2023 Q1 Methodology Update

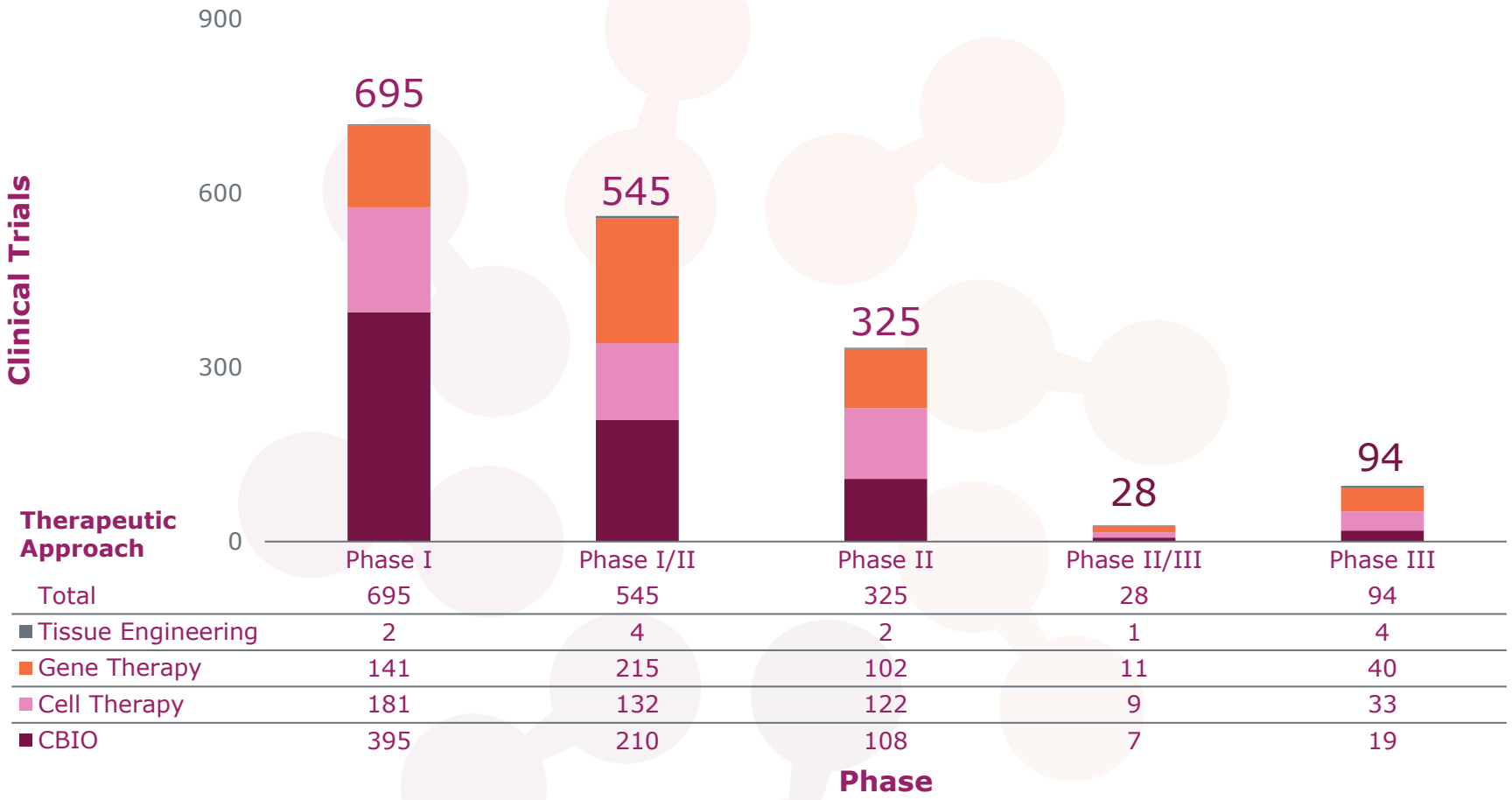
ARM is always looking for new ways to increase clarity in our data and reporting, better identify and follow sector trends, and create opportunities for positive impacts from and for our sector. In 2023, we have recently updated our approach to collecting sector data.

