

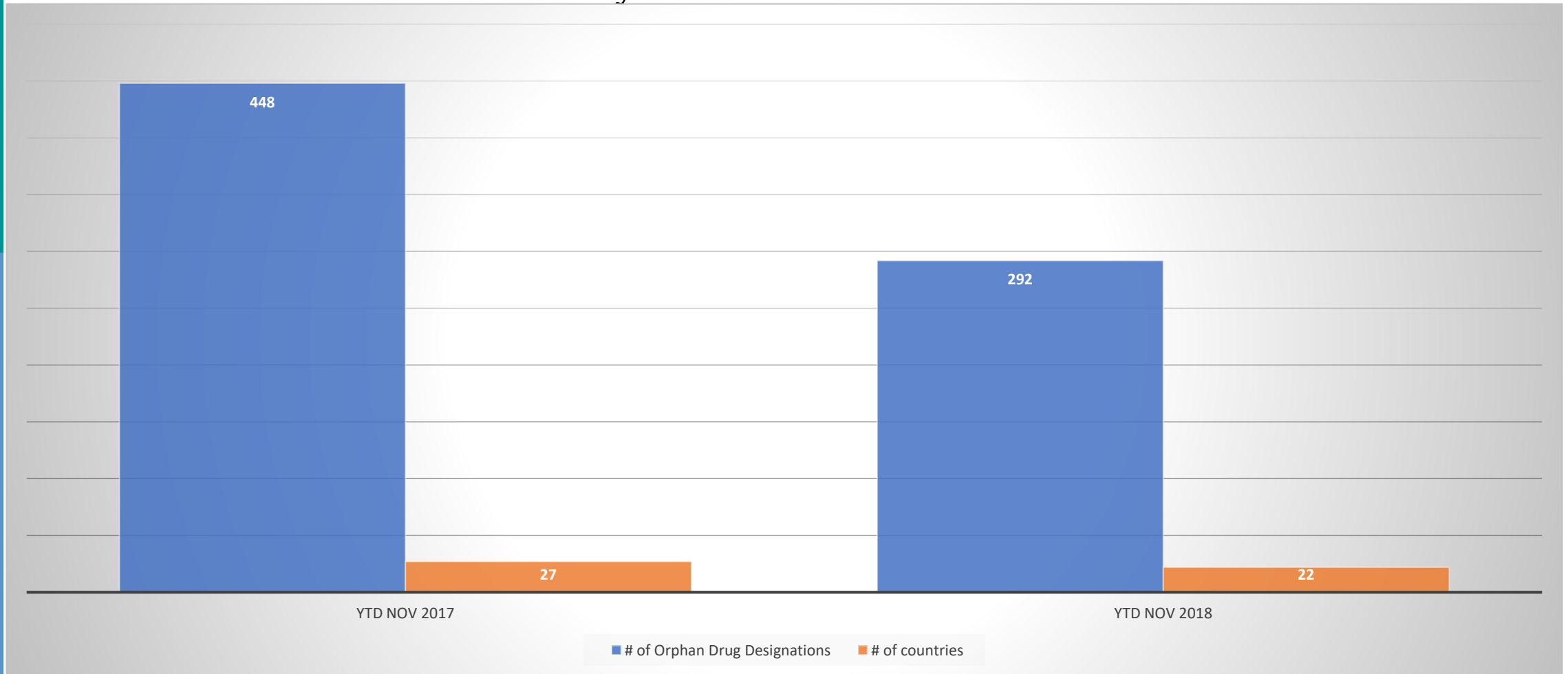
Orphan Drug Designations in the USA YTD October 2018

