



국가신약개발사업단
Korea Drug Development Fund

2023 국내 신약개발 파이프라인 조사 결과

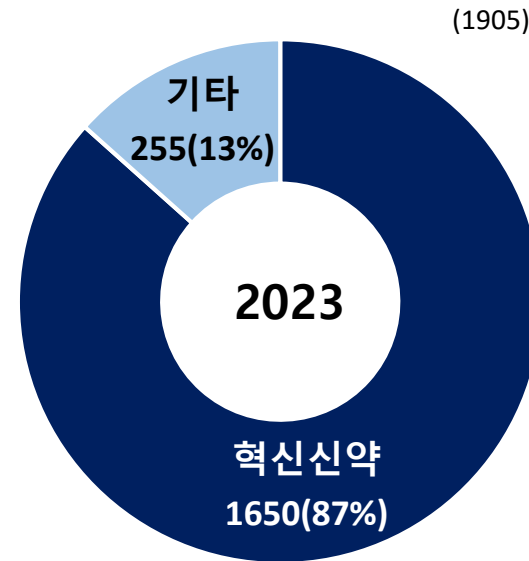
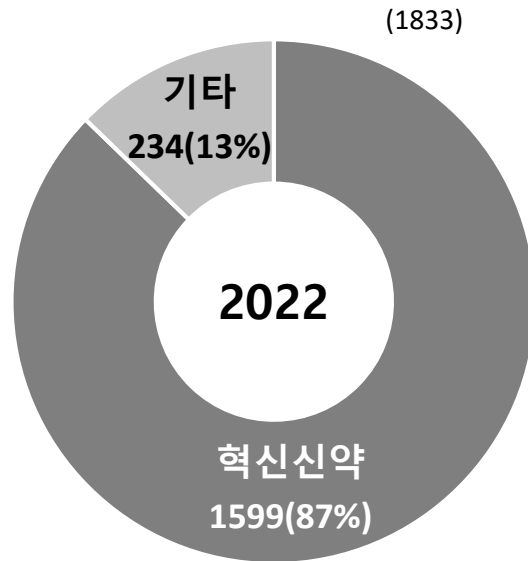
2023.04.05.

국가신약개발사업단

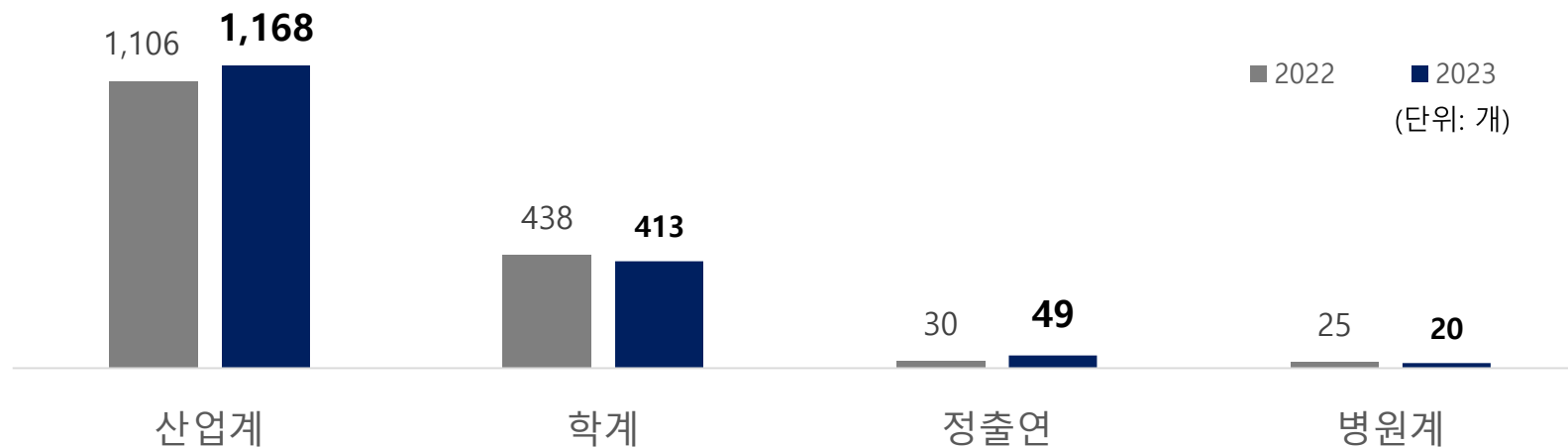
경영본부 기획팀장 박효진(문의: hjinpark@kddf.org)

2023 국내 파이프라인 조사

혁신신약



기관

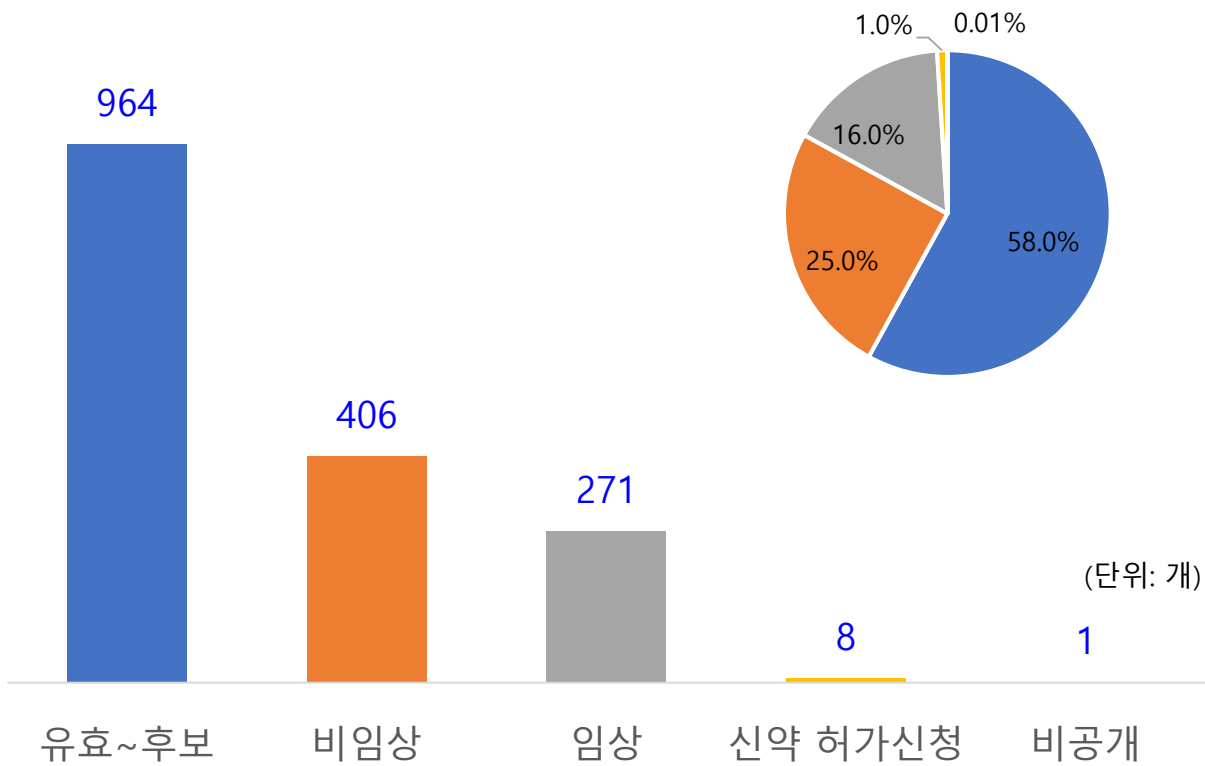




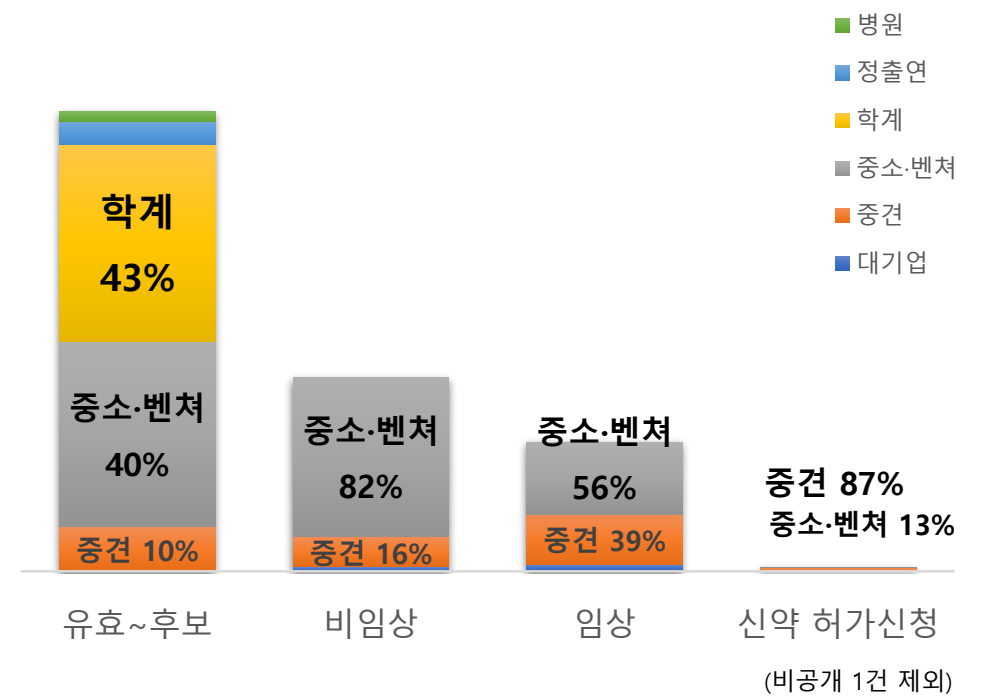
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Korea Drug Development Fund