Alliance *for* Regenerative Medicine

As of Q1, ARM will begin by creating a baseline of cell and gene therapies with information available in the public domain (e.g., trial registries, developer websites, and scientific papers). Using these regenerative medicines as a baseline, we then curate our reports on their developers, the clinical trials that they are involved in, and related investments. This approach improved our sector data in multiple ways, including identifying over 200 new assets and increasing granularity in therapeutic approach classification, indications, development stages, and trial phases.

Along with this improved specificity, we have identified a group of clinical trials that ARM will no longer report on. To this end, we have removed nearly 400 trials from our reporting between 2022 FY and 2023 Q1. Removed trials involve minimally manipulated stem cells or are not linked with adequate details or relevant identifiers to ascertain official therapeutic development or drug profile. For example, assets identified only as "*natural killer cells*" are excluded, whereas "*NK cell therapy XY-2*" would be included. Notably, a majority of assets without available drug or pipeline identifiers are found in clinical trials with institutional sponsors.

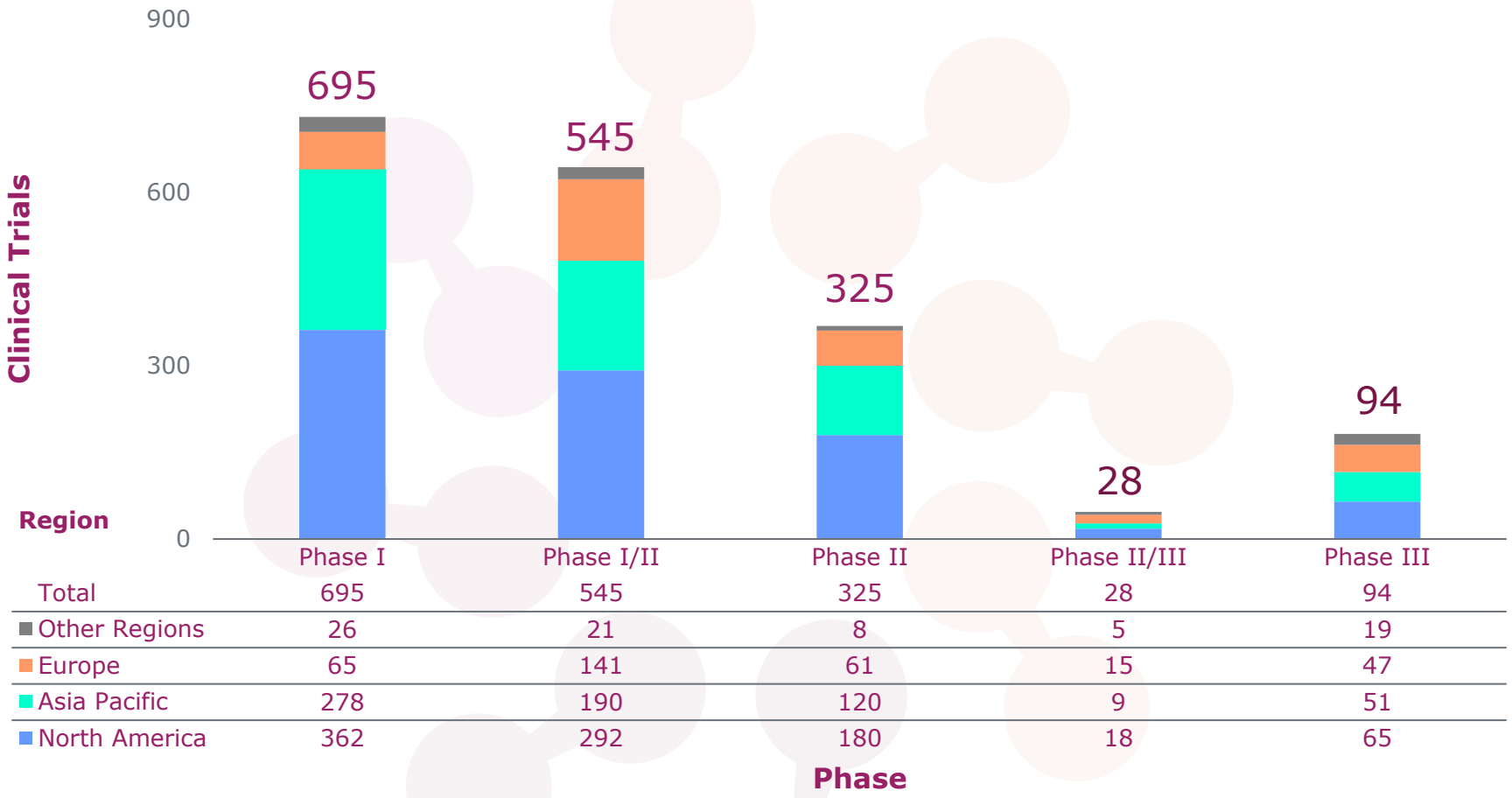
Ongoing Clinical Trials by Phase and Therapeutic Approach



