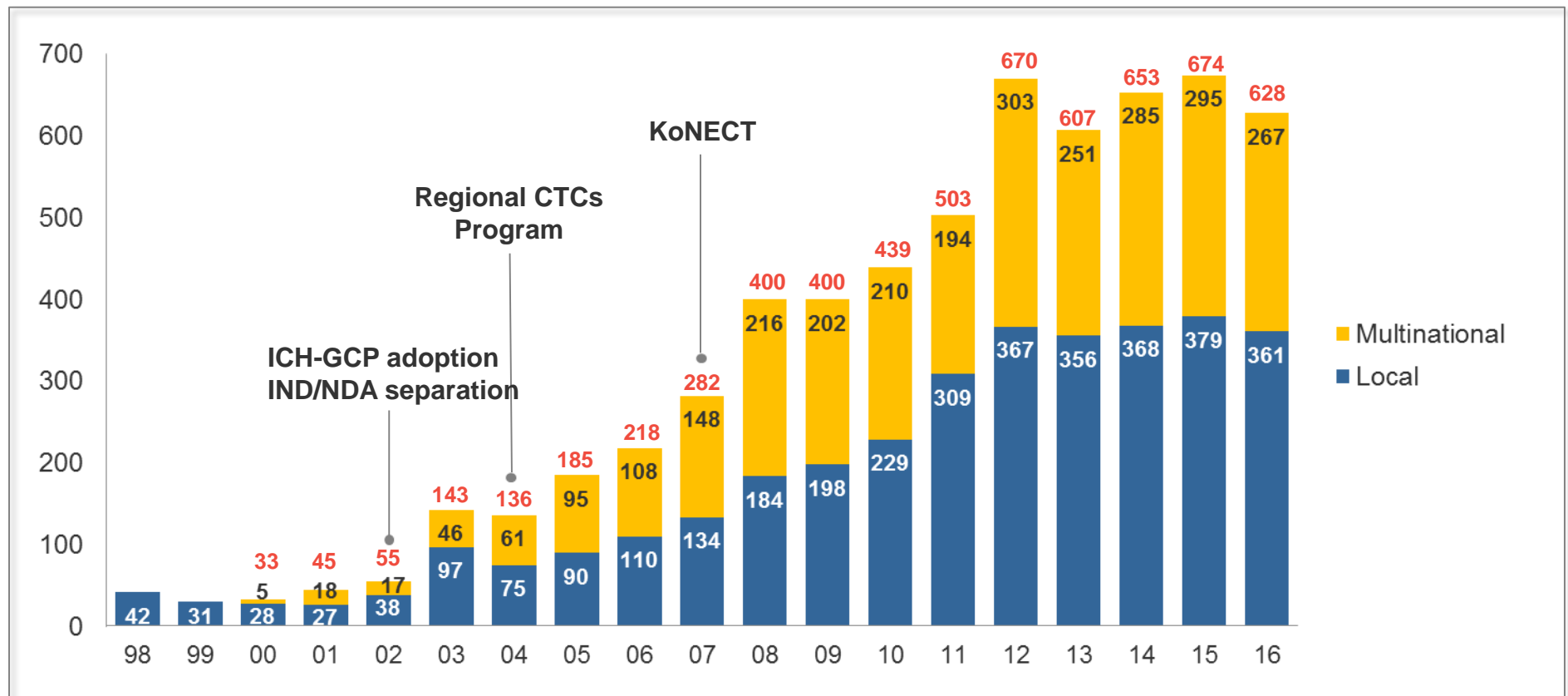


Clinical Trials Industry

4.1. Clinical Trials Industry

(1) Number of CTA approvals

- The No. of clinical trials has dramatically increased by 15 times over the past 15 years.
- Multinational clinical trials started in 2000 and in 2016, 267 multinational clinical trials were performed, making Korea a rising global clinical trial hub in Asia.