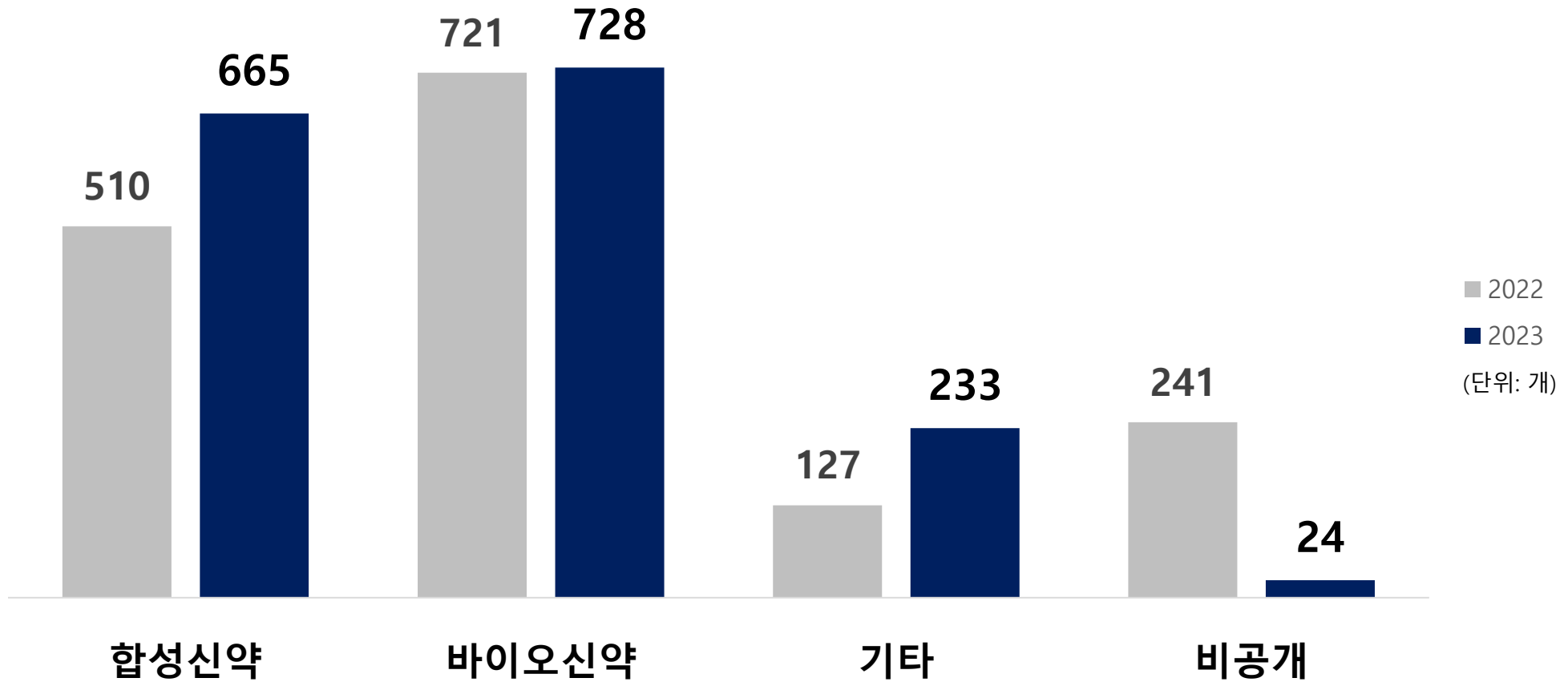
혁신신약

| 개발단계



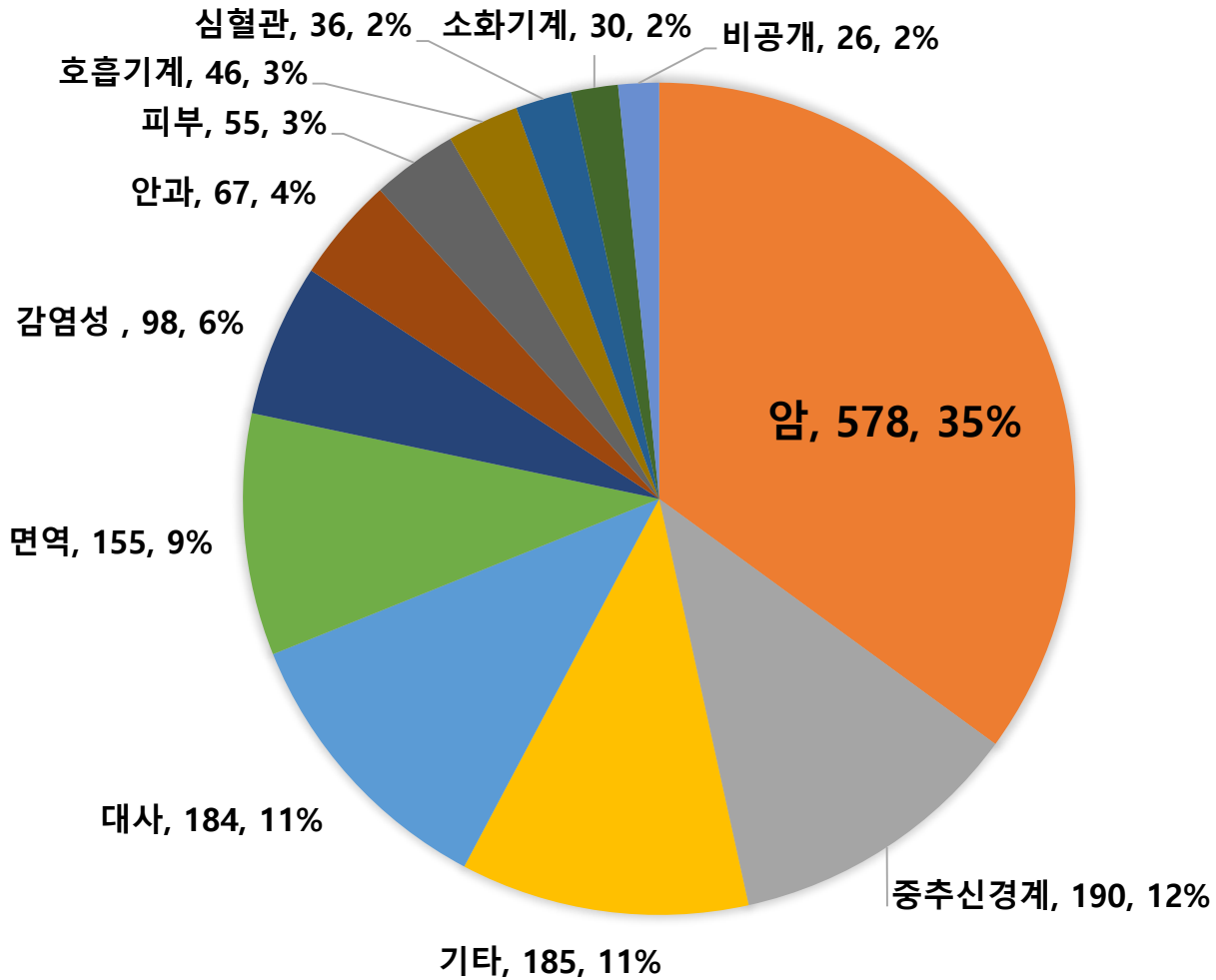
| 개발단계별 기관유형





(기타: 천연물, 마이크로바이옴, 엑소솜, 융복합물질 등 분류가 어려운 물질)

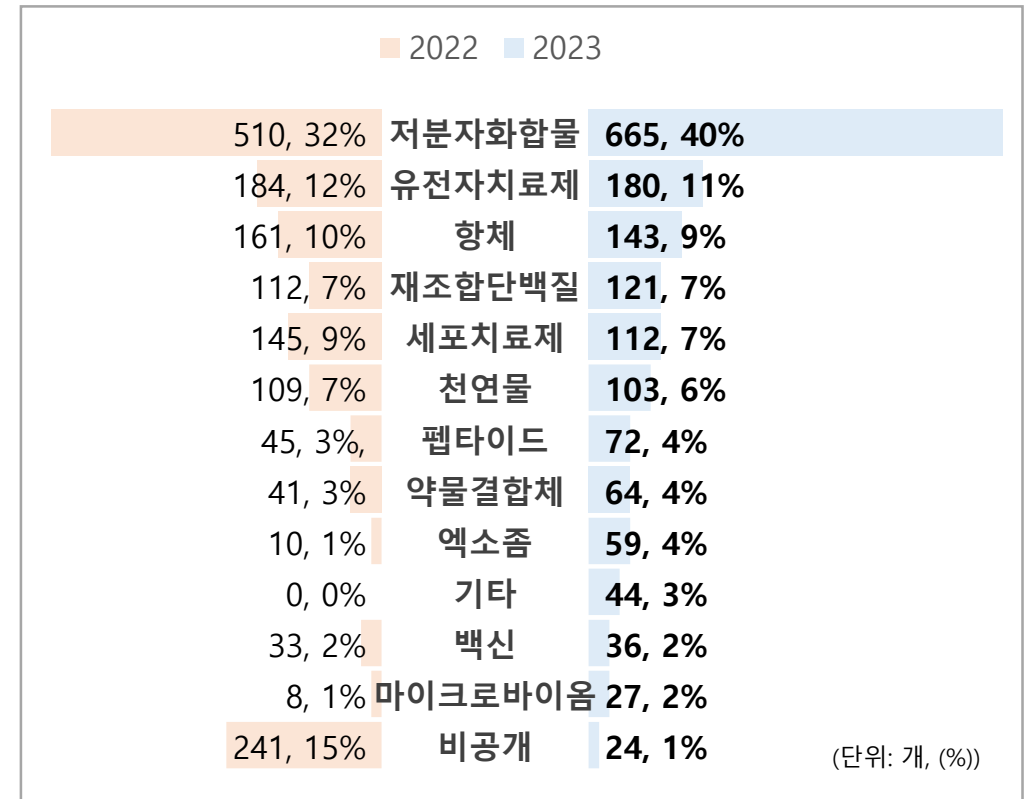
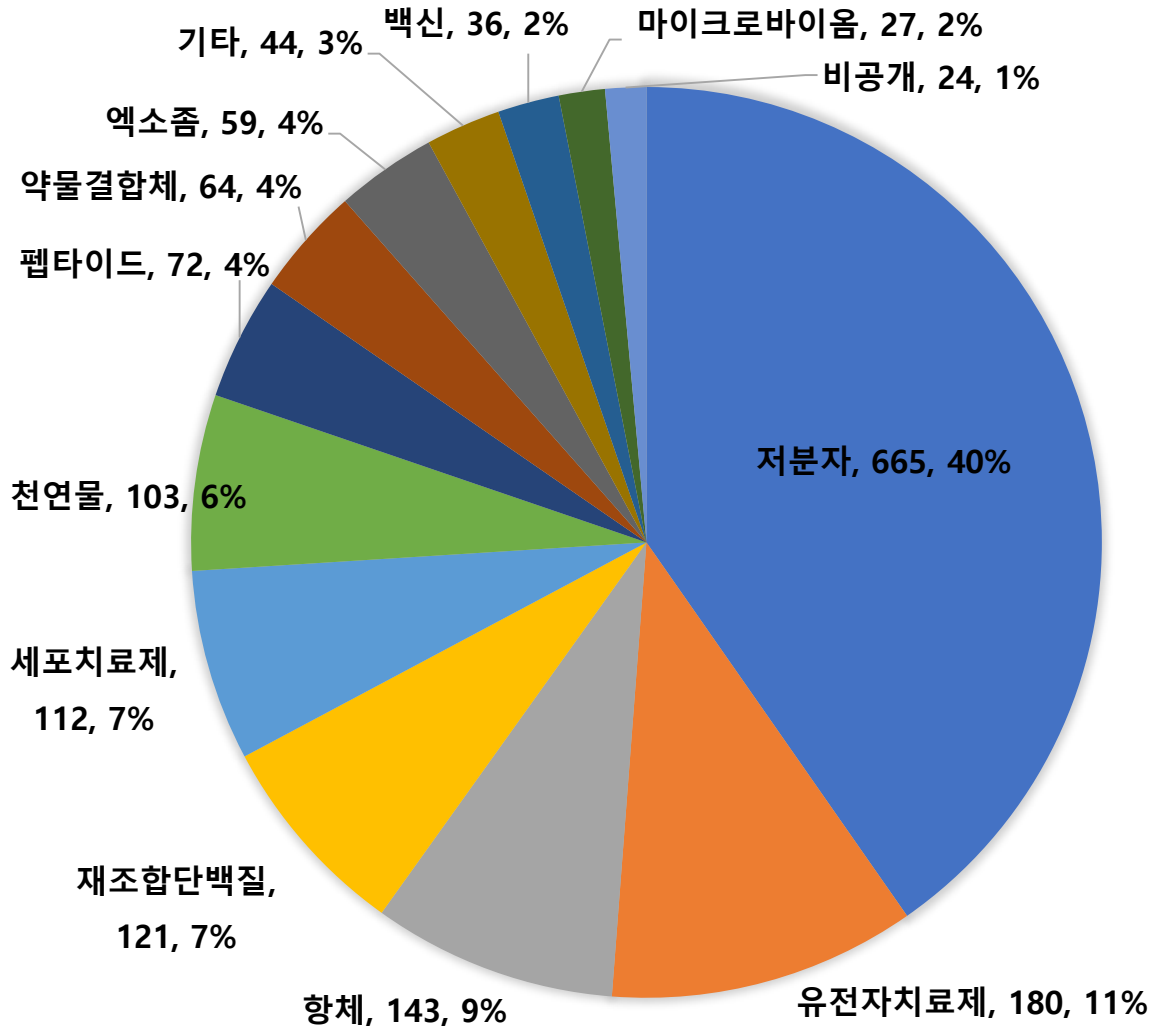
질환별 파이프라인