Therapeutic Approach	Phase I	Phase I/II	Phase II	Phase II/III	Phase III
Total	695	545	325	28	94
Tissue Engineering	2	4	2	1	4
Gene Therapy	141	215	102	11	40
Cell Therapy	181	132	122	9	33
CBIO	395	210	108	7	19

1. Within-graph labels represent phase totals

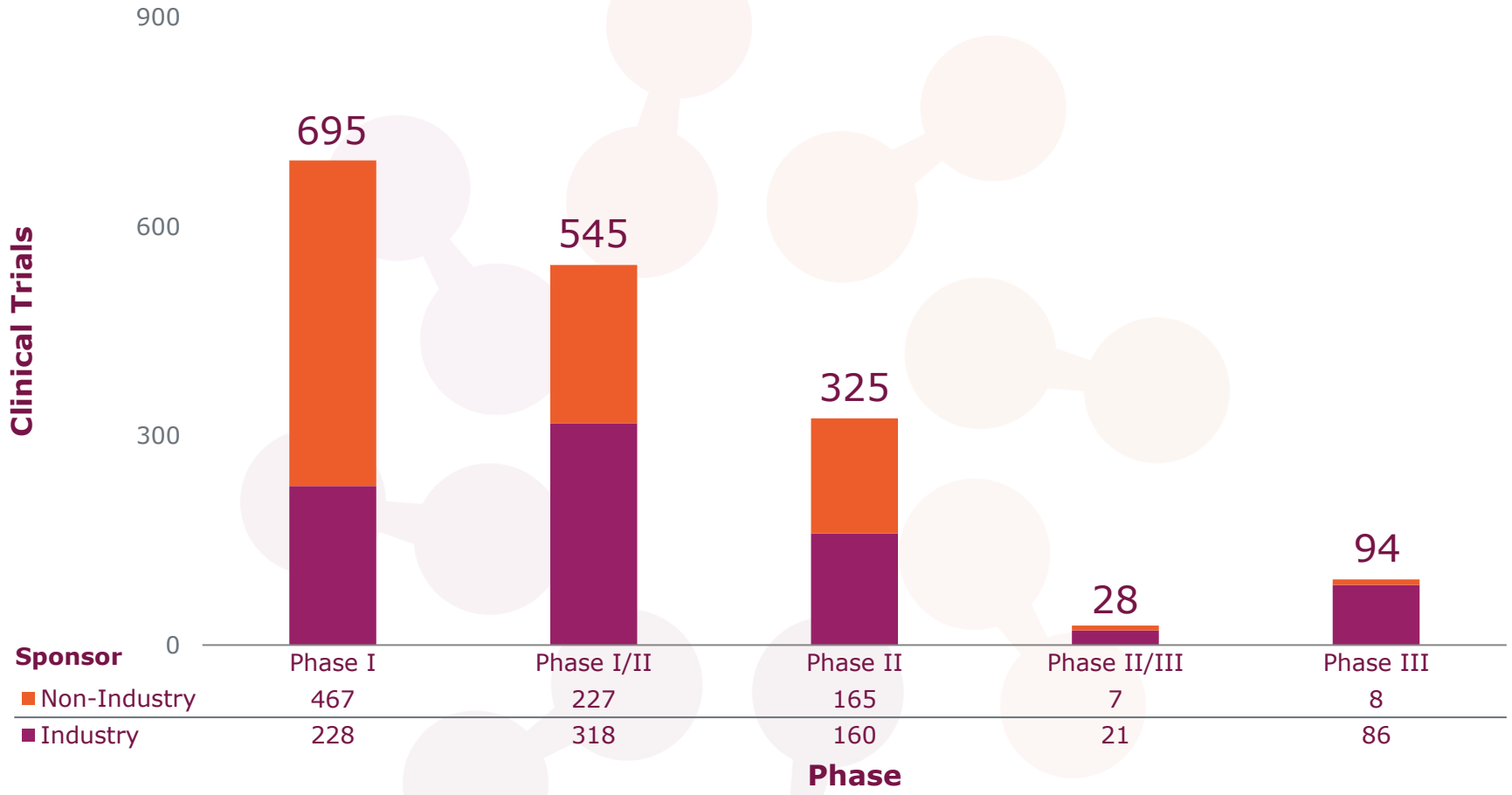
Ongoing Clinical Trials by Phase and Region