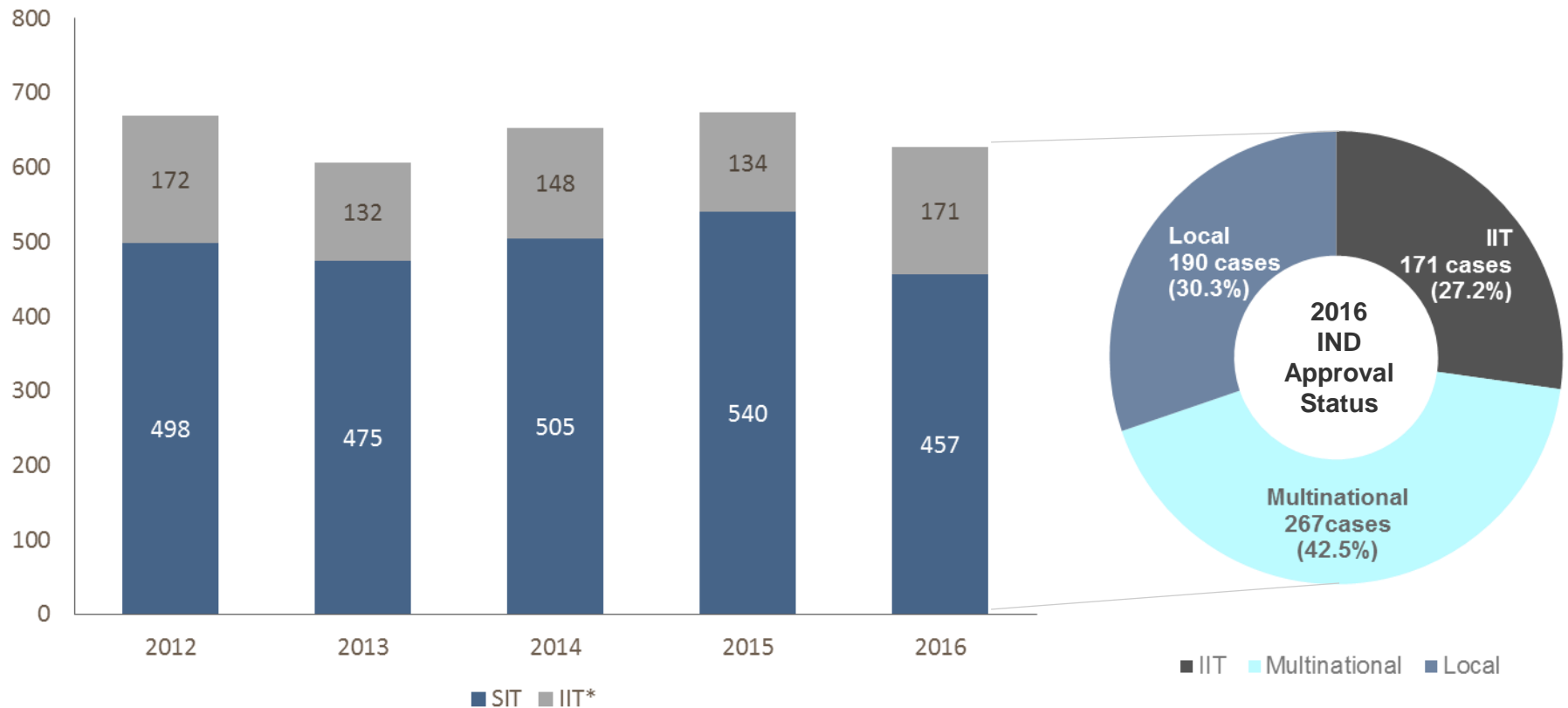
* Source: 2016 MFDS(Korean Ministry of Food and Drug Safety) IND Approval Status

1) Local: Conducting clinical trials only in Korea

2) Multinational: Conducting clinical trials in two or more countries including Korea