(단위: 개, %)

		2022	2023
암	40%, 647	35%, 578	
중추신경계	12%, 191	12%, 190	
기타	12%, 187	11%, 185	
대사	8%, 129	11%, 184	
면역	8%, 120	9%, 155	
감염성	6%, 89	6%, 98	
안과	4%, 67	4%, 67	
피부질환	1%, 22	3%, 55	
호흡기계	3%, 46	3%, 46	
심혈관	3%, 47	2%, 36	
소화기	2%, 37	2%, 30	
비공개	1%, 17	2%, 26	

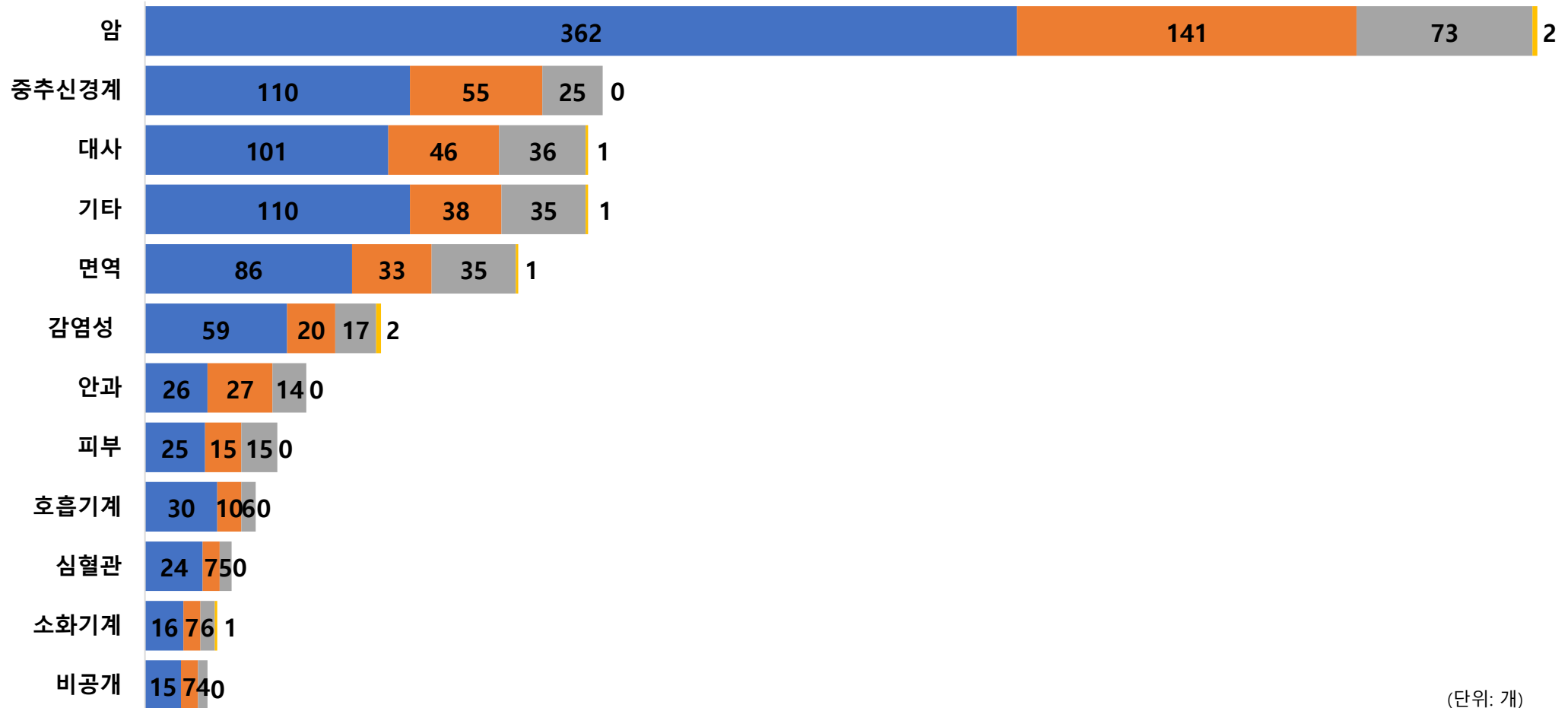
(단위: 개, %)



개발단계별 모달리티

연구 단계	저분자 665								바이오 728				기타 233				비공개 24	총합계
	저분자	유전자 치료제	항체	재조합 단백질	세포 치료제	펩타이드	약물 결합체	백신	천연물	엑소좀	마이크로 바이옴	기타	비공개					
유효~후보	401	101	79	62	48	33	43	16	80	35	18	31	17	964				
비임상	141	58	38	31	37	24	15	10	11	22	6	9	4	406				
임상 1상	57	10	18	13	21	8	2	4	2	2	2	2	2	143				
임상 2상	47	9	6	12	2	5	3	4	10		1	1	1	101				
임상 3상	13	2	2	3	3	2	1	1						27				
신약 허가신청	5				1			1				1		8				
비공개	1													1				
총합계	665	180	143	121	112	72	64	36	103	59	27	44	24	1,650 (단위: 건)				

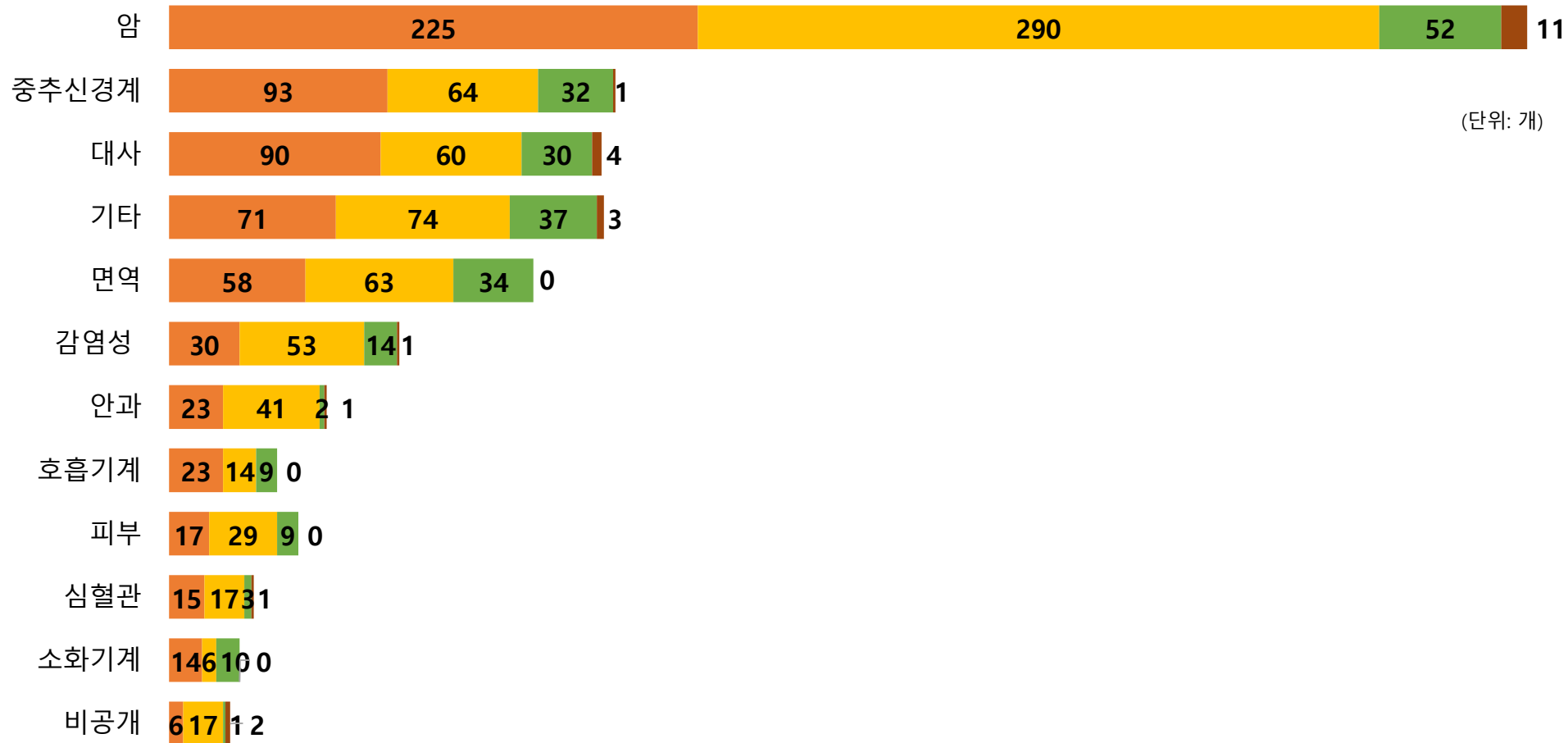
■ 유효~후보 ■ 비임상 ■ 임상 ■ 신약 허가신청



(단위: 개)
(비공개 1건 제외)