Region	Phase I	Phase I/II	Phase II	Phase II/III	Phase III
Total	695	545	325	28	94
Other Regions	26	21	8	5	19
Europe	65	141	61	15	47
Asia Pacific	278	190	120	9	51
North America	362	292	180	18	65

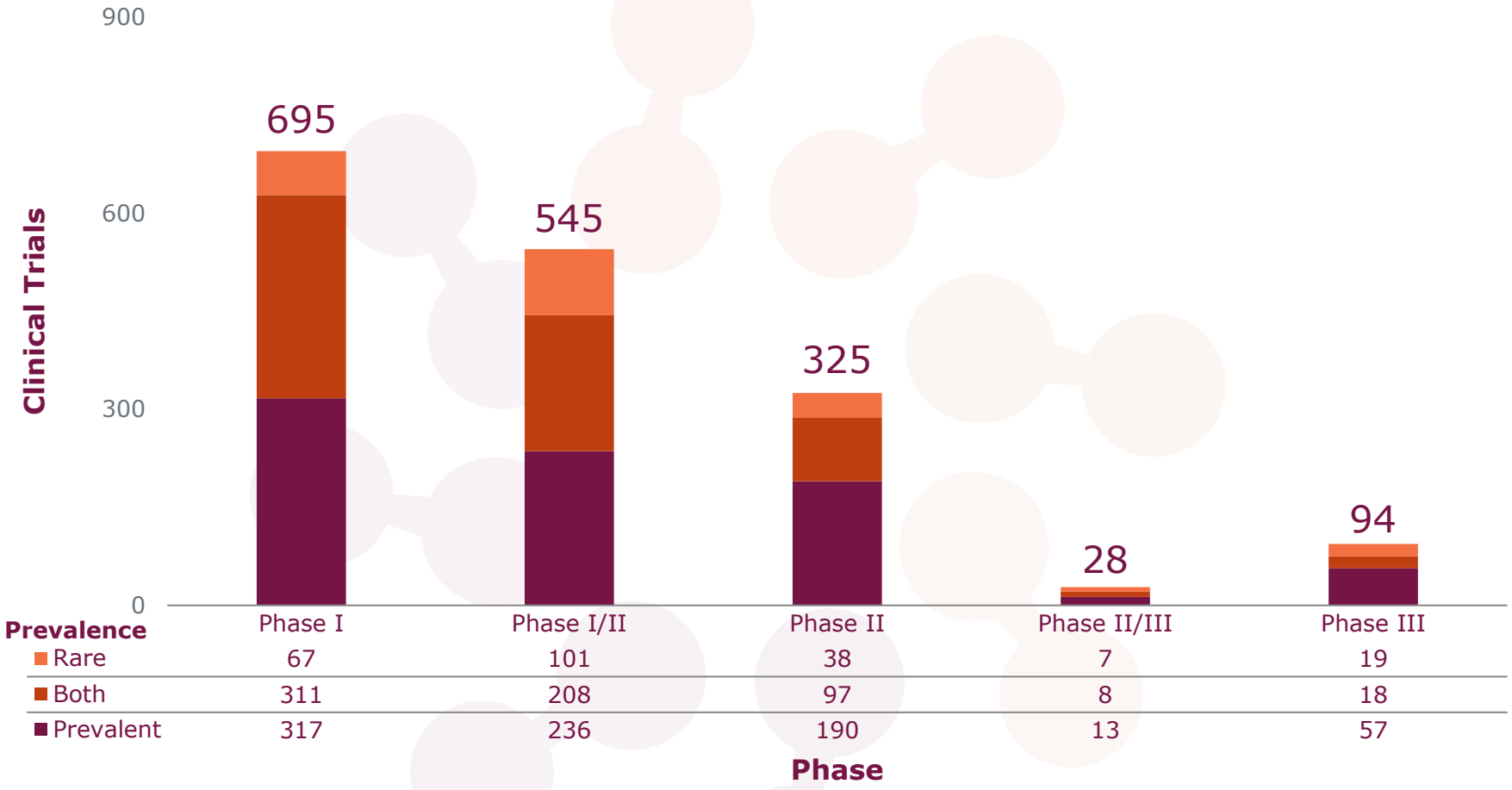
1. Within-graph labels represent phase totals
2. Clinical trials take place in multiple regions; sum of regional totals will not be equivalent to phase totals