K&A Schaefer Consulting

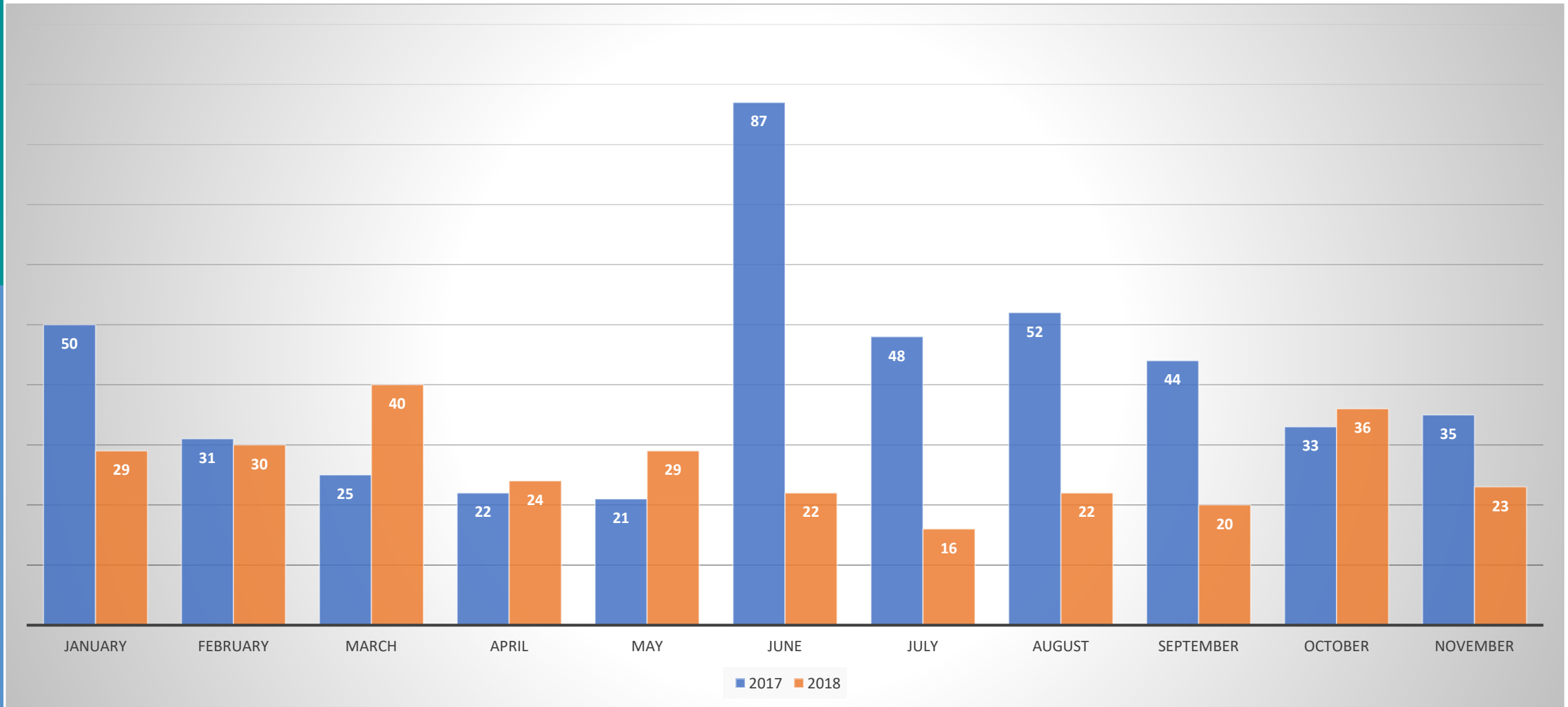
Summary YTD November 2018

- YTD November 2018 FDA approved 291 Orphan Drug Designations
 - In the same timeframe of 2017 a total of 448 have been approved
 - The YTD designations are only slightly above the 2014 number
 - YTD November 2018 35% less designations have been approved compared to last year. This is the same percentage as last month
- Companies from a total of 22 countries received at least one Orphan Drug Designation from the FDA in 2018
 - 71% (unchanged to YTD October) of all Orphan Drug Designations come from the USA
 - In 2017 Orphan Drug Designations from 27 countries were approved by FDA
- YTD November a total of 247 companies received at least one Orphan Drug designation. The majority of companies received one designation (89%), unchanged from October
 - 18 companies received two designations YTD November 2018,
 - 5 companies received three designations and
 - 4 company received approval for four designations
 - 1 company received approval for five designations