질환별 신약 유형

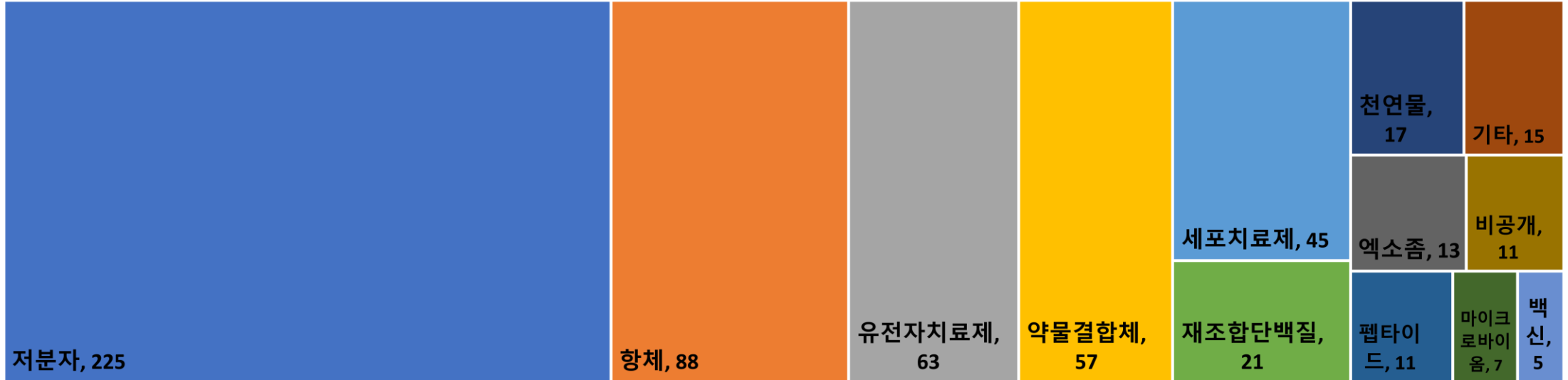
■ 합성 ■ 바이오 ■ 기타 ■ 비공개



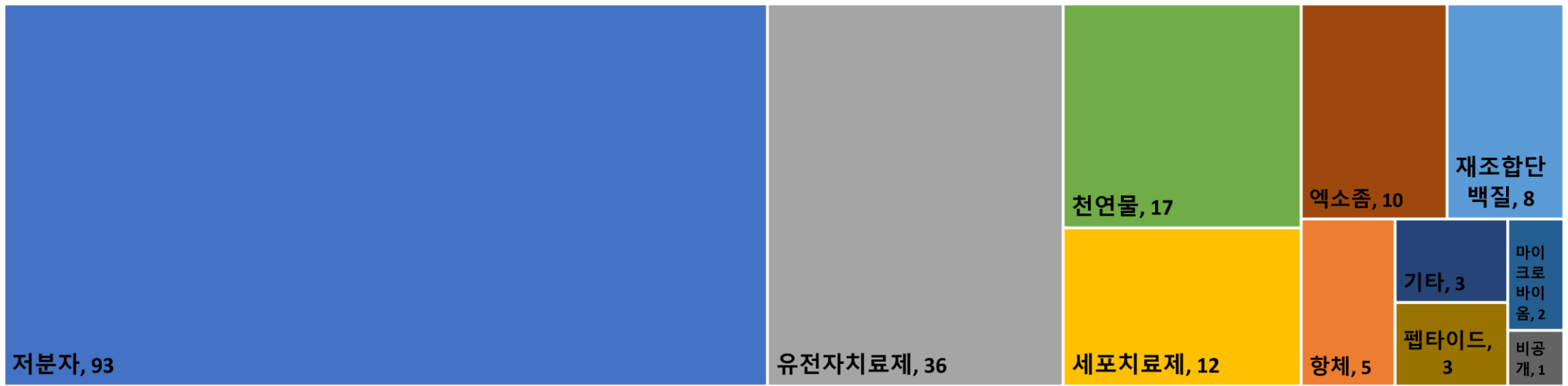
(기타: 천연물, 마이크로바이옴, 엑소솜, 융복합물질 등 분류가 어려운 물질)

질환별 모달리티(암, 중추신경계)

암

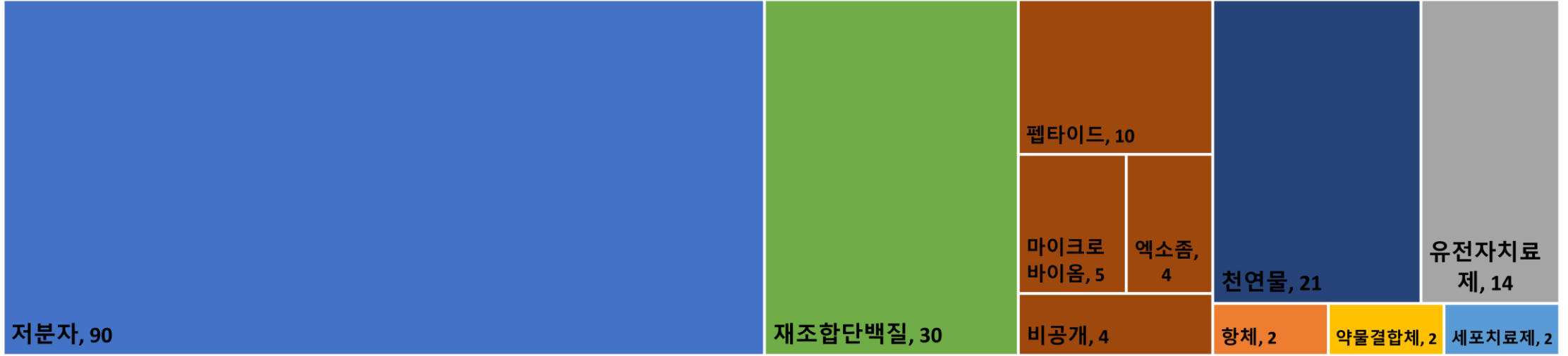


중추신경계

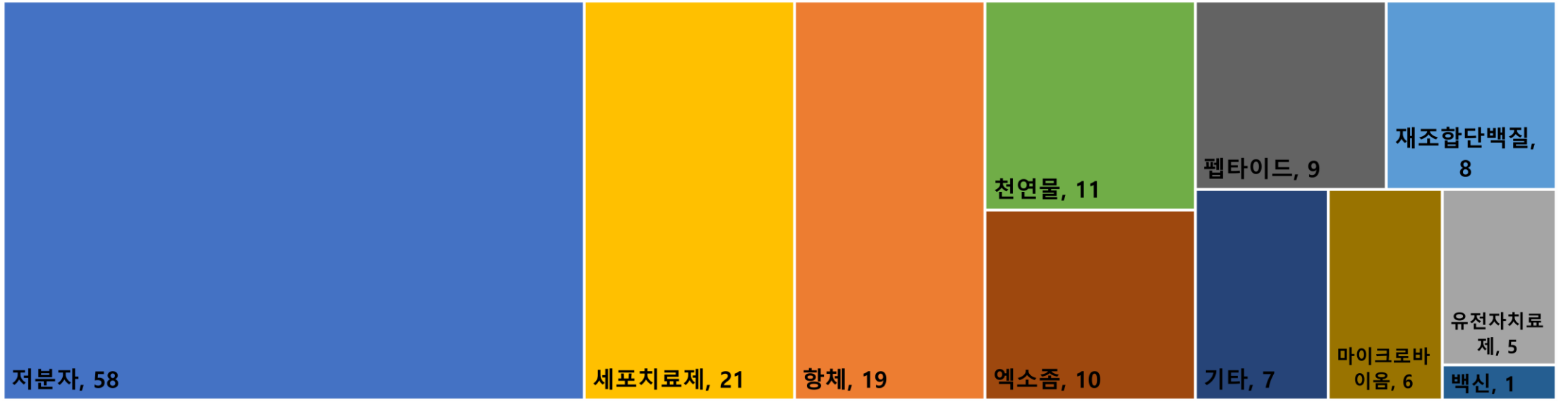


(단위: 개)

대사



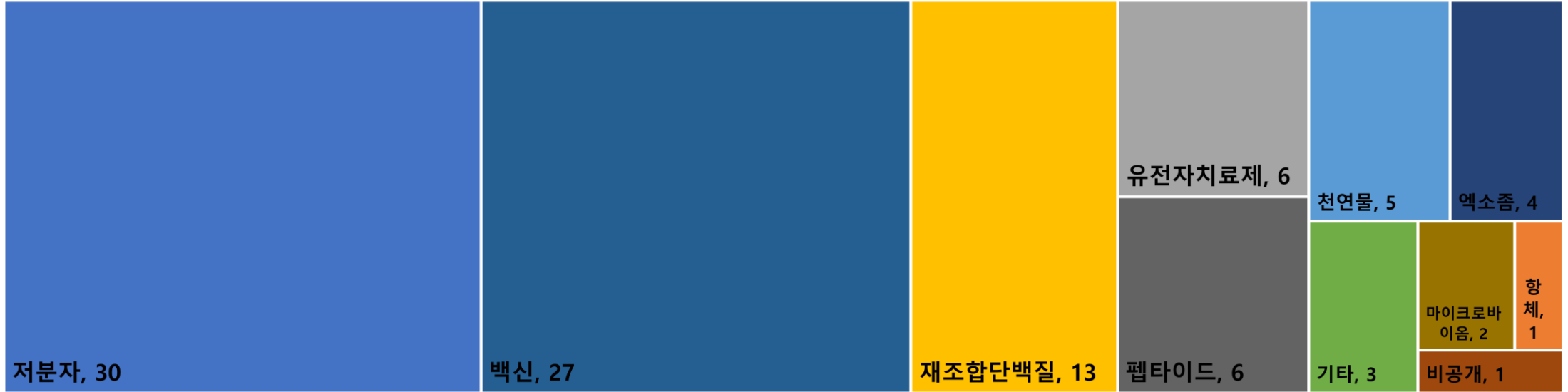
번역



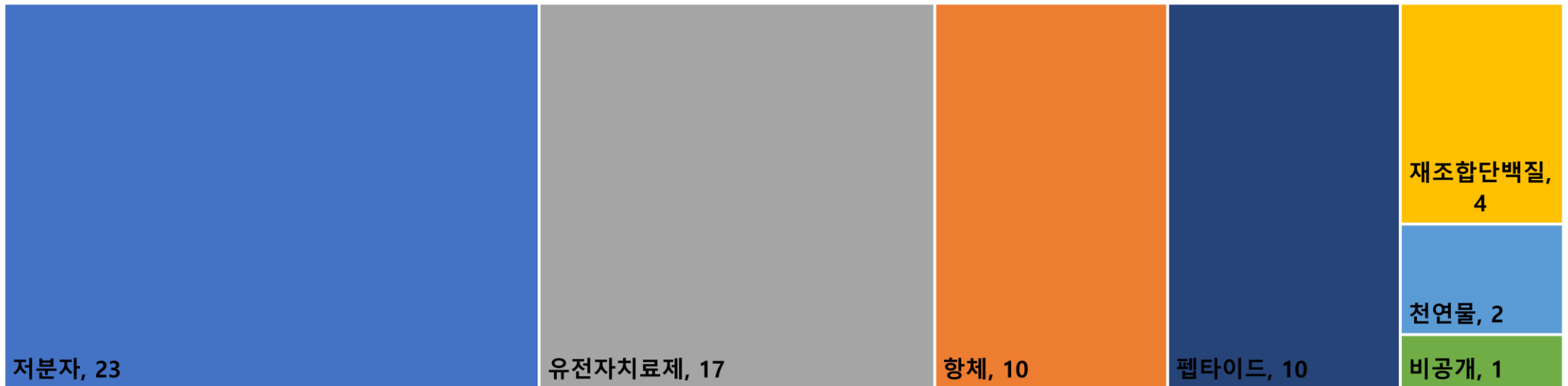
(단위: 개)

질환별 모달리티(감염, 안과)