Ongoing Clinical Trials by Phase and Sponsor



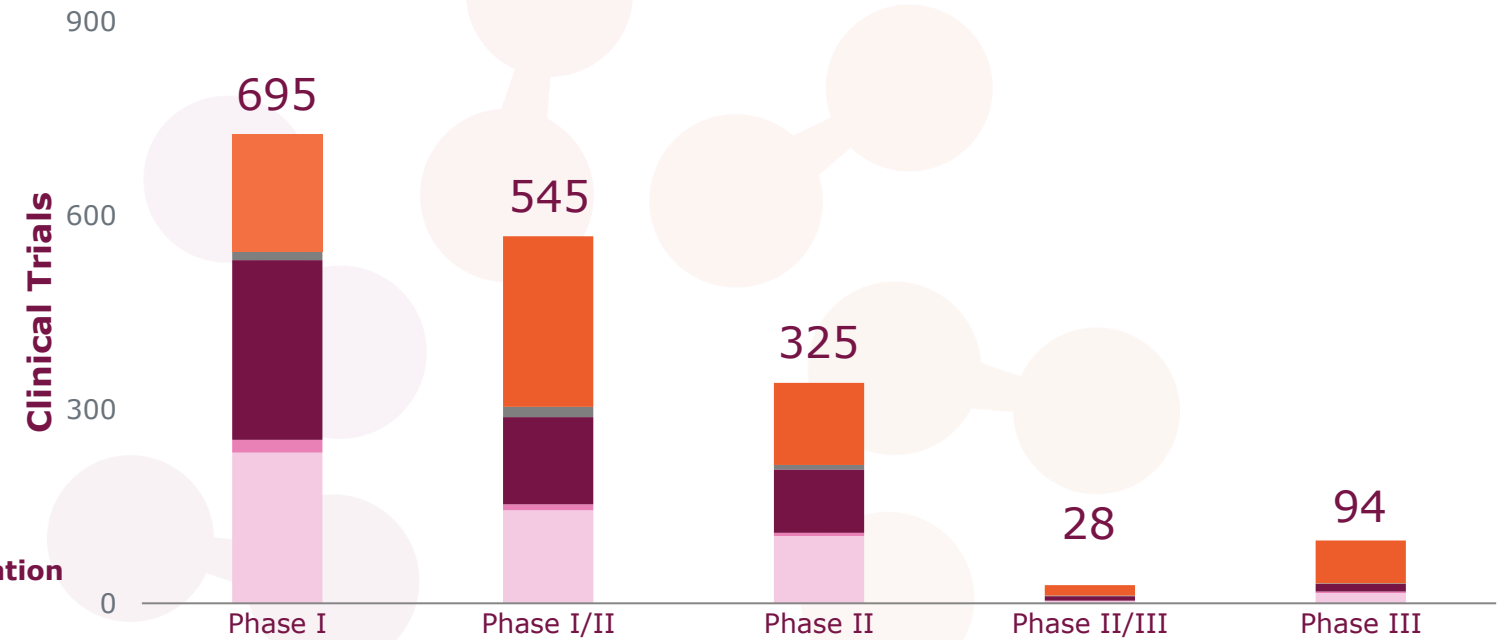
1. Within-graph labels represent phase totals
2. Non-industry includes academic and governement sponsors

