agreed that 24-hour spirometry studies can be conducted in India, provided necessary logistic arrangements are made. One of the challenges in India is regarding the spirometry reference equations. The group said there is a lack of reference equations with good representative samples from different regions of India. The current practice is to use European equation error correction codes with 10% correction factor. Since the Global Lung Function Initiative equation has no representation of the Indian population, it should only be used with proper evidence/validation. The selection of spirometry reference equations should be governed by the sponsor as per the protocol.

All the panelists routinely use calibrated spirometers. Newer spirometers, which do not require calibration, will certainly reduce the burden on sites and will save a lot of time. However, this should be supported by publications and should be incorporated in the ATS/ERS guidelines. Though home spirometry is an encouraging option, the panelists felt that it was too early to conduct unsupervised spirometry at home for clinical trials, as this could lead to considerable variability. The group said there is a need to develop indicators for patient safety (process/indicators that will help indicate when to stop the test, mitigation strategy on patient safety, and strategy to identify patients at potential risk). Proper training should be provided to patients, including video clips in local languages.

The role of advanced lung function testing — oscillometry — and acoustics and artificial intelligence (AI) in clinical trials were also considered. The group agreed that oscillometry is a sensitive test that is easy to perform and can be used in all age groups (3 years and older). However, more evidence/research is needed to validate its use in clinical trials. The panelists agreed that the use of AI in quality assurance holds promise. However, AI should assist and not completely

replace human intervention. The panelists eagerly look forward to the sound- and acoustics-related wearables used for cough monitoring and auscultation-related diagnosis in clinical trials. On the other hand, while they are promising for use in clinical trials, more evidence of their efficacy is warranted.

Global Asthma and COPD trials — The Indian perspective

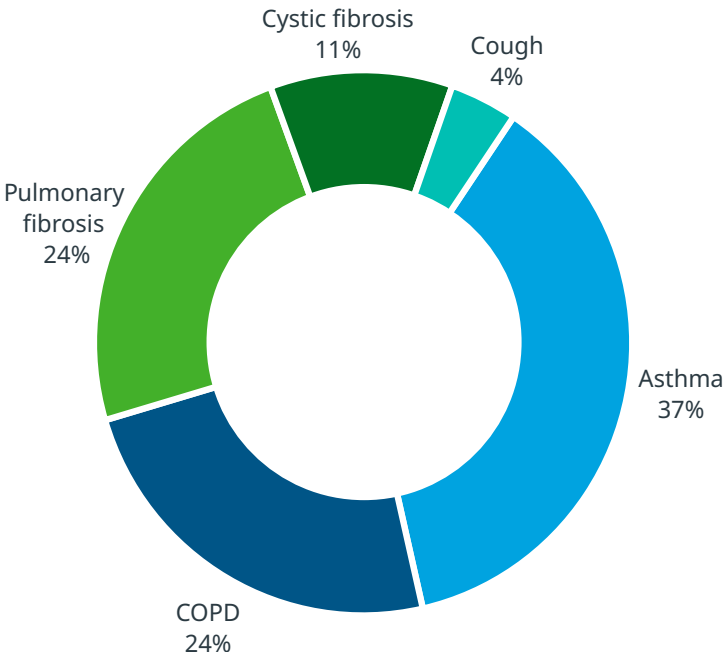
According to IQVIA, 75% of the active respiratory trials globally are currently ongoing and 25% are in the pipeline. Most of these clinical trials are in Phase II. Of the presently opened trials, 56% started in 2022 and 37% of them will be completed in 2023.

Among the trials started in 2022, asthma predominates with 18% (Phase II) and COPD is in third position with 8% of (Phase II) trials. Of the planned respiratory trials, 37% were for asthma and 24% were for COPD, according to IQVIA data on file.

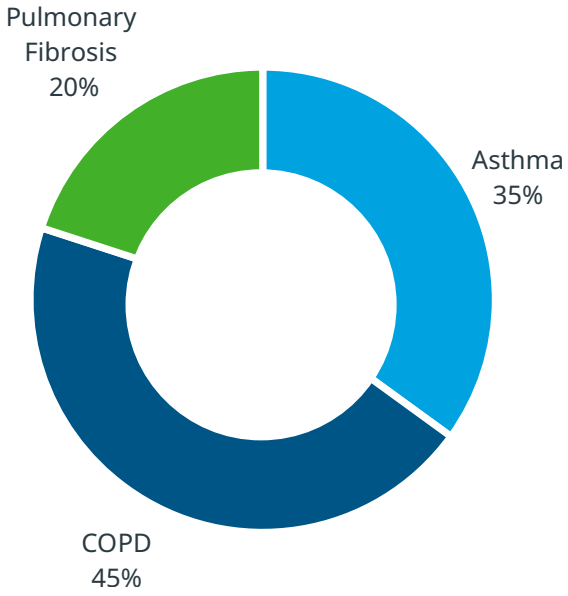
Figure 1: Global and Indian Respiratory Trial Landscape

Of the active and planned respiratory disease trials

Landscape of global studies



Landscape of active studies in India



in India, 90% are in Phase III. COPD and asthma dominate, representing 80% of all studies, while generic drug development represents less than 40% of the market.

