

# Roche Canada Clinical Trials

## Clinical trials globally

**70+** *new molecules* in clinical development in the fields of oncology, hematology, immunology, ophthalmology, neuroscience and infectious diseases

**311,726** patients enrolled in Phase I-IV clinical trials in 2016 globally<sup>1</sup>

**32,647** clinical trial sites globally<sup>2</sup>

**9.9** billion CHF invested in R&D globally in 2016<sup>1</sup>

Central to our clinical research is:

- 1** Patient protection
- 2** Integrity of the data

## Clinical trials in Canada<sup>3</sup>

**1 of 5** Roche Product Development sites is located in Canada

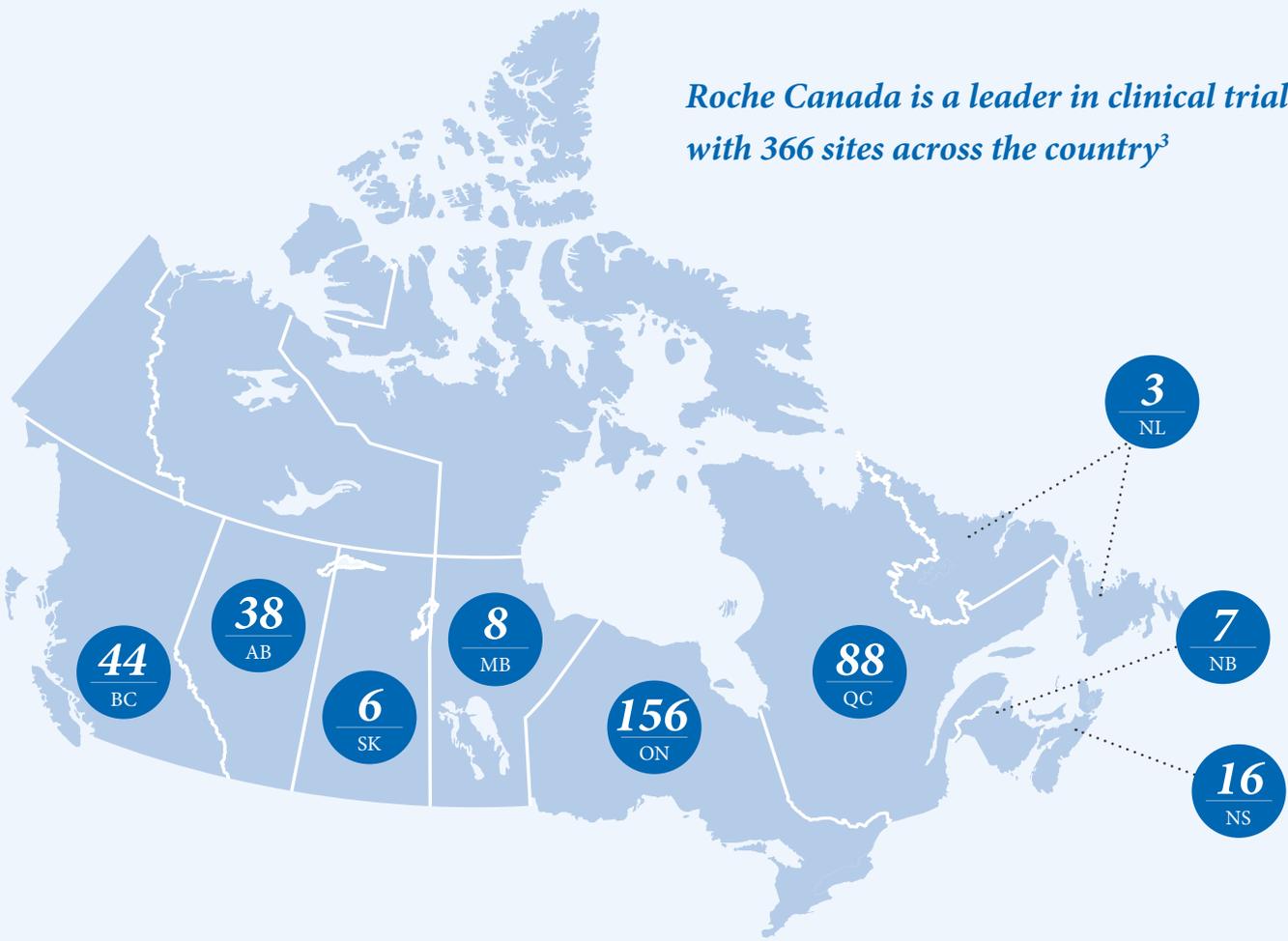
**366** active sites in 2016

**13.5%** of Roche trials globally are held in Canada

**6%** of Roche's global research spend is in Canada

**14.7** million CAD invested directly in R&D in Canadian institutions in 2016

Roche Canada is a leader in clinical trials, with 366 sites across the country<sup>3</sup>