Ongoing Clinical Trials by Phase and Prevalence



1. Within-graph labels represent phase totals

Ongoing Clinical Trials by Phase and Oncology Indication & Tumor Type

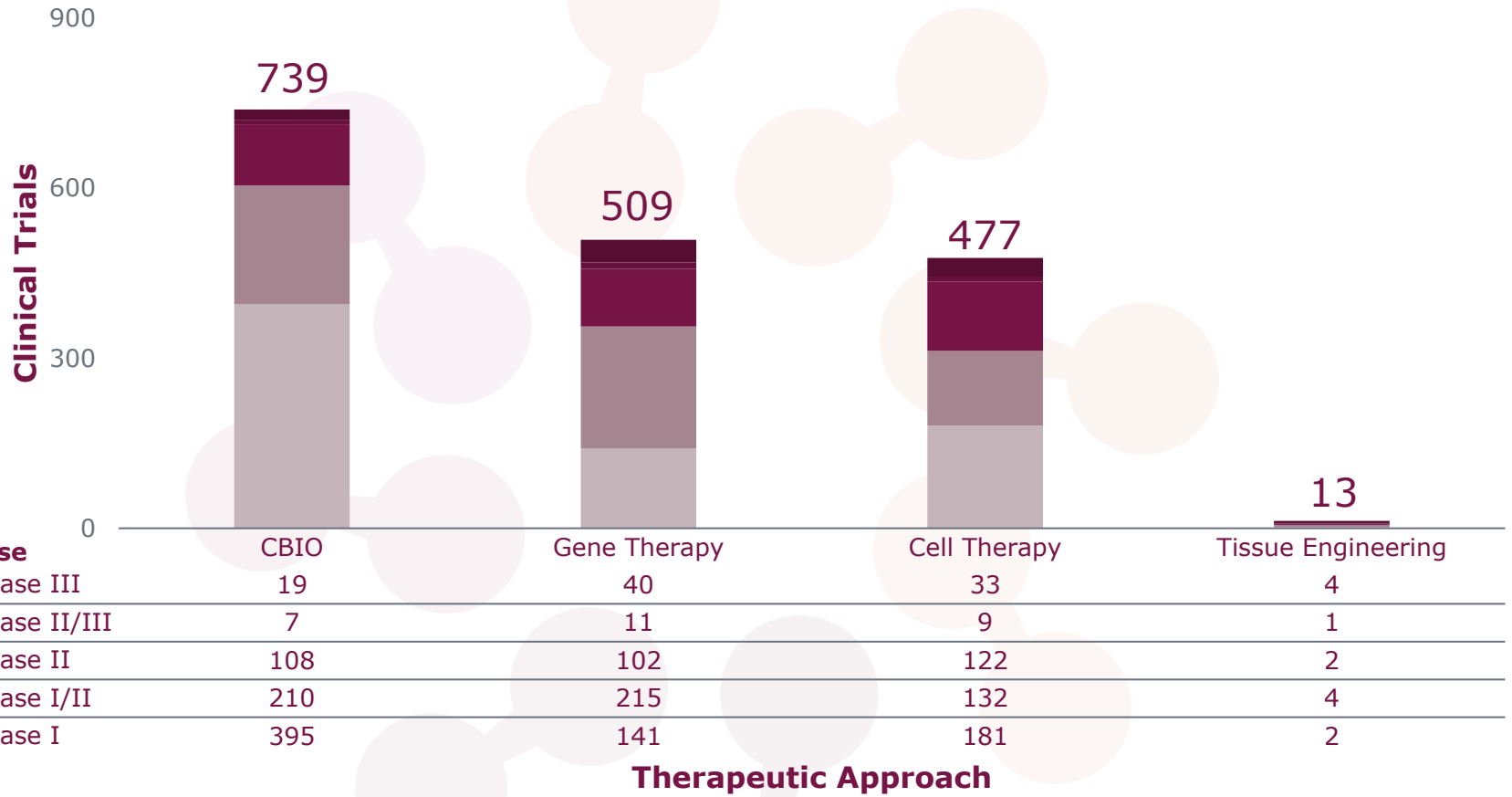


Oncology Indication & Tumor Type

	Phase I	Phase I/II	Phase II	Phase II/III	Phase III
Total	695	545	325	28	94
Non-Oncology	182	264	127	16	66
Unspecified	13	16	7	1	1
Solid Tumor	278	135	98	7	12
Both Tumor Types	20	9	5		2
Liquid Tumor	233	144	104	4	16