4.2. Clinical Trials Industry-Approval (1) Number of approvals on SITs and IITs

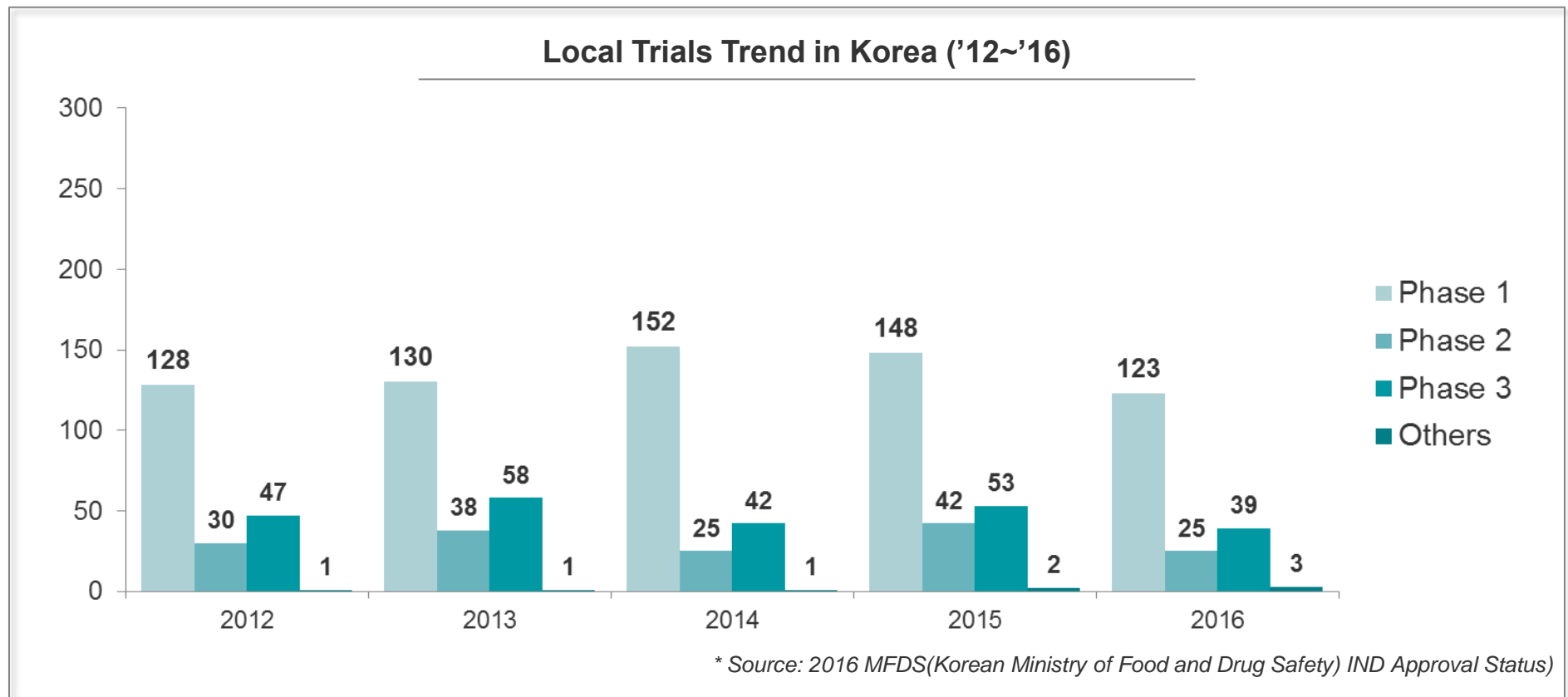
- The No. of SITs decreased from 540 cases in 2015 to 457 cases in 2016 (a 15.4% decrease from the previous year).
- The number of IITs increased from 134 cases in 2015 to 171 cases in 2016, showing a 27.6% increase from the previous year.



- Clinical trials are divided into sponsor-initiated trials (SITs) and investigator-initiated trials (IITs). IITs mean clinical trials independently conducted by an investigator on a clinical trial site mainly for clinical research purposes without external referral.

