

# The Compassionate Use Advisory Committee

## What is the Compassionate Use Advisory Committee (CompAC)?



Sometimes doctors request **compassionate use access to investigational medicines** on behalf of seriously ill patients



These requests need to be evaluated through a **thorough, transparent and fair process**



Johnson & Johnson Innovative Medicine (formerly called Janssen) **partnered with NYU Langone Health** to form CompAC



The innovative committee is made up of **bioethicists, physicians and patients**, selected and managed by NYU



CompAC **reviews requests submitted to Johnson & Johnson Innovative Medicine** for investigational medicines

### Guiding Principles

The Johnson & Johnson approach to evaluating individual requests for compassionate use are guided by three important ethical principles:



That we are **not putting patients at risk** of unnecessary harm



That we continue to conduct thorough scientific studies to understand the potential benefits of new medicines to provide the fundamental information needed to acquire approval from government health authorities and **bring new medicines to all patients who need them**



That we treat **all patients** fairly and equally

### CompAC Pilot in Action

Results published in *Therapeutic Innovation & Regulatory Science* reflect 19 months of the CompAC pilot for daratumumab



**324**

requests received by Janssen



**180**

requests evaluated by CompAC



**144**

requests **excluded** based on pre-established criteria



**163**

requests **recommended for approval** by CompAC



**165**

requests **approved** by Janssen

**62**

had an unfavorable or unknown benefit-risk profile

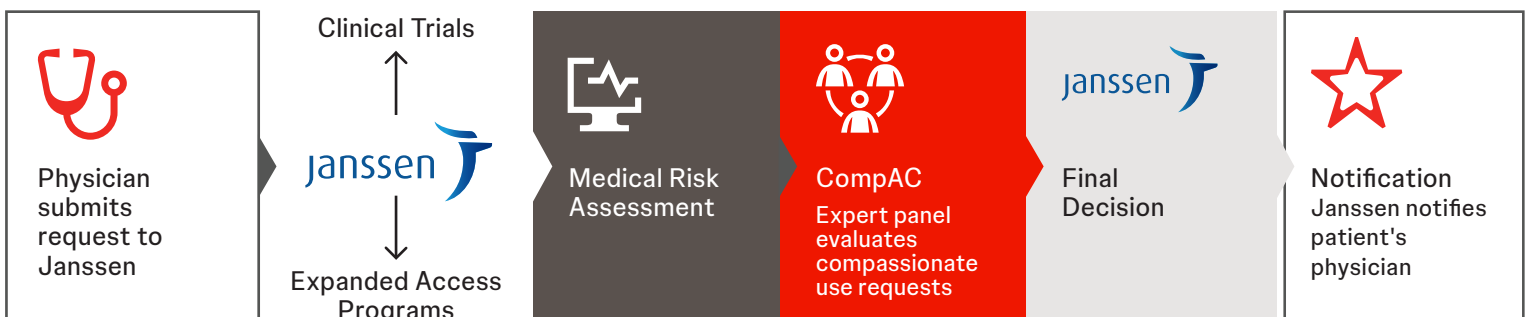
**56**

were eligible for expanded access programs, clinical trials or other approved therapies

**26**

were excluded for other reasons, like incomplete data for assessment, or prior exposure to the investigative agent

### CompAC Model



### For More Information

Physicians seeking early access to investigational medicine on behalf of their patients can contact Medical Information Center.

In the U.S. visit <http://www.janssen.com> OR call 1-800-Janssen

Outside of the U.S. contact the country-specific Janssen office at [JanssenMedInfo@its.jnj.com](mailto:JanssenMedInfo@its.jnj.com)

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