

### Leaders in clinical trial data transparency

Providing information on clinical trials and their results serves everyone including study participants, patients and healthcare providers. For more than 15 years, Novartis has supported data transparency and was the first to publish trial results of innovative medicines within one year of study completion, regardless of outcome. As time passes, we only continue to strengthen our commitment to data transparency.

#### 1999: Novartis begins registering innovative clinical trials on public U.S. registry

• Since 1999, Novartis has registered more than 2700 clinical trials on www.ClinicalTrials.gov.

#### 2005: Novartis Clinical Trial Results website launched

IIb-IV

Before it became a legal requirement, Novartis was the first company to publically disclose
clinical trial results for Phase IIb – IV trials of our innovative medicines on <a href="www.novctrd.com">www.novctrd.com</a> within
one year of trial completion. This included all trials, irrespective of outcome or subsequent approval.

## **2007:** Novartis registers results from controlled trials in U.S. approved medicines at www.ClinicalTrials.gov





• Since 2007, Novartis has published the results from **more than 500 controlled trials** for U.S. approved innovative medicines on <u>www.ClinicalTrials.gov</u> and expanded results disclosure to include Phase IIa trials on <u>www.novctrd.com</u>.

#### 2009: Novartis posts Phase I results on company website



 Public disclosure of clinical trial results expanded to include Phase I – IV trials on www.novctrd.com in unapproved and approved innovative medicines.

#### 2014: More than 1,700 study results available on www.novctrd.com



 Since 2005, more than 1,700 clinical trial results were made available on the Novartis Clinical Trial Results website.

# **2014:** Novartis will provide access to anonymized patient-level data and commits to providing expanded information about clinical trial results on company website





- Researchers can now request **access to patient-level data** from trials of innovative medicines approved in 2014 through <a href="https://www.clinicaltrialstudydatarequest.com">www.clinicaltrialstudydatarequest.com</a>.
- By the end of 2014, participants in pivotal trials will find **simplified language summaries** and **additional data interpretation** on <u>www.novctrd.com</u>.



Phase I-Phase IV trials: The development of innovative medicines takes place in phases from I to IV. These phases all involve in-human clinical trials designed to assess the new drug in terms of safety, dosing regimen, efficacy and eventual use in the real world.



**Controlled trial:** A clinical trial in which one group of participants receives an experimental drug and the other receives either a placebo or a previously approved therapy.



**Patient-level data:** Detailed trial data from each patient that is anonymized to protect patient privacy.



#### $\underline{www.clinical trial study data request.com}:$

A website that qualified external researchers can access to request anonymized patient-level data and redacted clinical study results to conduct analyses on the original trial objectives.