4.2. Clinical Trials Industry-Approval (2) Number of CTA approvals by Phases

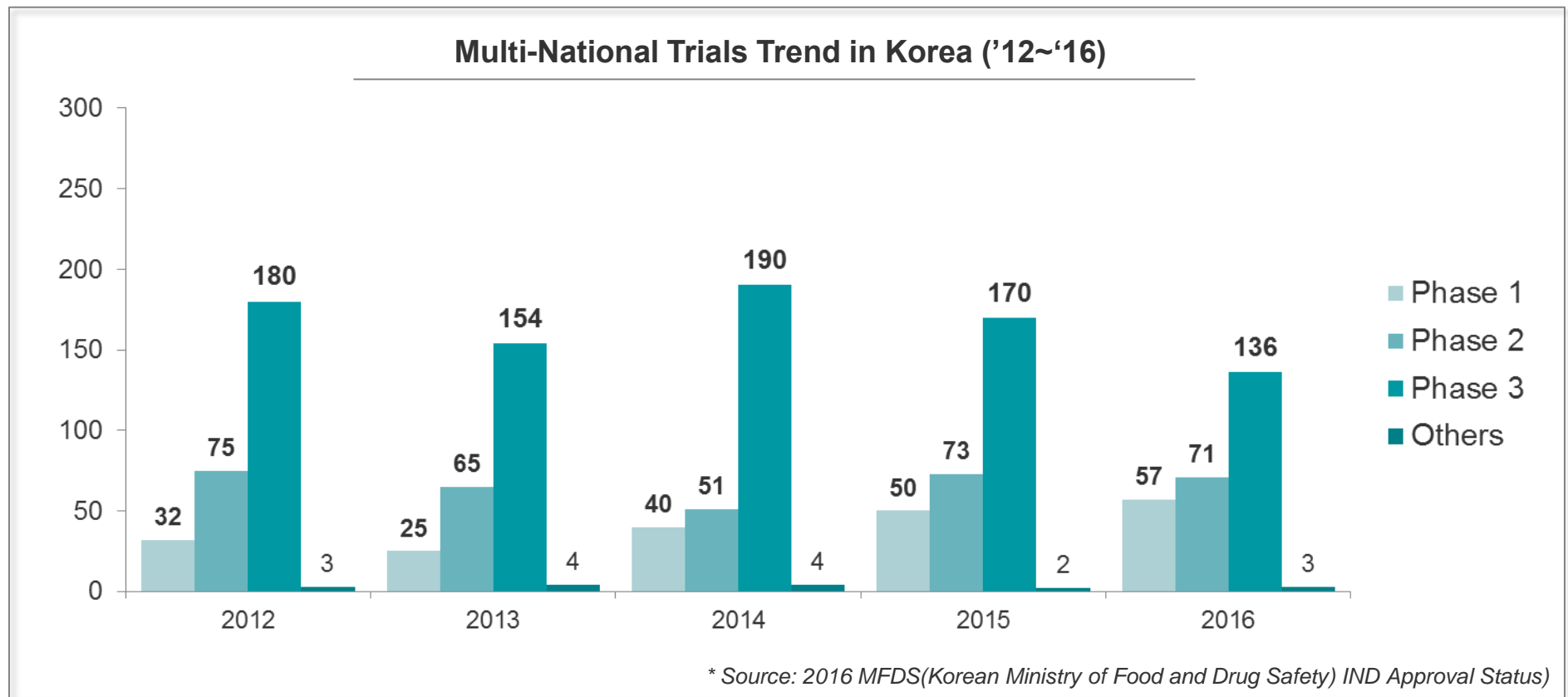
- The number of local trials decreased to 190 cases (a decrease by 22.4% from the previous year); a decrease was observed in the number of trials at all phases.