# Roche Clinical Trials

## How clinical trials work<sup>4</sup>

Traditional clinical trials are broken down into several phases to assess the safety and effectiveness of a potential treatment within a patient population



### Phase I

- Involves small groups (20-100) of healthy volunteers
- Focuses on medicine safety and how it works



### Phase II

- Involves larger groups of patients
- Studies dosage, efficacy and continues to look at safety



### Phase III

- Final phase before regulatory approval
- Medicines are tested on large groups of patients who live with the condition in question
- Validation of safety and efficacy



### Phase IV

- Study of approved medicines in real-world setting, examining long term effects compared with other treatment options
- Explores effectiveness for additional indications

## Innovative clinical trial design

We are exploring new ways to evolve the drug development process, so that personalized medicines can reach patients faster while still meeting rigorous safety standards. We design clinical trials based on our growing body of scientific knowledge to support more targeted, rapid, and cost-effective delivery of treatments to patients



**Umbrella trials** test different medicines on different mutations of a single type of cancer “under the umbrella of one disease,” allowing researchers to assess multiple treatment options in patients and identify subgroups who could benefit most



**Basket trials** group patients together based on a specific mutation found in a tumor, regardless of where the cancer originated, to test the effect of a medicine on a single mutation in a variety of tumor types, at the same time



**Adaptive trials** allow for certain parameters – such as treatment regimen, study population, and sample size – to be modified based on interim results, allowing for adjustments based on new scientific knowledge gained through the trial without compromising data quality

## How clinical trials benefit Canadians<sup>5,6</sup>

### Create jobs

Research investment creates jobs for highly-skilled personnel in research institutions, as well as suppliers and vendors who support trials

### Save money

Trial costs, including patient care and the price of investigational, as well as comparator treatments are covered, resulting in savings for the healthcare system

### Build expertise

Cutting-edge science keeps researchers at the forefront of clinical innovation and supports our knowledge economy



### Early access

Patients get access to promising new treatments not otherwise available, which is critical in areas of high unmet medical need

### Excellent patient care

Participating patients receive specialized care from leaders in their field, and are closely monitored during and following clinical research

### More treatment options

Clinical trials are a critical step in the development of medicines and increase adoption of new innovations within the healthcare system

## References

1. Roche Annual Report 2016. Available at: [http://static.roche.com/annual-report-2016/downloads/roche\\_full\\_annual\\_report16.pdf](http://static.roche.com/annual-report-2016/downloads/roche_full_annual_report16.pdf) [Accessed May 2017] 2. Roche 2017. Clinical Trials. Available at: [http://www.roche.com/research\\_and\\_development/who\\_we\\_are/how\\_we\\_work/clinical\\_trials.htm](http://www.roche.com/research_and_development/who_we_are/how_we_work/clinical_trials.htm) [Accessed May 2017] 3. Roche Canada data on file – Clinical trials investment in Canada 2016 4. From Idea to Market: The Drug Approval Process. Available at: <http://www.medscape.com/viewarticle/405869> 4. [Accessed May 2017] 5. Canadian Clinical Trials Coordinating Centre. Clinical Trials: The Canadian Advantage. Available at: [http://www.cctcc.ca/default/asses/File/CCTCC\\_CT%20Investment%20Case\\_June%202017\\_Final.pdf](http://www.cctcc.ca/default/asses/File/CCTCC_CT%20Investment%20Case_June%202017_Final.pdf) [Accessed October 2017] 6. Innovative Medicines Canada. Clinical Trials Help Save Lives. Available at: <http://innovativemedicines.ca/resource/clinical-trials-help-saves-lives/> [Accessed October 2017] © Copyright 2017, Hoffmann-La Roche Limited