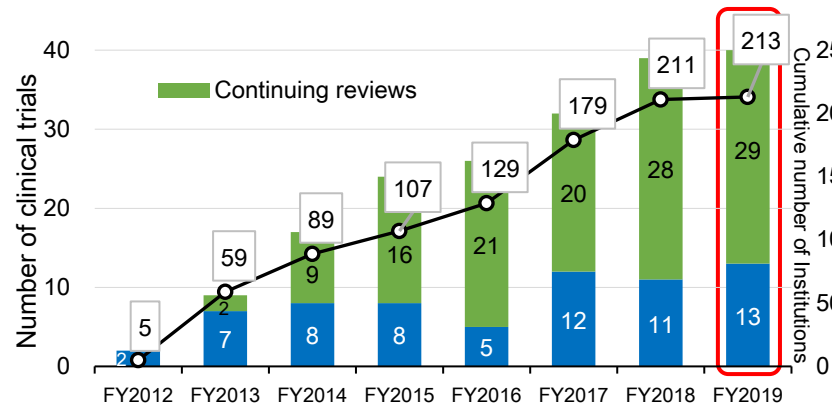


## FY 2019 (From April 1, 2019 to March 31, 2020)

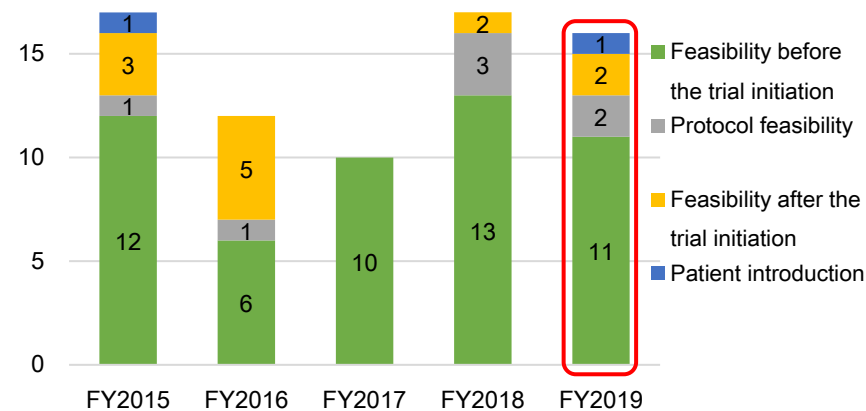
### ✓ Number of Contracts

Initial reviews: 13 trials	Continuing reviews: 29 trials	Cumulative total number of Institutions: 213
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### ✓ Number of Feasibility Surveys

Number of surveys: 16	Response rate: 91.3%
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## Cumulative Performance since 2010

### ✓ Target Indications & Status: 37 trials

Target Indications
Neurogenic detrusor overactivity
Pulmonary arterial hypertension
Haemophilia A
Haemophilia B
Retinopathy of prematurity
Growth hormone deficiency
Heart failure
Pediatric epilepsy
Spinal Muscular Atrophy
Ulcerative colitis(2)
Glioma
Thromboprophylaxis after Fontan surgery
Reflux esophagitis, ulcer prophylaxis with NSAIDs
Mucopolysaccharidosis type II
Gram-positive cocci infections
Extremely premature infants (Preventing chronic lung disease)
Juvenile idiopathic arthritis
Hyperuricemia
Short stature in SHOX disorders
Constipation
Procedural sedation of pediatric subjects undergoing MRI scans
Hepatic encephalopathy
Severe asthma

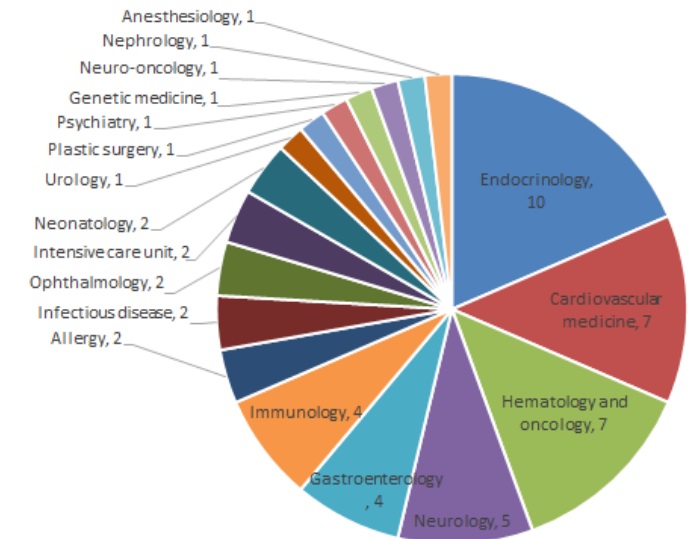
### ✓ Completed : 2 trials

### ✓ Terminated : 3 trials

### ✓ Approved for marketing: 16 trials

Approval Status	Trade name (Target Indications)
Approved in 2016	Hemangioli (Infantile hemangioma), Autologous Cultured Epidermis, JACE (Giant congenital melanocytic nevi)
Approved in 2017	Intuniv (Attention deficit hyperactivity disorder), Revatio (Pulmonary arterial hypertension), NORDITROPIN (Noonan syndrome)
Approved in 2018	Nexium (Gastrointestinal Diseases), IBULIEF (Patent ductus arteriosus), ORENCIA (Juvenile idiopathic arthritis), ILARIS (Systemic juvenile idiopathic arthritis), Refixia (Haemophilia B), LORA-PITA (Status epilepticus), HEMLIBRA (Haemophilia A), Precedex (Pediatric subjects in the intensive care unit)
Approved in 2019	Fiasp (Type 1 diabetes), Esperoct (Haemophilia A), LUCENTIS (Retinopathy of prematurity)

### ✓ Clinical department



Distribution of the clinical trial by clinical department (Excluding continuation studies of the same formulation)