Bioequivalence studies in respiratory patients

The generic drug approval process usually requires submission of a bioequivalence study. The most common way to demonstrate bioequivalence is by conducting comparative pharmaco kinetic (PK) studies. When it is not possible to use PK methods, well-controlled studies with comparative clinical endpoints in patients can be used to establish bioequivalence.

Inhalational therapies usually are unable to be absorbed adequately through blood streams and therefore require clinical end-point studies in patients with asthma/COPD. The usual designs are randomized, controlled, three-arm studies with a reference drug, a test drug and a placebo. The standard designs require a 2-week placebo run-in period, followed by treatment phase. The studies require very precise serial spirometry for a 24-hour period. As seen above, less than 40% of respiratory studies in India are from companies producing generics.

Conclusion

Bronchial asthma and COPD are obstructive pulmonary diseases that affect millions of people all over the world. Although asthma and COPD have many differences, they also have some similarities. They are two different diseases with differences in etiology, symptoms, type of airway inflammation, inflammatory cells, mediators, consequences of inflammation, and response to therapy and course. Even at clinical trial stage, both have distinct challenges.

India is well-positioned to conduct more clinical trials in the respiratory therapeutic area. There are adequate, well-equipped sites with adequate infrastructure, experienced investigators and a large patient pool of willing trial participants. Moreover, the standard of care for treatment of these diseases in India is in line with global guidelines.

Disclosure statement

Authors Charu Gautam, Arijit Sil, Brian Churchill, Rashna Cama, Bernard Silverman, Nitin Vanjare, Ganesh Gundi and Tapan K. Raval are employees of IQVIA, a contract research organization that provides scientific and technical services for clinical trials conducted by pharmaceutical companies involved in new drug development. Other than this, all authors declare no professional, academic, competitive, or financial conflicts of interest related to this article. The Advisory Board conducted on November 29, 2022, was sponsored by IQVIA (financially supported). Other than this, no specific funding was used in the preparation of this article.

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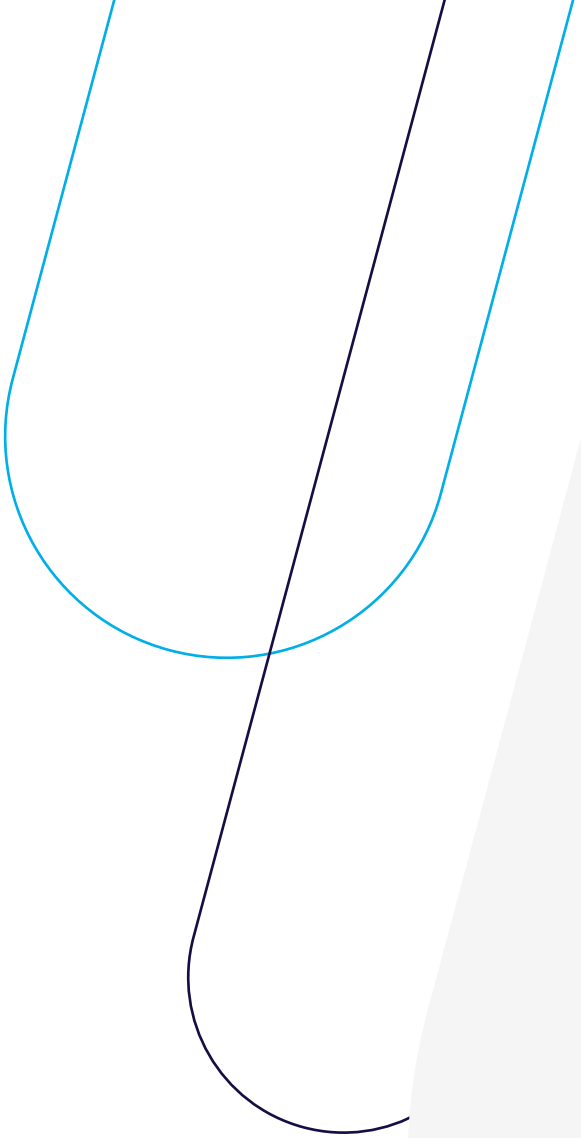

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