4.2. Clinical Trials Industry-Approval

(3) Number of CTA approvals by Phases

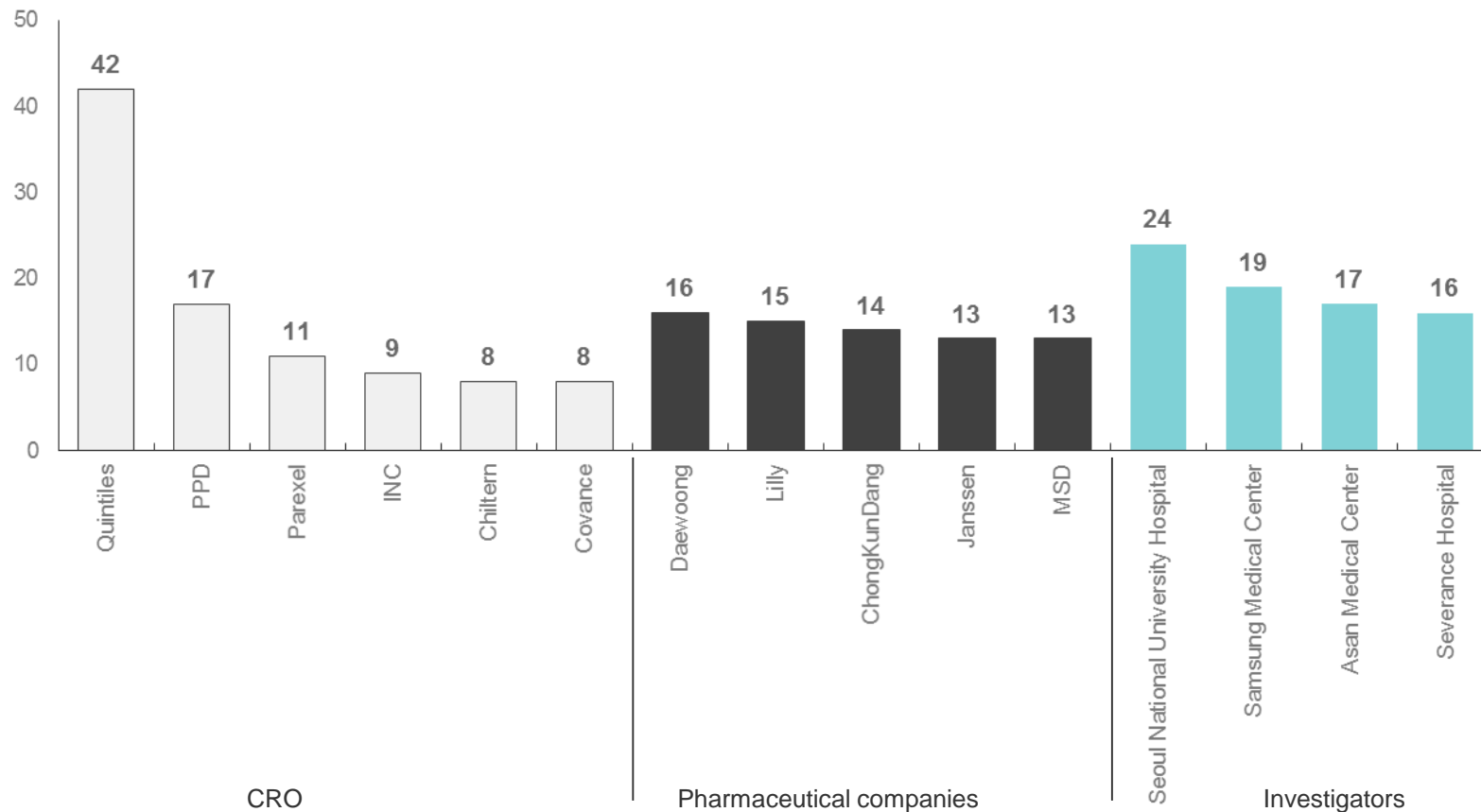
- Phase 1 of multinational companies' clinical trials had 57 cases in 2016, which was an increase of 128%, from 25 cases in 2013
- This increase is attributable to the international recognition of high regulation levels and well-equipped laboratories and facilities of clinical trial sites.



4.2. Clinical Trials Industry-Approval

(4) Number of approvals by CTA holders

- The No. of SITs decreased by 15.4% from the previous year, and the No. of multinational trials also decreased by 9.5% from the previous year.
- Despite this decline, the No. of approvals entrusted to the contract research organizations(CROs) by sponsors has been on a continuous rise.



* Source: 2016 MFDS(Korean Ministry of Food and Drug Safety) IND Approval Status)