감염



안과



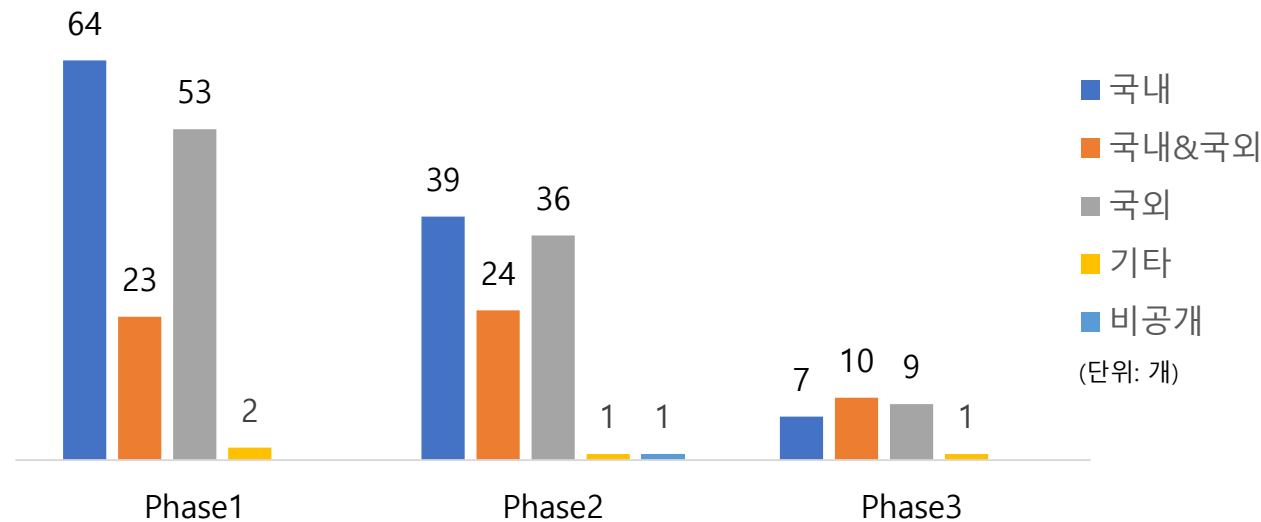
(단위: 개)



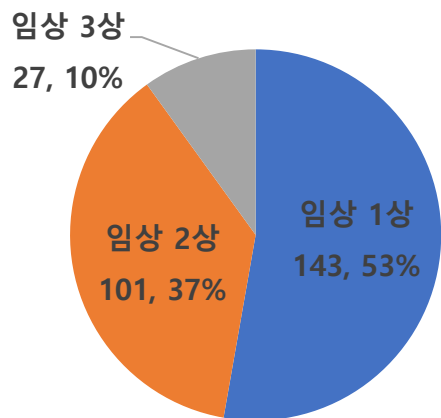
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Korea Drug Development Fund

임상시험

단계별 임상시험 지역

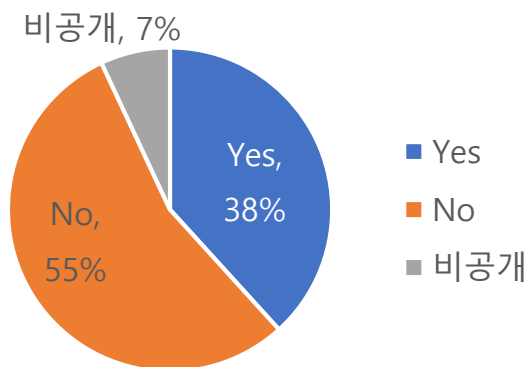


임상 단계별 (임상은 전체 파이프라인의 16%)

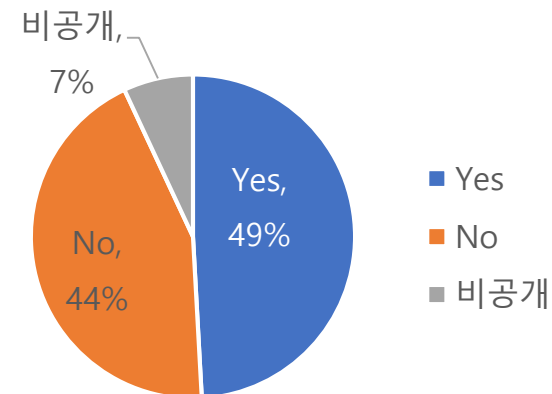


(단위: 개, %)

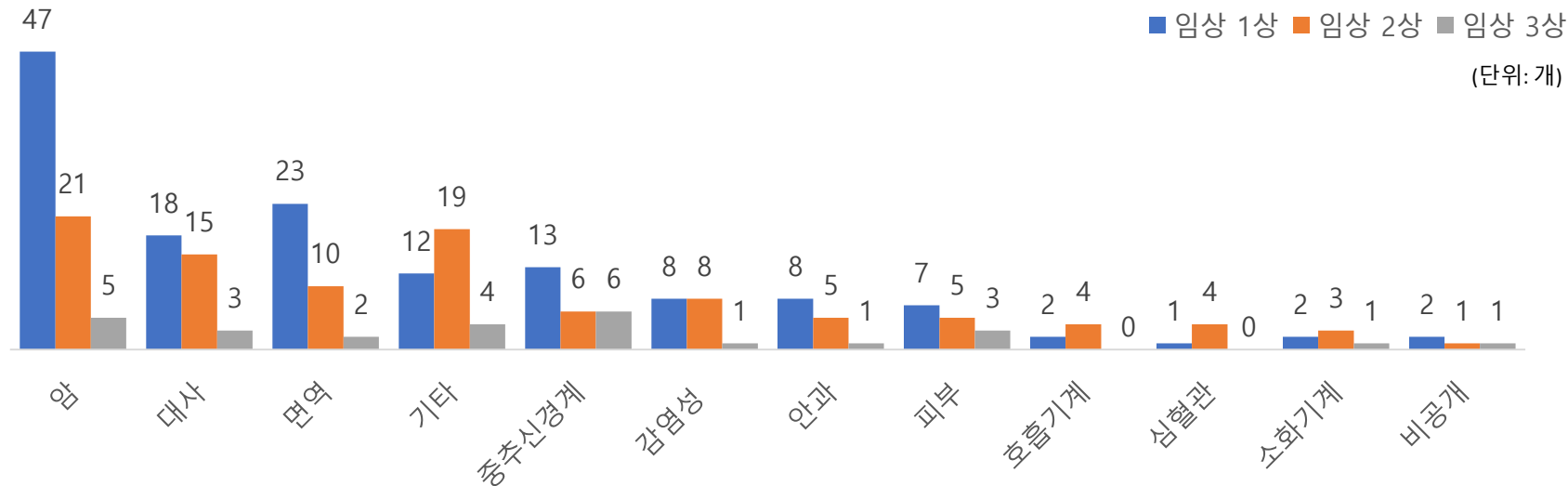
환자군 선택 바이오마커



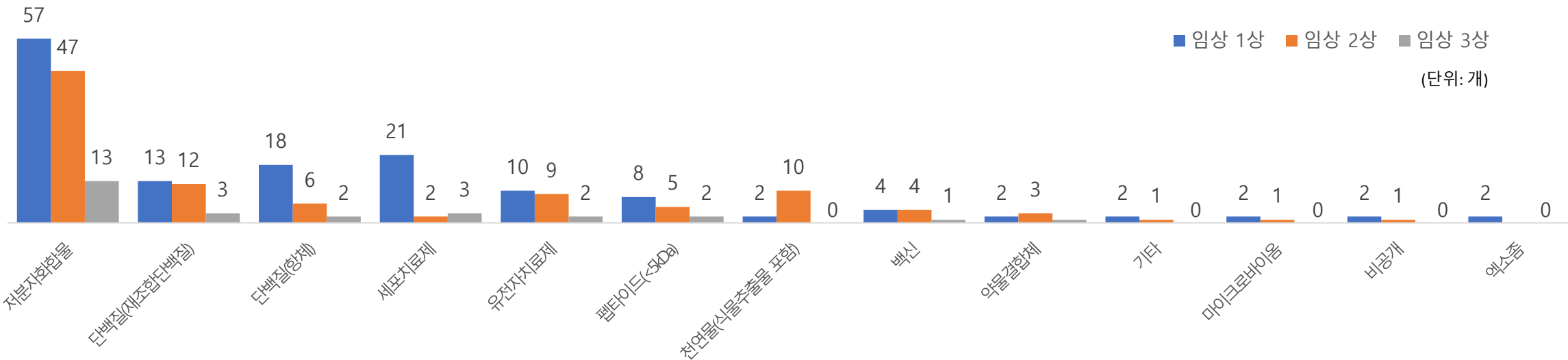
치료 효능 확인 바이오마커



질환별 임상시험 단계



모달리티별 임상시험 단계



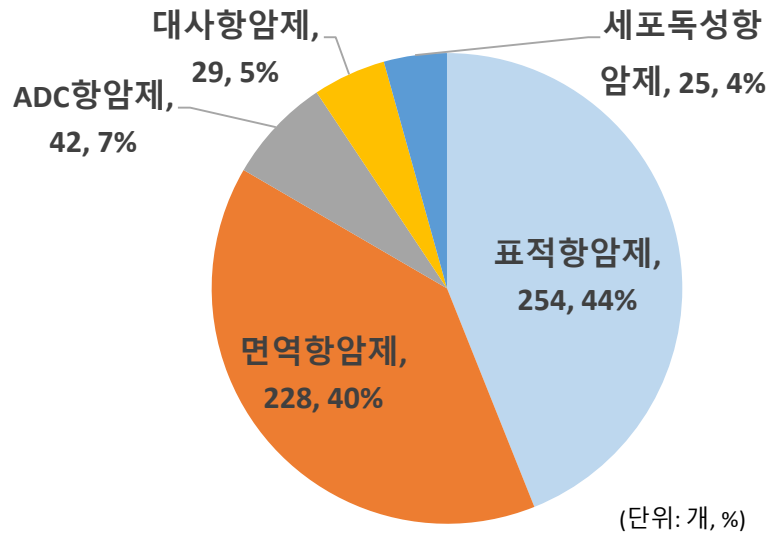


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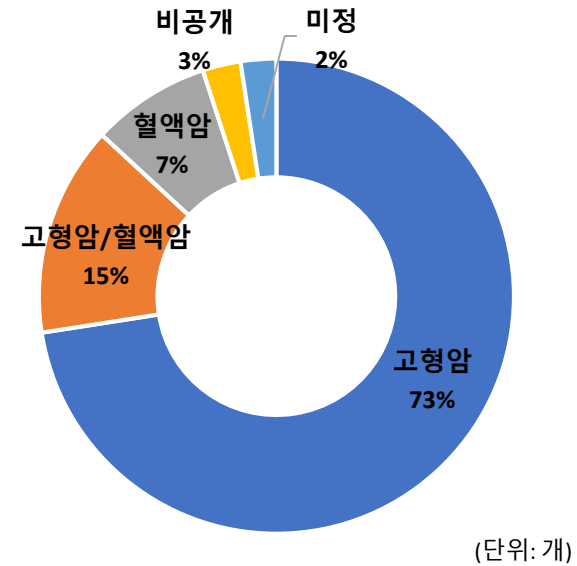
중양



치료기전 (암은 전체 파이프라인의 35%)

