

Post-Marketing Commitments ^[1]

Novartis Pharmaceuticals Corporation - US Post Marketing Study Commitments

As part of the US regulatory approval process, sponsors may agree or be required to conduct additional studies following FDA approval of a drug for marketing. These studies, known as post marketing commitments (PMCs), are intended to further understand the safety, efficacy, and/or optimal use of the drug.

This NPC website provides a summary of US post marketing commitments for Novartis Pharmaceuticals Corporation (NPC) and includes status information regarding such commitments. NPC provides ongoing updates to the FDA on the status and outcome of its PMCs which are in turn posted by FDA on their website at FDA.gov. In some cases, differences may occasionally appear between the status information of the PMCs posted on NPC's website and similar information posted on the FDA website. This is due to the difference in timing with respect to the updating of each website.

The PMC summary posted on this Novartis website is updated on a quarterly basis. PMCs for recently approved products will be added to the website at the next quarterly update.

This NPC website does not contain information on post marketing commitments outside of the US, or any PMC information concerning NPC's affiliates, e.g., Sandoz, Inc. Information on NPC-affiliate PMCs may be found at FDA.gov.

- [?PMC Ongoing Posted Data January 2020](#) ^[2]
- [PMC Fulfilled Posted Data January 2020](#) ^[3]

Source URL: <https://www.novartis.us/corporate-responsibility/post-marketing-commitments>

Links

[1] <https://www.novartis.us/corporate-responsibility/post-marketing-commitments>

[2] <https://www.novartis.us/sites/www.pharma.us.novartis.com/files/US-PMC-PMR-Ongoing-Posted-January-2020.pdf>

[3] <https://www.novartis.us/sites/www.pharma.us.novartis.com/files/US-PMC-PMR-Fulfilled-Posted-January-2020.pdf>