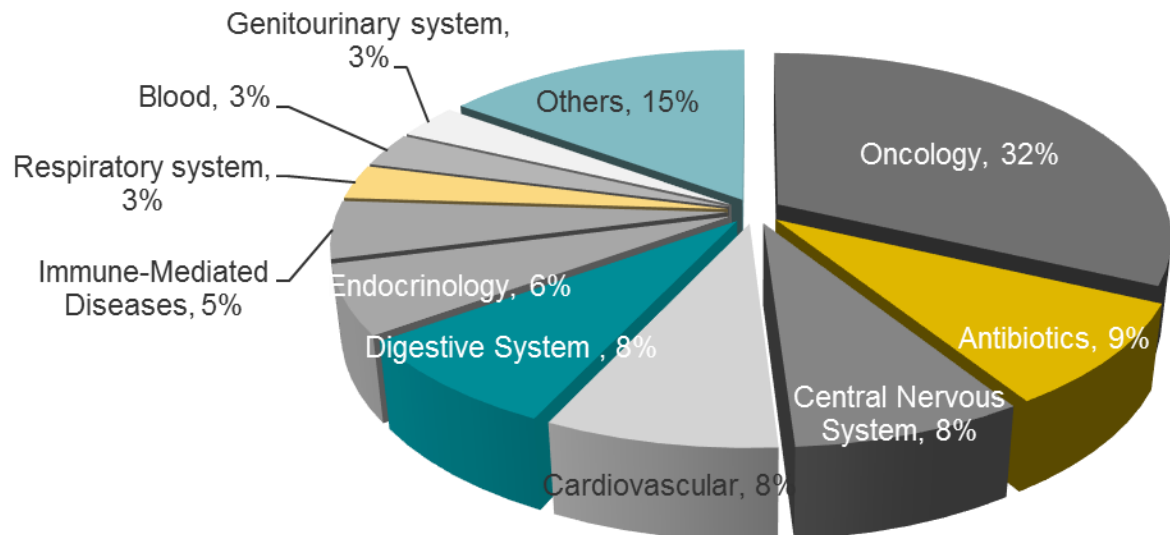
4.2. Clinical Trials Industry-Approval

(5) Number of CTA approvals by therapeutic areas

- The No. of trials on anticancer drugs dropped by 20.5% from the previous year, from 254 cases in 2015 to 202 cases in 2016, but still accounted for the highest percent (32.2%) of total clinical trials.

No. of approvals for clinical trials by therapeutic areas (2016)

Therapeutic area	No. of Approvals
Oncology	202
Antibiotics	55
Central Nervous System	51
Cardiovascular	50
Digestive System	48
Endocrinology	39
Immune-Mediated Diseases	32
Respiratory system	20
Blood	20
Genitourinary system	16
Others	95
Total	628



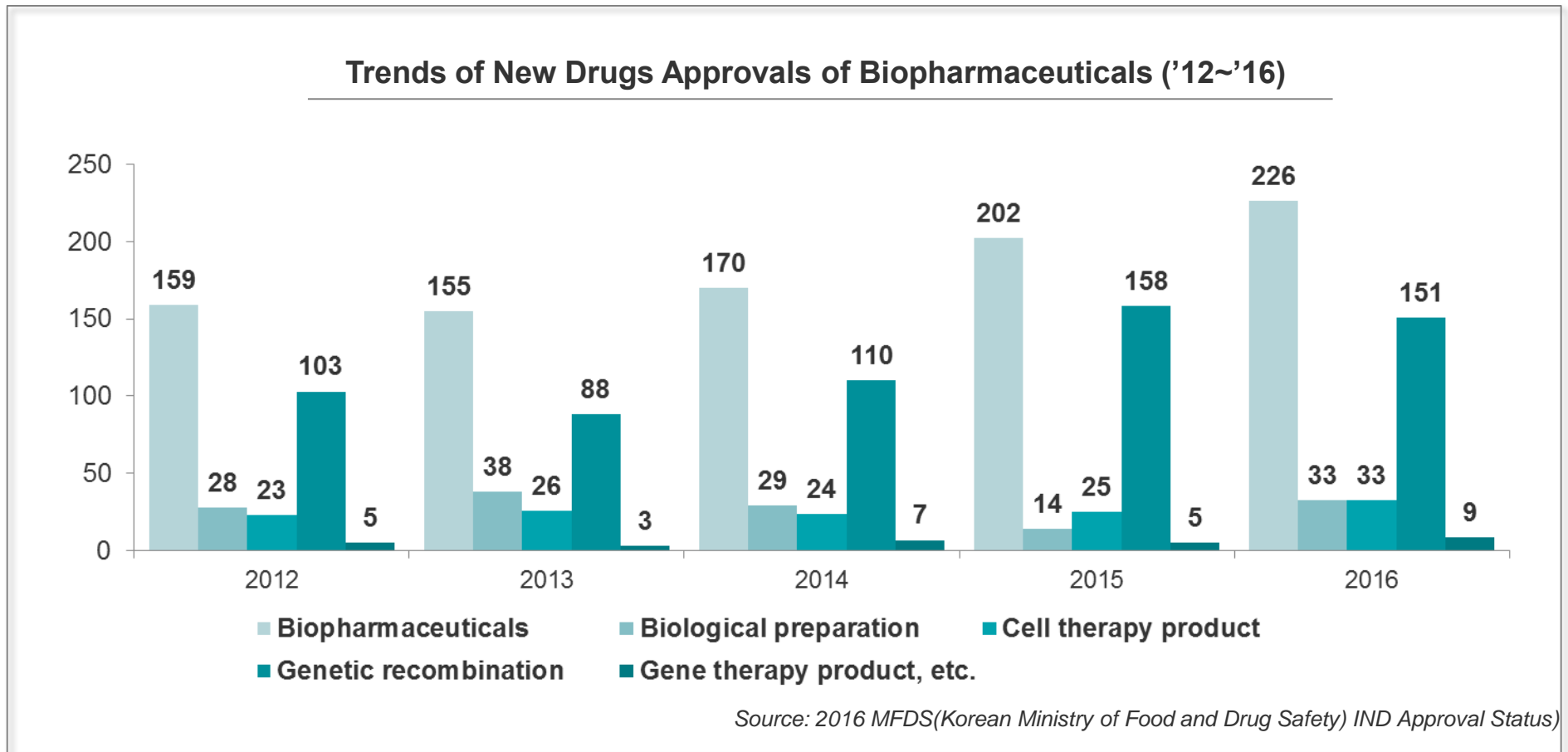
* Other: Skin diseases, musculoskeletal system, etc.