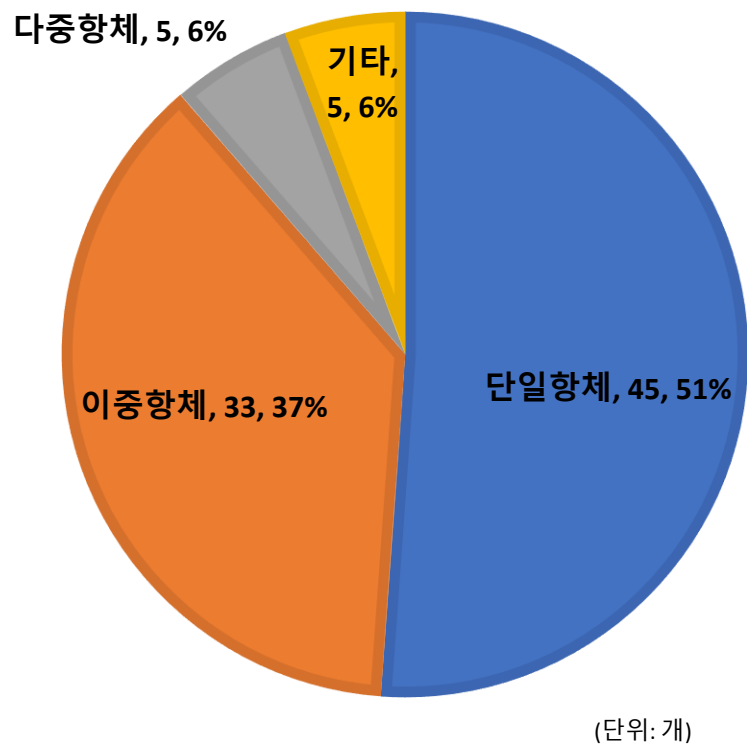


암 종류

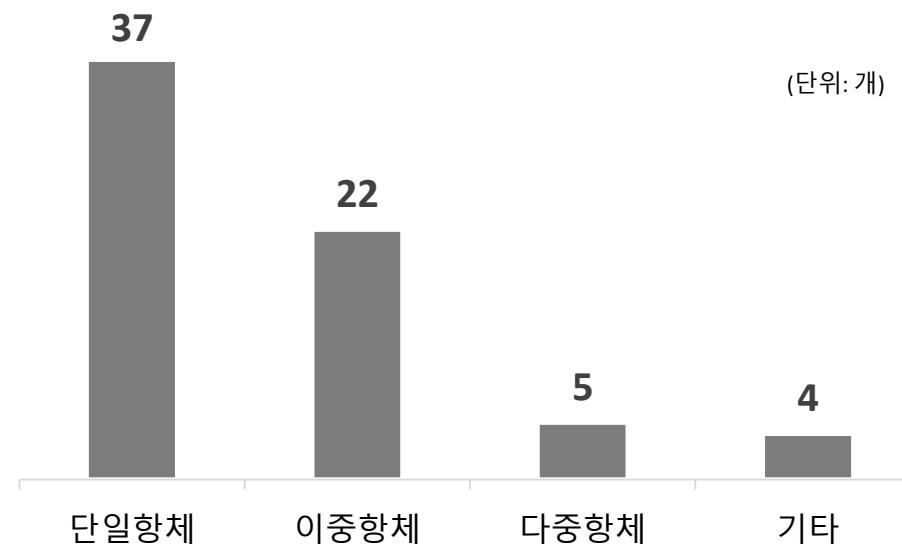


- 표적항암제(44%) > 면역항암제(40%) > ADC 치료제(7%) > 대사항암제(5%) > 세포독성항암제(4%)
- 면역항암제: 항체(30%) > 세포치료제(19%) > 저분자(18%) > 유전자치료제(10%) > 재조합단백질(7%) > 마이크로바이옴(3%) > 펩타이드(2%), 엑소솜(2%), 백신(2%) 등
- 표적항암제: 저분자(60%) > 유전자치료제(12%) > 항체(7%)
- 고형암(73%) > 고형암/혈액암(15%) > 혈액암 (7%)

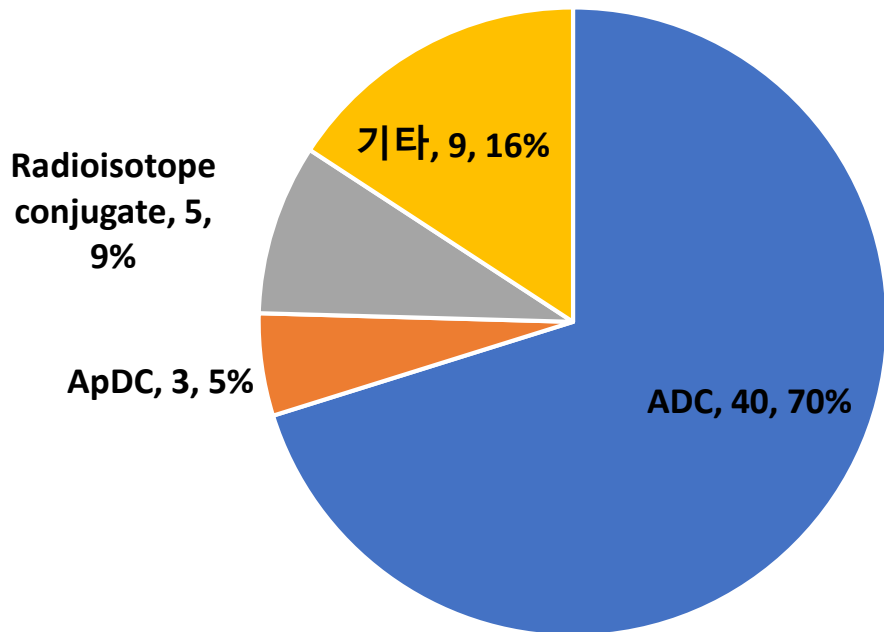
항체 유형
(항체는 15%/암)



고형암(76%)에서 항체 유형

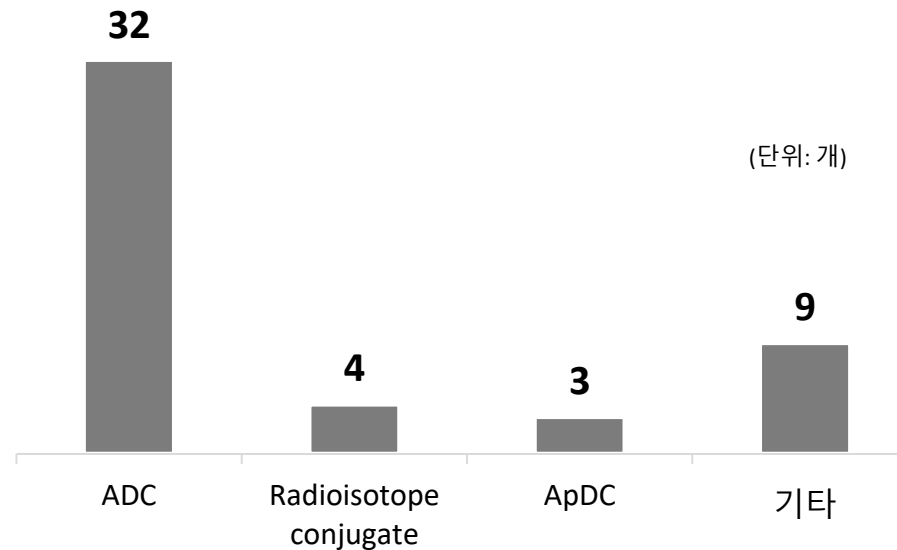


약물결합체 유형
(약물결합체는 10%/암)



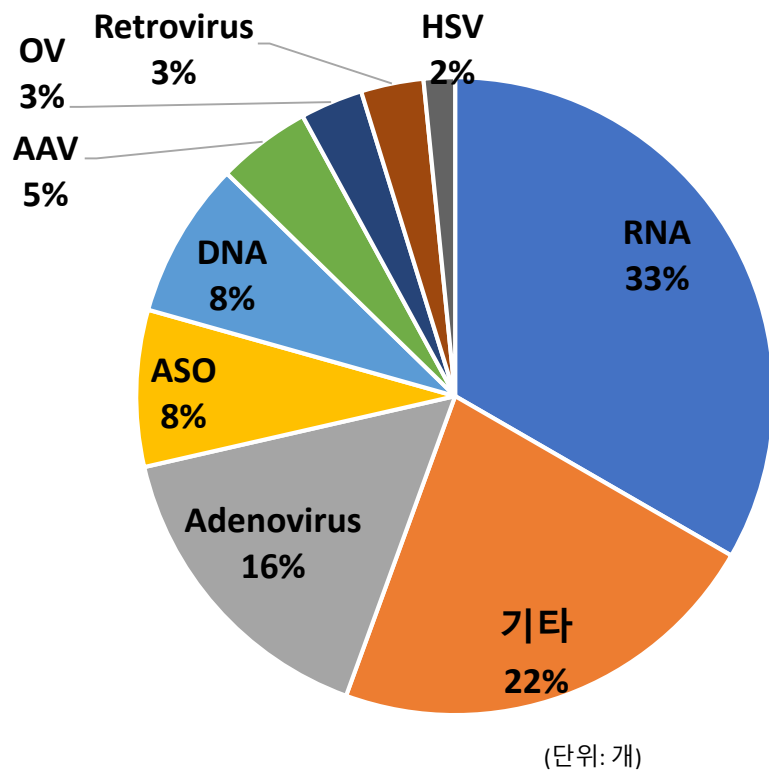
(단위: 개)

고형암(84%)에서 약물결합체 유형

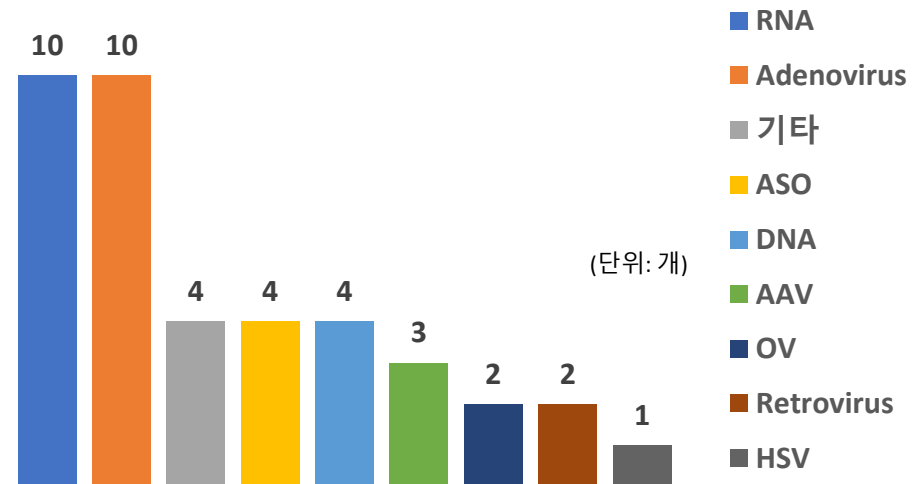


(단위: 개)

