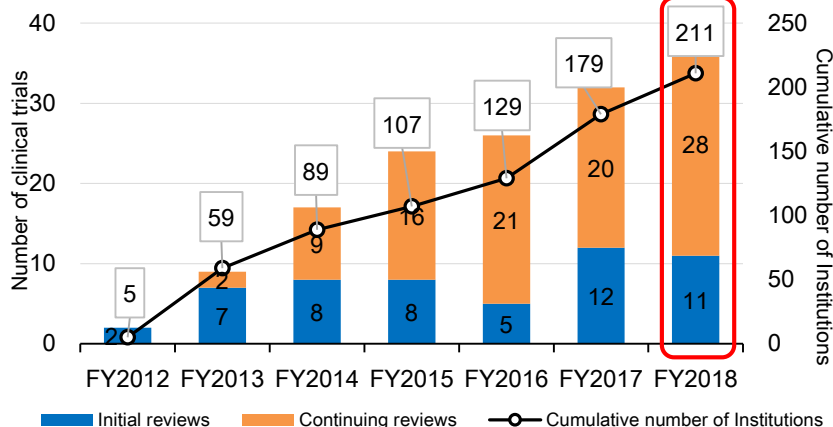


FY 2018

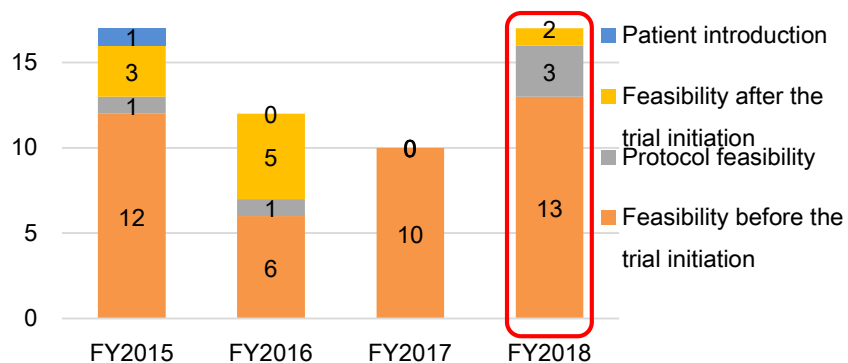
✓ Number of Contracts

Initial reviews: 11 trials	Continuing reviews: 28 trials	Cumulative total number of Institutions: 211
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✓ Number of Feasibility Surveys

Number of surveys : 18	Response rate : 89.9%
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Cumulative Performance since 2010

✓ Target Indications and Status : 30 trials

NO.	Target Indications
1	Pediatric neurogenic detrusor overactivity (2 trials)
2	Pulmonary arterial hypertension
3	Haemophilia A
4	Haemophilia B
5	Retinopathy of prematurity
6	Growth hormone deficiency
7	Hypertension
8	Heart failure
9	Growth hormone deficiency
10	Pediatric epilepsy
11	Spinal Muscular Atrophy
12	Pediatric epilepsy(2 trials)
13	Heart failure
14	Ulcerative colitis(2 trials)
15	Cancer pain
16	Glioma
17	Thromboprophylaxis after Fontan surgery
18	Reflux esophagitis, ulcer prophylaxis with NSAIDs
19	Respiratory failure associated with airway stenosis(Investigator-initiated)
20	Mucopolysaccharidosis type II
21	Gram-positive cocci infections
22	Type 2 diabetes mellitus
23	Juvenile idiopathic arthritis(2 trials)
24	Hyperuricemia
25	Short stature in SHOX disorders
26	Growth hormone deficiency

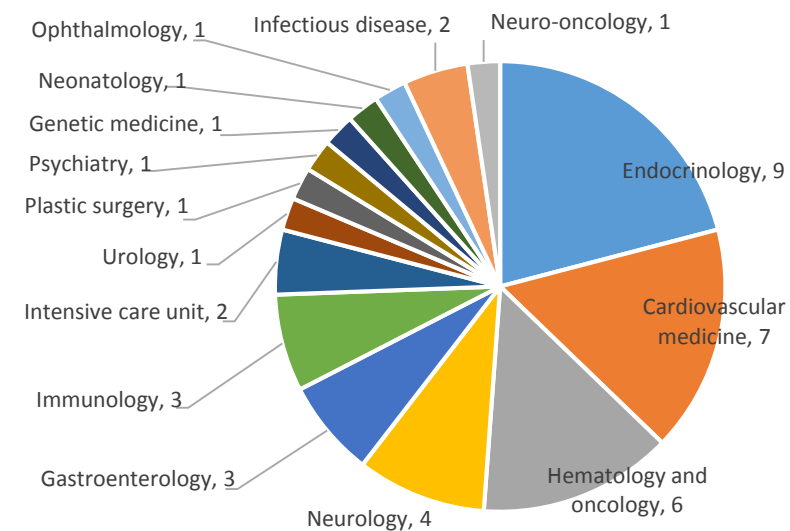
✓ Completed : 22 trials

✓ Terminated : 3 trials

✓ Approved for marketing : 12 trials

Approval Status	Trade name(Target Indications)
Approved in 2016	Hemangioli(<i>Infantile hemangioma</i>), Autologous Cultured Epidermis, JACE(<i>Giant congenital melanocytic nevi</i>)
Approved in 2017	Intuniv(<i>Attention deficit hyperactivity disorder.</i>) Revatio(<i>Pulmonary arterial hypertension</i>), NORDITROPIN(<i>Noonan syndrome</i>)
Approved in 2018	Nexium(<i>Gastrointestinal Diseases</i>), IBULIEF(<i>Patent ductus arteriosus</i>), ORENCIA(<i>Juvenile idiopathic arthritis</i>), ILARIS(<i>Systemic juvenile idiopathic arthritis</i>), Refixia(<i>Haemophilia B</i>), LORA-PITA(<i>Status epilepticus</i>), Precedex(<i>Pediatric subjects in the intensive care unit</i>)

✓ Clinical department



Distribution of the clinical trial by clinical department