* Source: 2016 MFDS(Korean Ministry of Food and Drug Safety) IND Approval Status)

4.2. Clinical Trials Industry-Approval

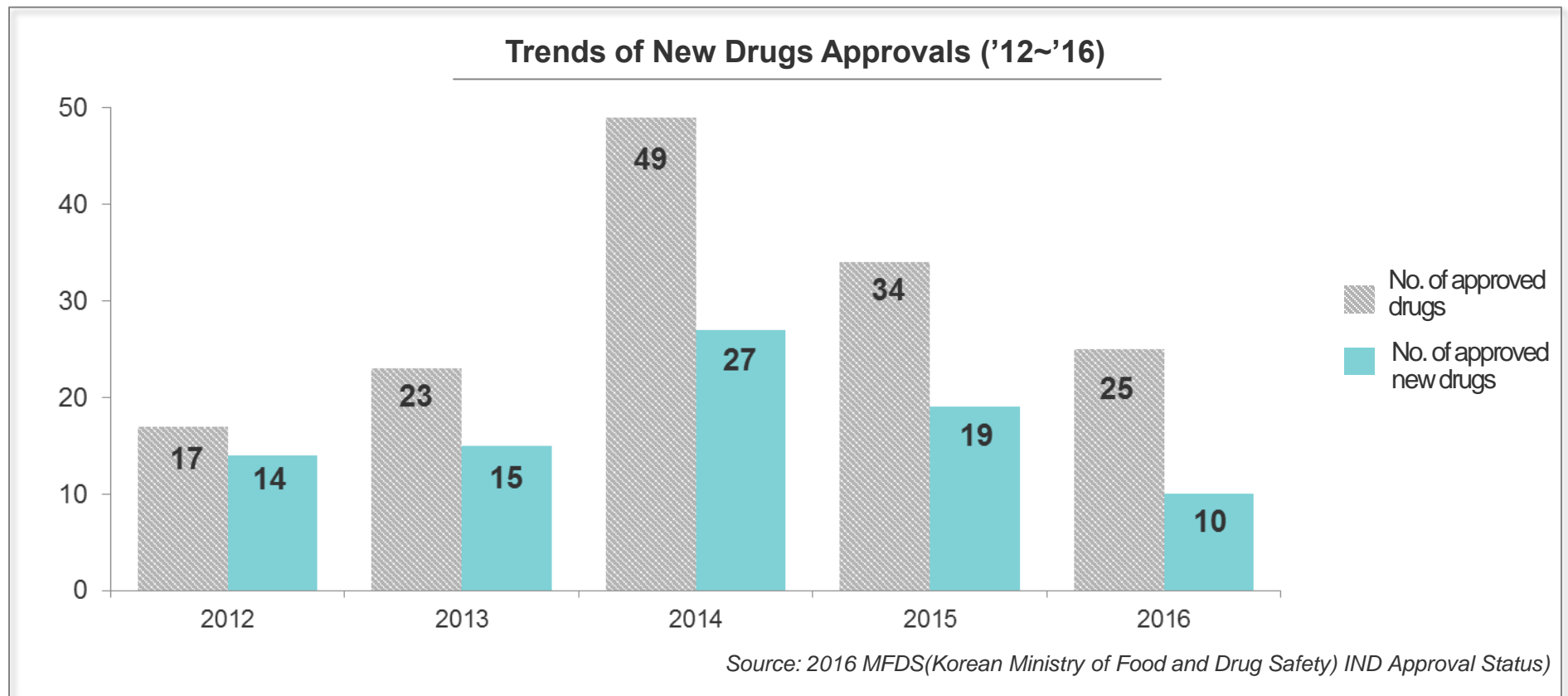
(6) New drugs Approvals of Biopharmaceuticals