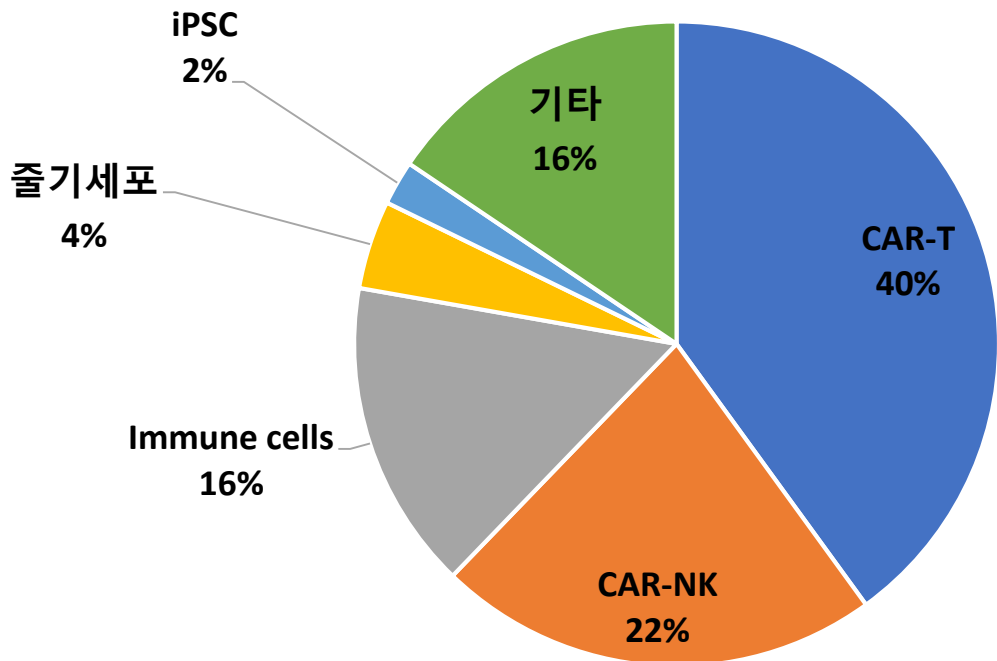
유전자치료제
(유전자치료제는 10%/암)



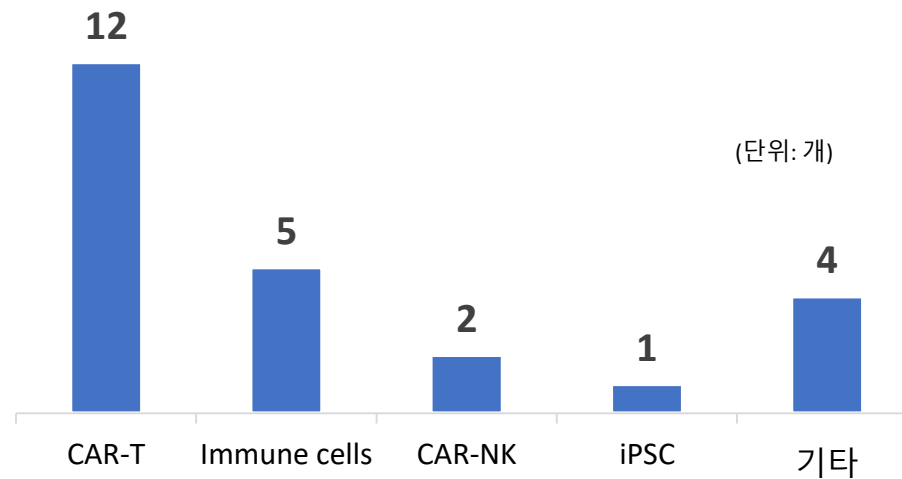
고형암(63%)에서 유전자치료제 유형



세포치료제
(세포치료제는 8%/암)



고형암(53%)에서 세포치료제 유형





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라이선스 인/아웃

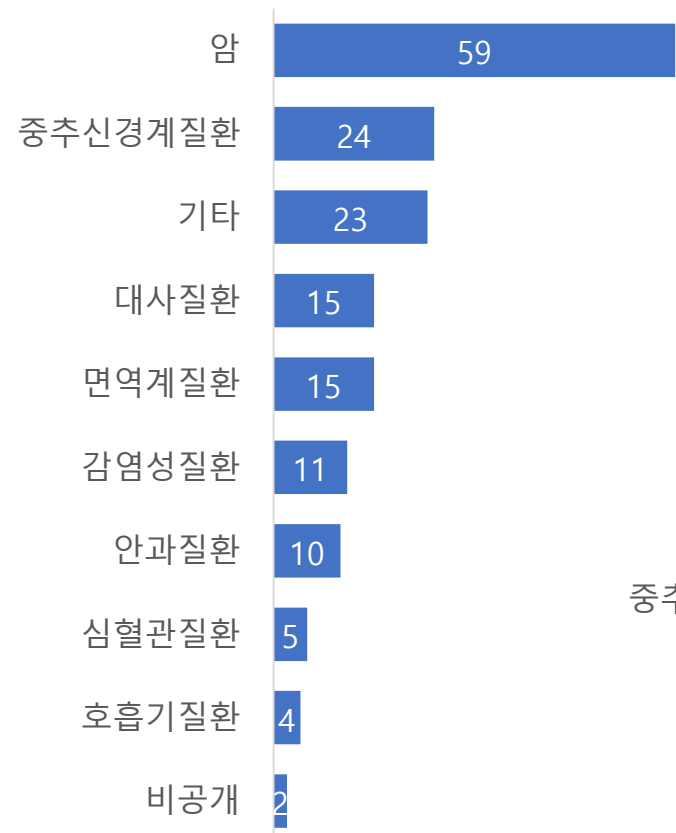
L/I (적응증별)

L/O (적응증별)

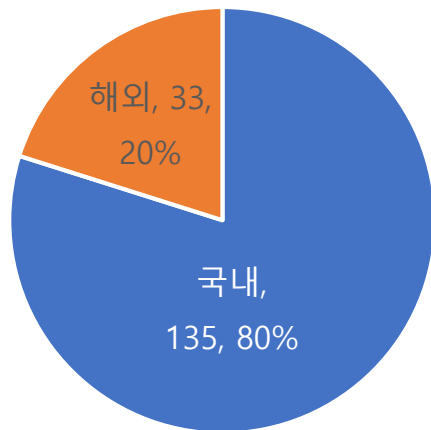
L/I (물질별)

L/O (물질별)

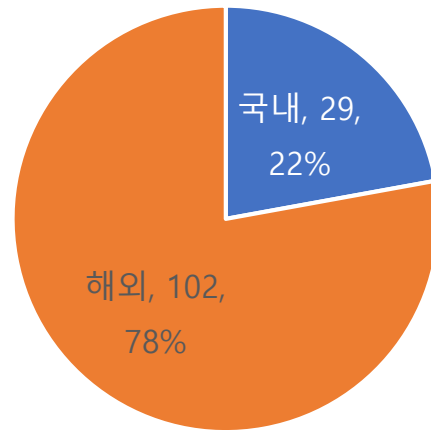
(단위: 건)



| L/I (국내/외)

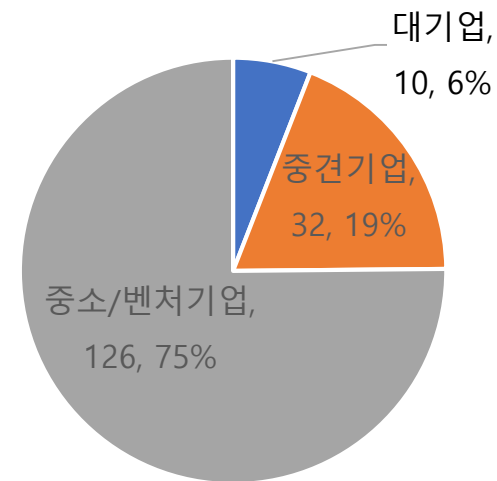


| L/O (국내/외)

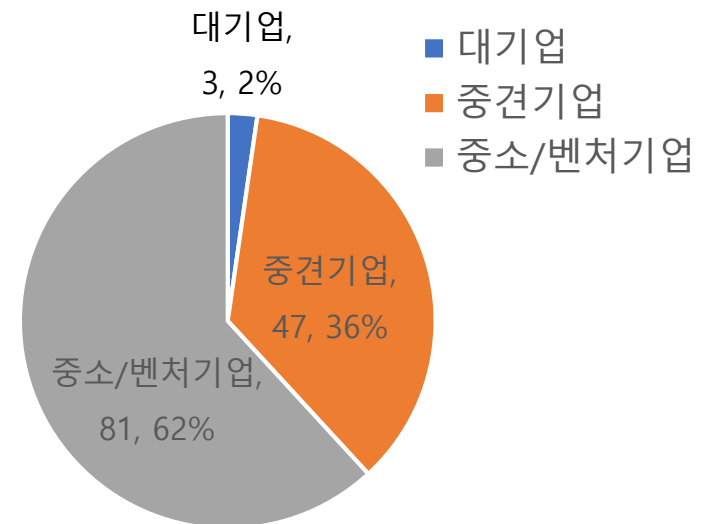


| L/I(기업규모별)

■ 국내
■ 해외



| L/O(기업규모별)



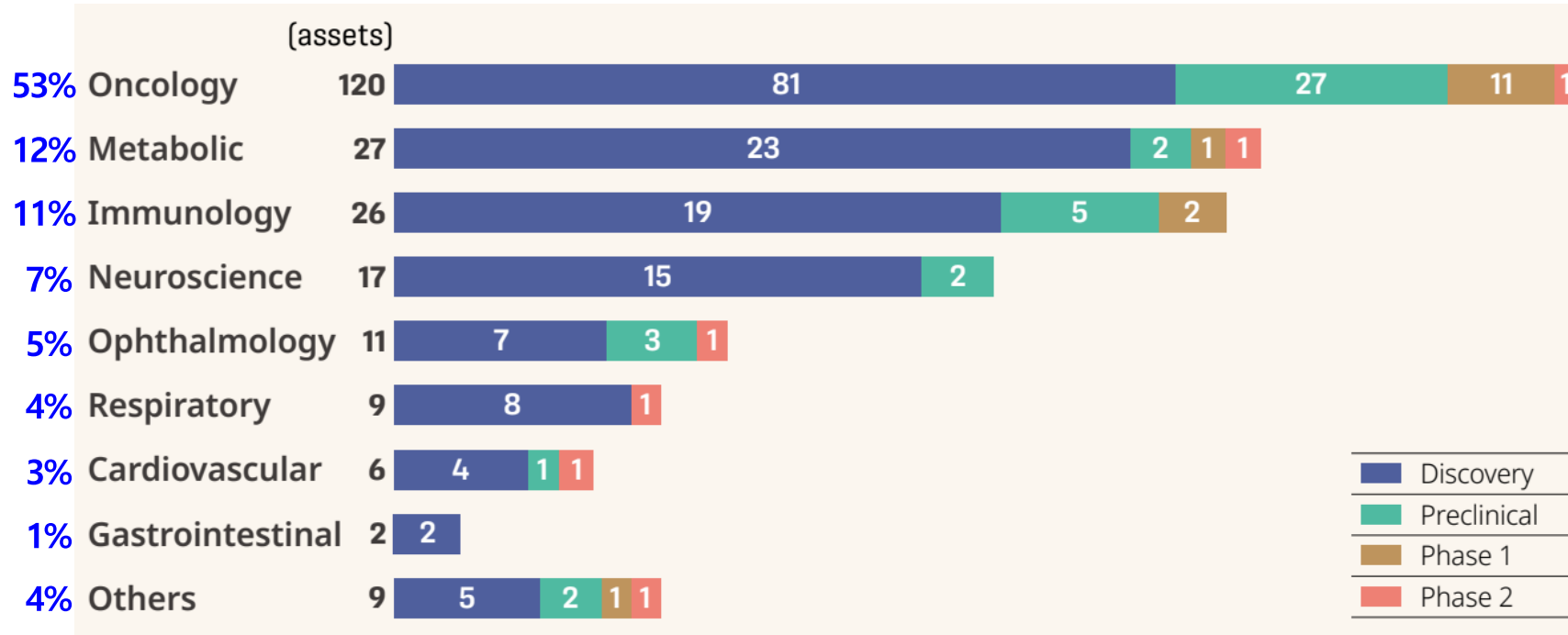


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KDDF 파이프라인(2021-2022)

