

## **Respiratory clinical trials: Putting patients at the heart of research** [1]

### Discovery [2]

Clinical trials are pivotal in the advancement of novel therapies for patients. We believe the essence to successful clinical research is a trusted partnership between the patient community, healthcare professionals and research scientists from the pharmaceutical industry. Participation of these groups is critical to all steps in the clinical development process.

In 2018 alone there were over 1 700 respiratory clinical trials worldwide<sup>1</sup>, of which over 150 were specifically focused on asthma<sup>2</sup>. Novartis is proud to have supported these with approximately 10 000 patients participating in our respiratory trials<sup>3</sup>. We are reimagining medicine to discover and develop breakthrough treatments, and clinical trials are the foundation of how we aim to achieve this.



### Discovery [2]

## **Taking clinical trials to the next level through technology** [3]

To celebrate the relationship between patients, healthcare professionals and the pharmaceutical industry we hear from three key people involved in clinical research about their perspectives and experiences on clinical trials.

Ms. Gaye Elizabeth Stokes is a respiratory clinical trial participant from the UK.

[Video of Clinical Trial Experiences: Patient Perspective, Gaye Stokes](#)

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Professor Chris Brightling is a renowned respiratory physician and a clinical trials investigator from the UK.

## Video of Clinical Trial Experiences: Clinical Investigator Prof. Chris Brightling

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Dr. Linda Armstrong is the global head of respiratory development at Novartis.

## Video of Clinical Trial Experiences: Novartis Respiratory Development, Linda Armstrong

Inspired to participate in a clinical trial? The best way to get involved is to discuss your options with your healthcare professional team or with a local or disease specific patient group.

Currently Novartis is actively recruiting for approximately 50 trials in the respiratory space.<sup>8</sup>

Each trial consists of specific requirements, which outline the characteristics required by patients that are interested in participating in a clinical study. Potential trial participants undergo a thorough screening process to ensure they meet the criteria of the study before they are officially enrolled. This is extremely important to ensure the trial qualifies according to the protocol and most importantly, the safety of those participating individuals.

In order to progress to the next stage of the trial process, each phase must meet its planned outcome measures – also known as ‘endpoints’. The stages of a clinical trial fall into three ‘Phases’ before marketing authorization<sup>4</sup>:

Novartis’ Dr. Linda Armstrong explains the three phases of clinical trials.

## Video of Clinical Trial Experiences Clip: Linda Armstrong

Once this comprehensive three-phase process is successfully completed, a drug can be taken forward for market authorization and made available to patients. The authorization application requirements differ by country.

Throughout each step of the process, collaboration between patient, healthcare professionals and pharmaceutical companies is essential - without these groups, government health authorities would not approve medicines, as adequate clinical evidence with an appropriate patient population sample is required.

## Our work in the respiratory space

Over one billion people suffer from lung conditions worldwide<sup>5</sup>, with chronic conditions such as asthma and chronic obstructive pulmonary disease (COPD) being among the leading causes of death and imposing a vast worldwide health burden<sup>6</sup>. The symptoms of these conditions can have significant impacts on the quality of the daily and professional lives of patients and their carers, affecting them physically and mentally<sup>7</sup>.

At Novartis, we are committed to remain at the frontier within the respiratory innovation space to help improve the outcomes of patients throughout their journeys. An average of over 1,700 clinical trials take place in the respiratory space each year<sup>1</sup> and over 150 asthma clinical trials took place in 2018<sup>2</sup>. Currently, we are actively recruiting for approximately 50 trials<sup>8</sup> within the respiratory space. In 2018, we worked with over 60 000 patients in our clinical trials<sup>2</sup>.

## **The formula to successful clinical research - a trusted partnership between these groups**

### **Patients**

- Provide input into study design
- Provide insights into the unmet needs of particular disease areas
- Participate in clinical trials

### **Clinical research team**

- Perform and lead clinical and scientific research
- Recruitment of patients into clinical trials
- Working closely with trial sponsors and patients on clinical research
- Maintaining research records and results

### **Pharmaceutical company**

- Sponsoring clinical research
- Development of the drug
- Working closely with investigators and scientific experts on clinical research, from preclinical to post-launch of a drug
- Working closely with patients to understand their perspectives and needs

## **Your support is needed in respiratory research**

Despite recent medical advancements, many patients suffering with lung conditions still experience an impact on their quality of life. With the aim to achieve our goal in reducing the disease burden, more clinical research is yet to be done.

Everyone can contribute in some way, discuss with your medical team or local/specific patient group on how you can help.

For more information about clinical trials, visit the following links:

[How are clinical trials done?](#) <sup>[4]</sup>

[What should I know before joining a clinical trial?](#) <sup>[5]</sup>

[What questions should I ask before I participate in a clinical trial?](#) <sup>[6]</sup>

[About Novartis Clinical Trials](#) <sup>[7]</sup>

### **Disclaimer:**

#### References

1. Available at:

[https://clinicaltrials.gov/ct2/results?cond=Respiratory+Disease&term=&strd\\_s=01%2F](https://clinicaltrials.gov/ct2/results?cond=Respiratory+Disease&term=&strd_s=01%2F)

<sup>[8]</sup>. Last accessed: May 2019

2. Available at:  
[https://clinicaltrials.gov/ct2/results?cond=Asthma&term=&strd\\_s=01%2F01%2F2018&strd\\_e=12%2F01%2F2018](https://clinicaltrials.gov/ct2/results?cond=Asthma&term=&strd_s=01%2F01%2F2018&strd_e=12%2F01%2F2018)  
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4. The Drug Development Process. Available at:  
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<https://clinicaltrials.gov/ct2/results?cond=Respiratory+Disease&term=Novartis&type=&rslt=&recrs=0>  
[14]. Last accessed: May 2019

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[3] <https://www.novartis.com/stories/discovery/taking-clinical-trials-next-level-through-technology>

[4] <https://www.novartis.com/our-science/novartis-clinical-trials/how-are-clinical-trials-done>

[5] <https://www.novartis.com/our-science/novartis-clinical-trials/what-should-i-know-joining-clinical-trial>

[6] <https://www.novartis.com/our-science/novartis-clinical-trials/what-questions-should-i-ask-i-participate-clinical-trial>

[7] <https://www.novartis.com/our-science/clinical-trials>

[8]

[https://clinicaltrials.gov/ct2/results?cond=Respiratory+Disease&term=&strd\\_s=01%2F01%2F2018&strd\\_e=12%2F01%2F2018](https://clinicaltrials.gov/ct2/results?cond=Respiratory+Disease&term=&strd_s=01%2F01%2F2018&strd_e=12%2F01%2F2018)

[9]

[https://clinicaltrials.gov/ct2/results?cond=Asthma&term=&strd\\_s=01%2F01%2F2018&strd\\_e=12%2F01%2F2018](https://clinicaltrials.gov/ct2/results?cond=Asthma&term=&strd_s=01%2F01%2F2018&strd_e=12%2F01%2F2018)

[10] <https://clinicaltrials.gov/ct2/results?>

[11] <https://www.fda.gov/forpatients/approvals/drugs/ucm405622.htm>

[12] <http://www.globalasthareport.org/Global%20Asthma%20Report%202018.pdf>

[13] [https://www.who.int/gard/publications/The\\_Global\\_Impact\\_of\\_Respiratory\\_Disease.pdf](https://www.who.int/gard/publications/The_Global_Impact_of_Respiratory_Disease.pdf)

[14]

<https://clinicaltrials.gov/ct2/results?cond=Respiratory+Disease&term=Novartis&type=&rslt=&recr>

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