- In 2016, the No. of New Chemical Entities(NCE) declined by 14.2% from 2015, but biopharmaceuticals increased by 11.9% from 2015.
- The phase I clinical trial showed a 25.0% increase from the previous year and there were many early development stage products for commercialization.



4.2. Clinical Trials Industry-Approval (7) New drugs Approvals

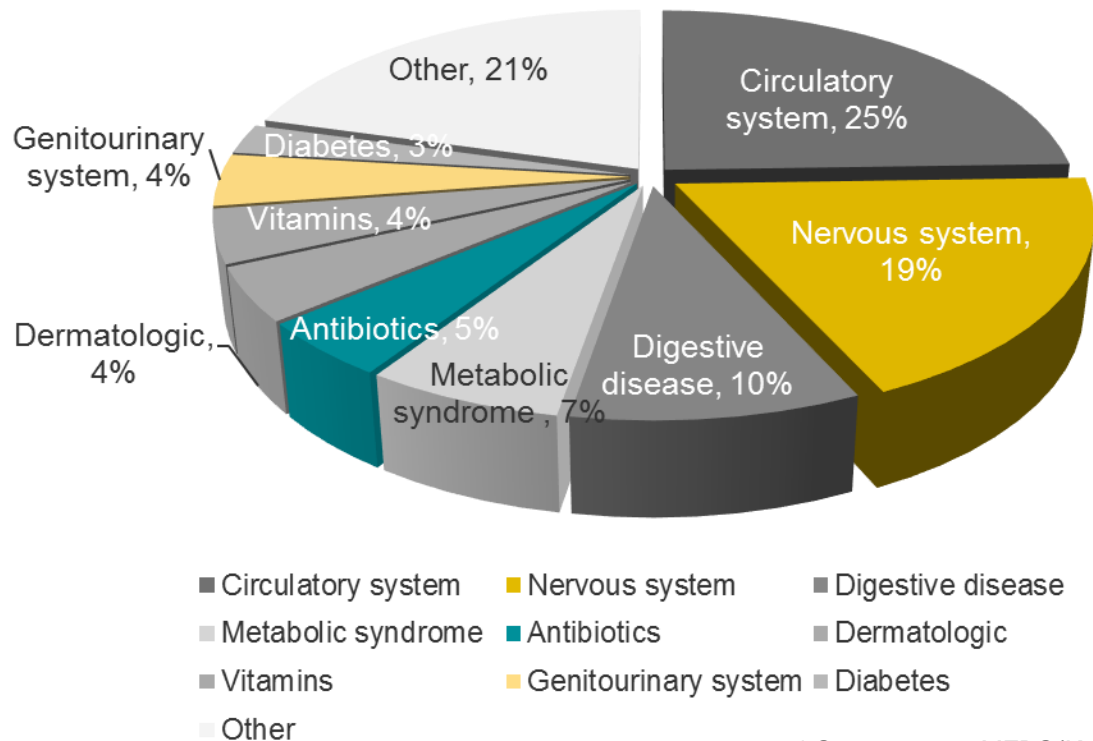
- In 2016, 25 new drugs were approved by the Korean regulatory agency (MFDS).
- With strong manpower and potential for success, 31 of new drugs are expected by 2020.



4.2. Clinical Trials Industry-Approval (8) Approved/Registered Drugs (by therapeutic areas)

- In 2016, among 2,761 finished medicinal products registered for clinical trials to Ministry of Food and Drug Safety(MFDS), as many as 2,014 is approved.

Approved/Registered Drugs by therapeutic areas (2016)



Therapeutic areas	Number of items	% of total items
Circulatory system	676	24.5%
Nervous system	517	18.7%
Digestive disease	262	9.5%
Metabolic syndrome	247	8.9%
Antibiotics	128	4.6%
Others	931	33.7%
Total	2,761	100%

* Source: 2016 MFDS(Korean Ministry of Food and Drug Safety) IND Approval Status)