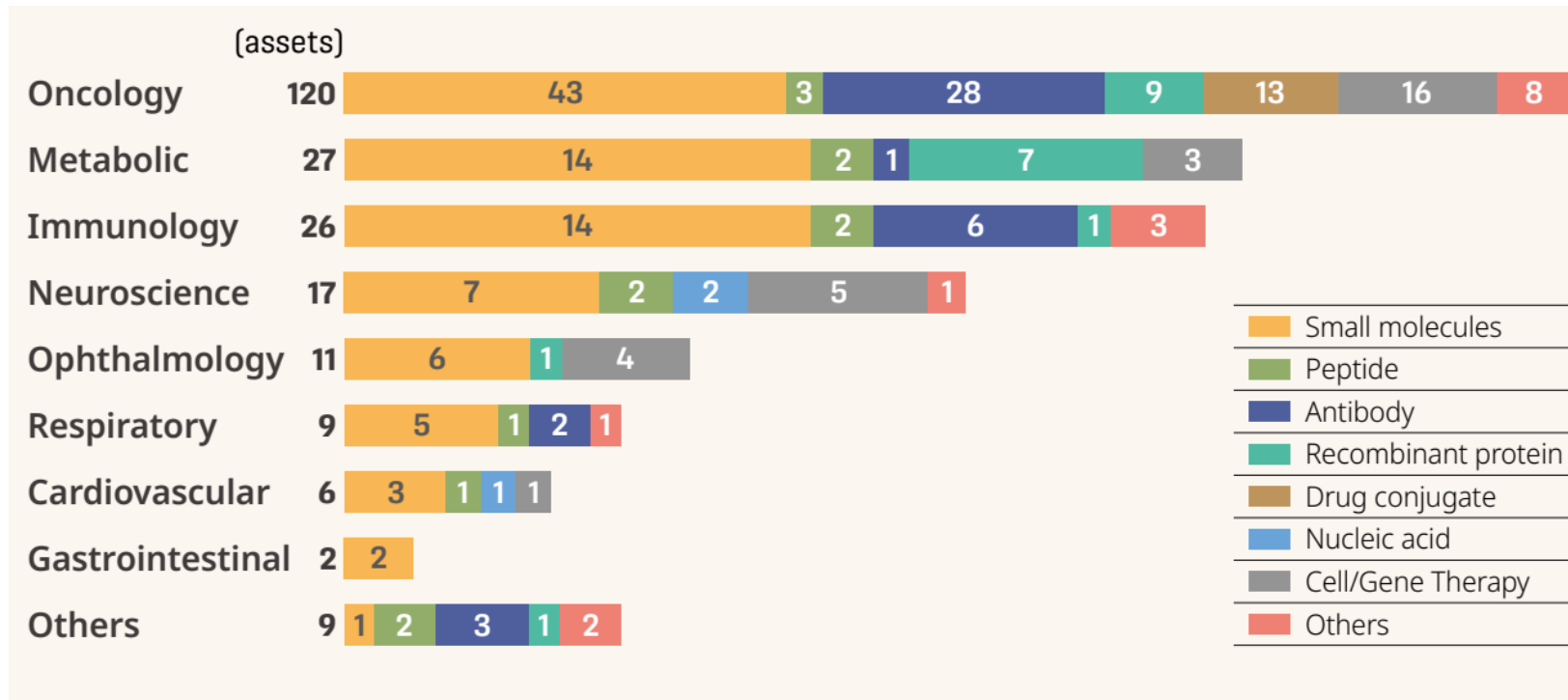


10대 글로벌 빅파마 파이프라인

질환분야	개수(개)	비율
Oncology	484	42.9%
Immunology	157	13.9%
Infectious	150	13.3%
Neuroscience	70	6.2%
Hematology	68	6.0%
Cardiovascular	31	2.8%
Metabolic	24	2.1%
Ophthalmology	30	2.7%
Renal	9	0.8%
Respiratory	11	1.0%
Gastrointestinal	7	0.6%
Musculoskeletal	3	0.3%
Dermatology	2	0.2%
Genitourinary	1	0.1%
Others	76	7.1%
합계	1,123개	100%

※ J&J, Pfizer, Roche, AbbVie, Novartis, MSD, GSK, BMS, Sanofi, Takeda (웹페이지, BioCentury, GlobalData)

KDDF 파이프라인(2021-2022)



10대 글로벌 빅파마 파이프라인

모달리티	개수(개)	비율
Small molecules	455	40%
Antibody	418	37%
Vaccine	72	6.4%
Protein	52	4.6%
ADC	45	4.0%
Cell Therapy	28	2.5%
Gene Therapy	20	1.8%
RNA	17	1.5%
Peptide	11	1.0%
Others	9	0.8%
합계	1,123개	100%

※ J&J, Pfizer, Roche, AbbVie, Novartis, MSD, GSK, BMS, Sanofi, Takeda (웹페이지, BioCentury, GlobalData)

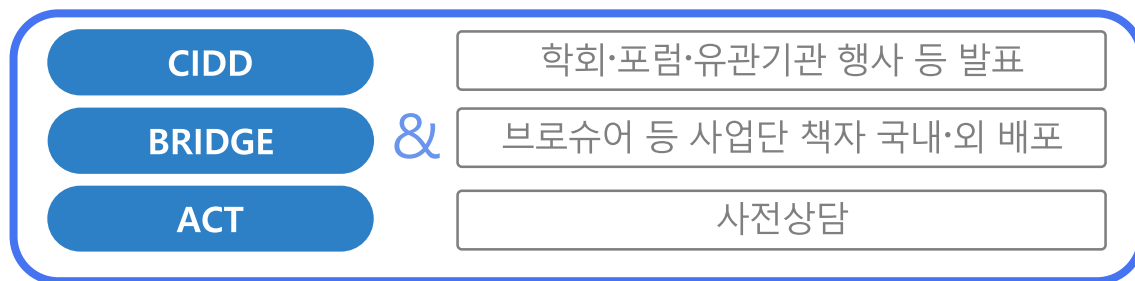
KDDF_신규 Modality, 신규 Target

신규 Modality, 신규 Target을 목표로 하는

“혁신신약 후보물질의 발굴”

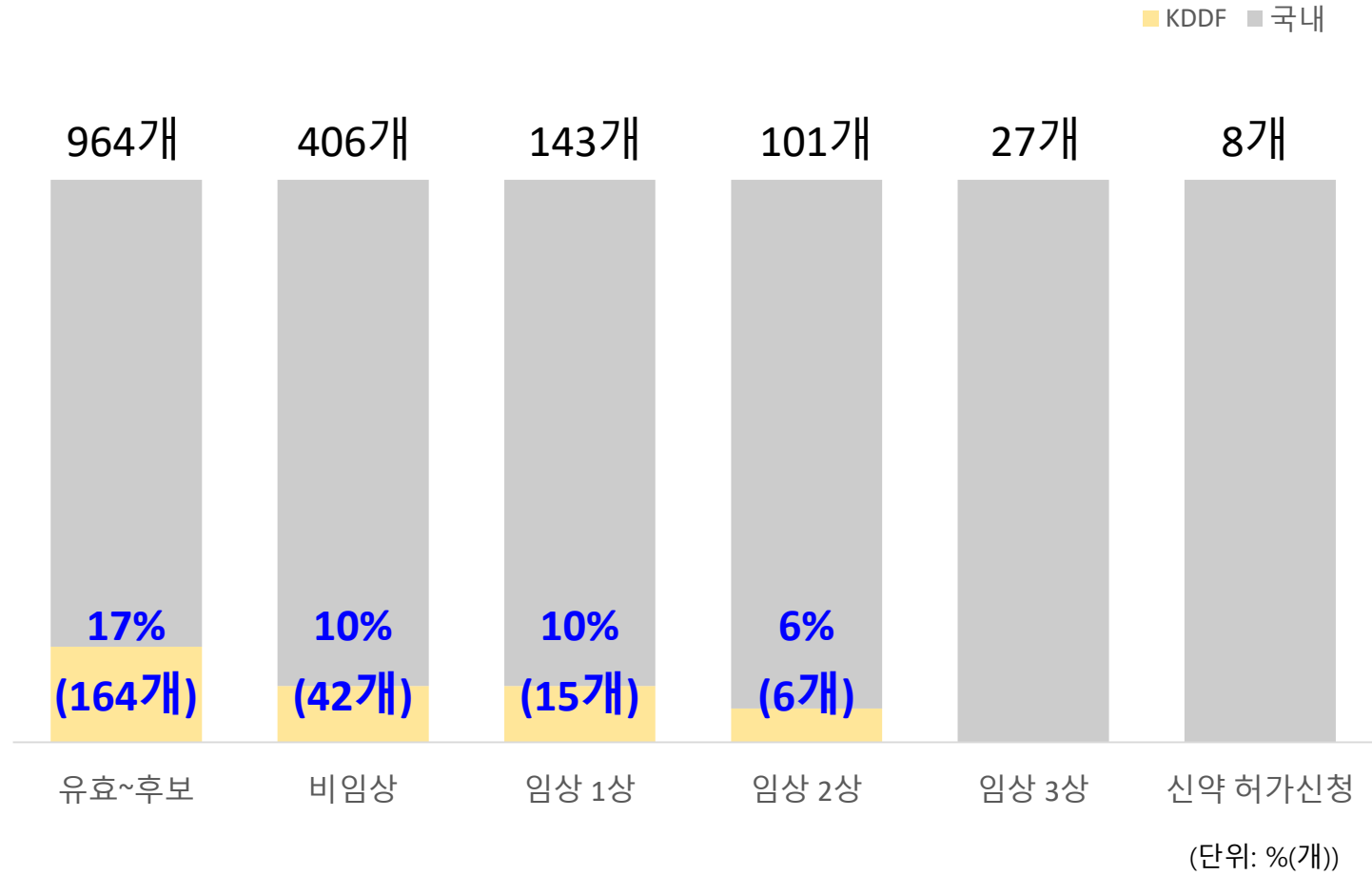
다수의 좋은 과제 선정
사업 성공 가능성 제고

개발단계	신규 T·M 과제 수			2021-2022년 선정과제 수	신규 T·M 비율
	신규 Target	신규 Modality	신규 Target or Modality		
유효·선도	49	23	66	123	53.7%
후보·비임상	17	10	24	83	28.9%
임상1상·임상2상	6	2	8	21	38.1%
합계	72	35	98	227	43.2%



성공적 과제 수행을 지원하여
글로벌 시장에서 경쟁력 있는
약물로 개발되도록 촉진

국내 파이프라인 및 KDDF 지원현황





감사합니다

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