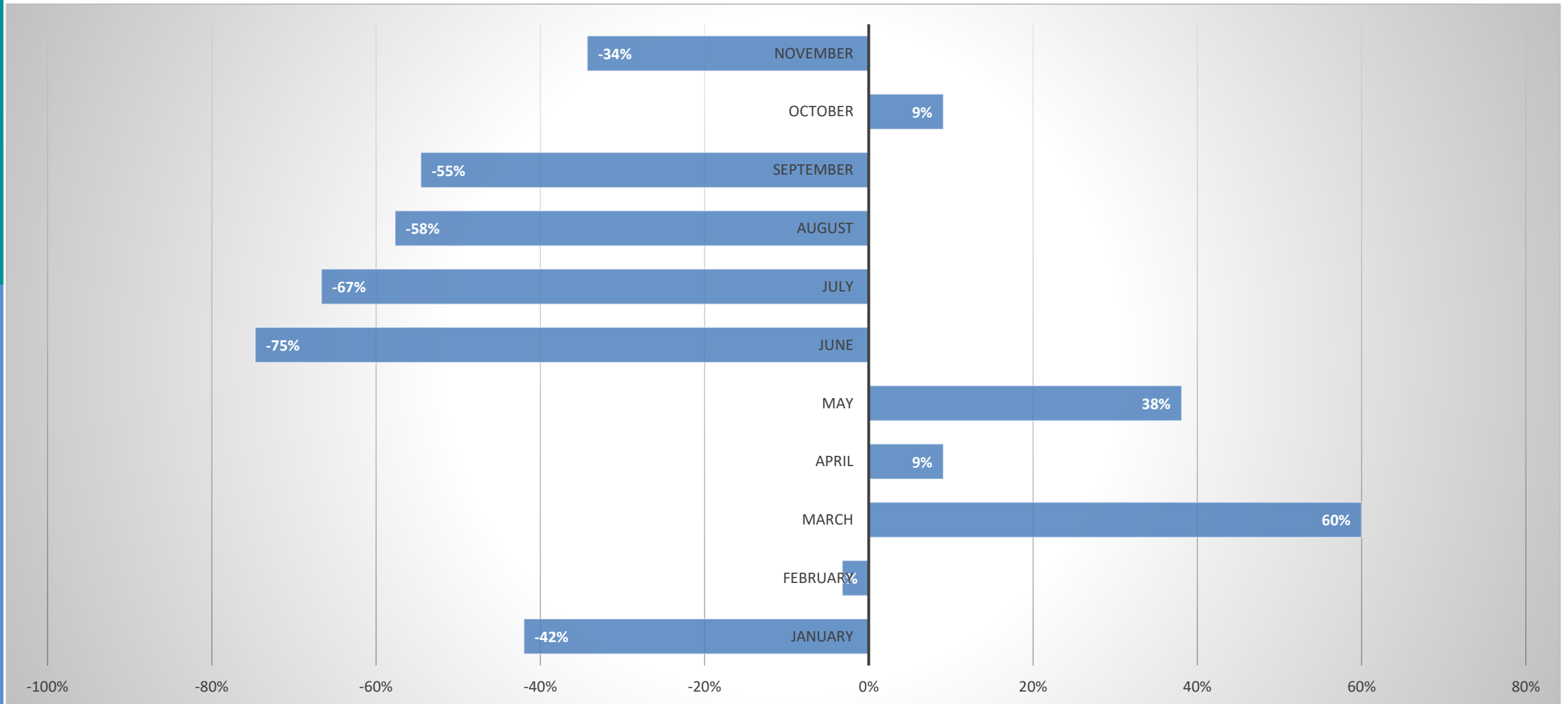
The Total Number Of Orphan Drug Designations declined by 35% YTD November 2018



Designations 2017 vs 2018 on a monthly basis

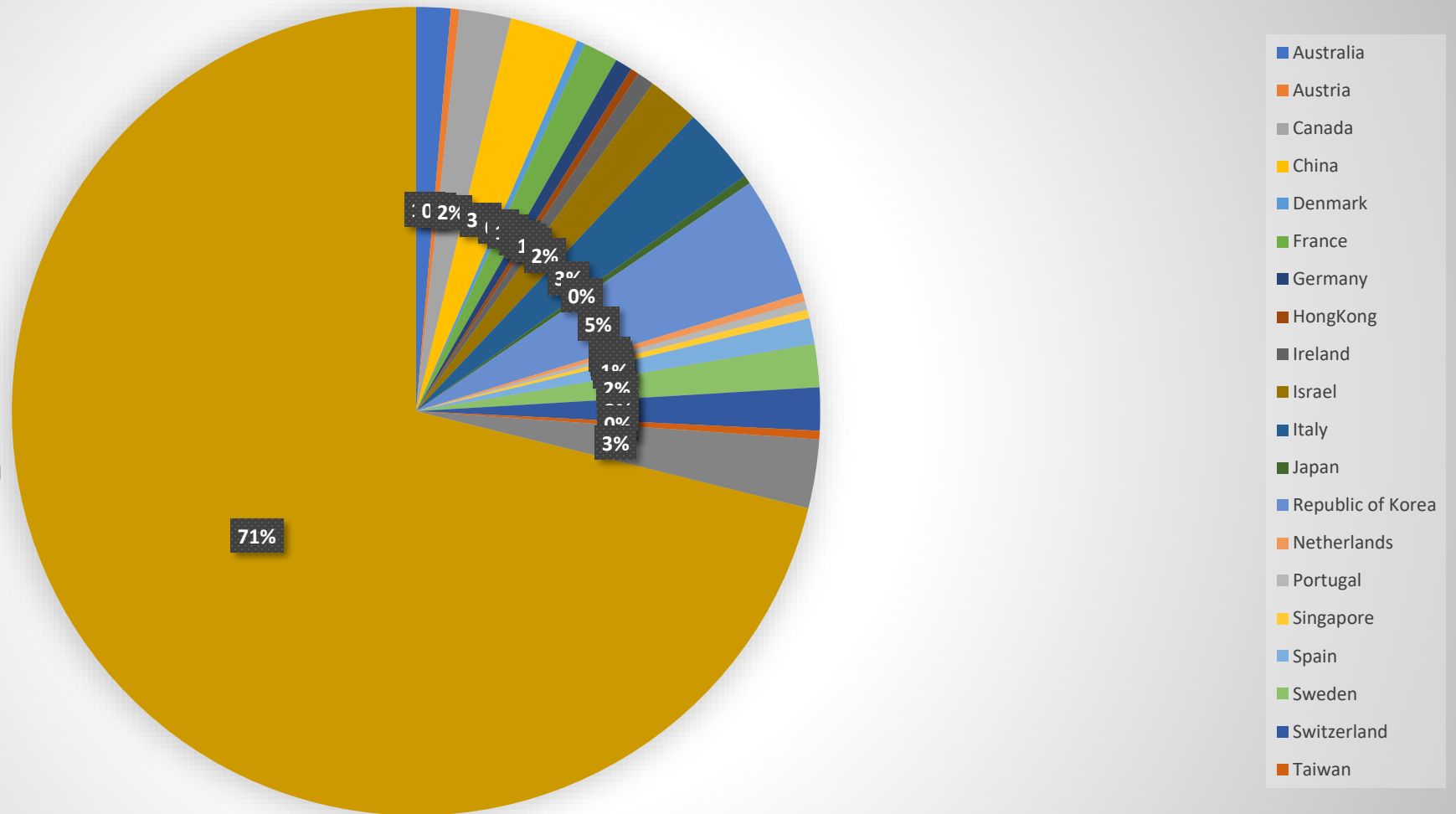


Development 2017 vs 2018 on a monthly basis in %

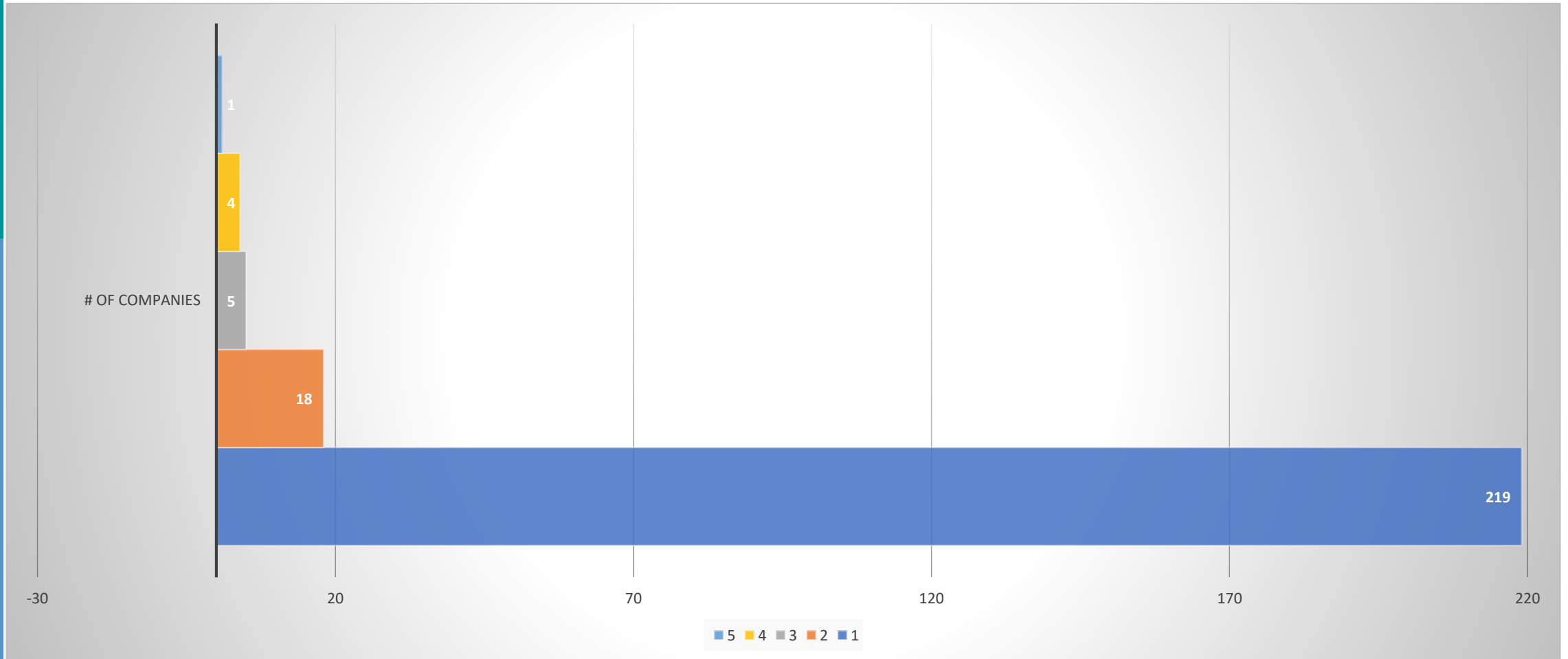


The Vast Majority Of Orphan Drug Designations Are From The USA

Percentage of Orphan Drug Designations for US based companies the same as YTD October



89% Of All Companies Received Approval for One Orphan Drug Designation YTD October 2018



Development of Orphan Drug Designations over time