1. Within-graph labels represent phase totals

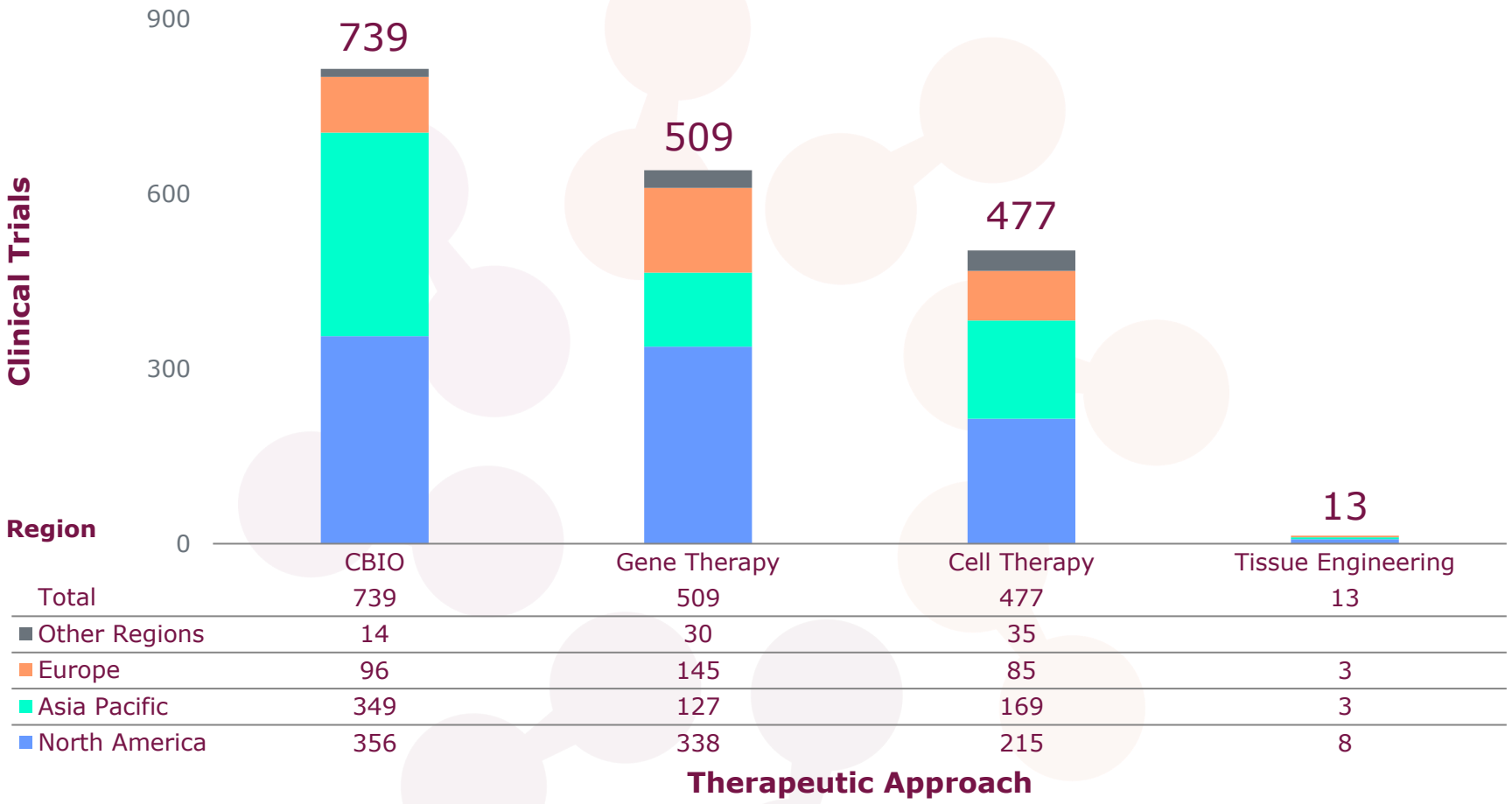
Ongoing Clinical Trials by Therapeutic Approach and Phase



Phase	CBIO	Gene Therapy	Cell Therapy	Tissue Engineering
Phase III	19	40	33	4
Phase II/III	7	11	9	1
Phase II	108	102	122	2
Phase I/II	210	215	132	4
Phase I	395	141	181	2

1. Within-graph labels represent therapeutic approach totals

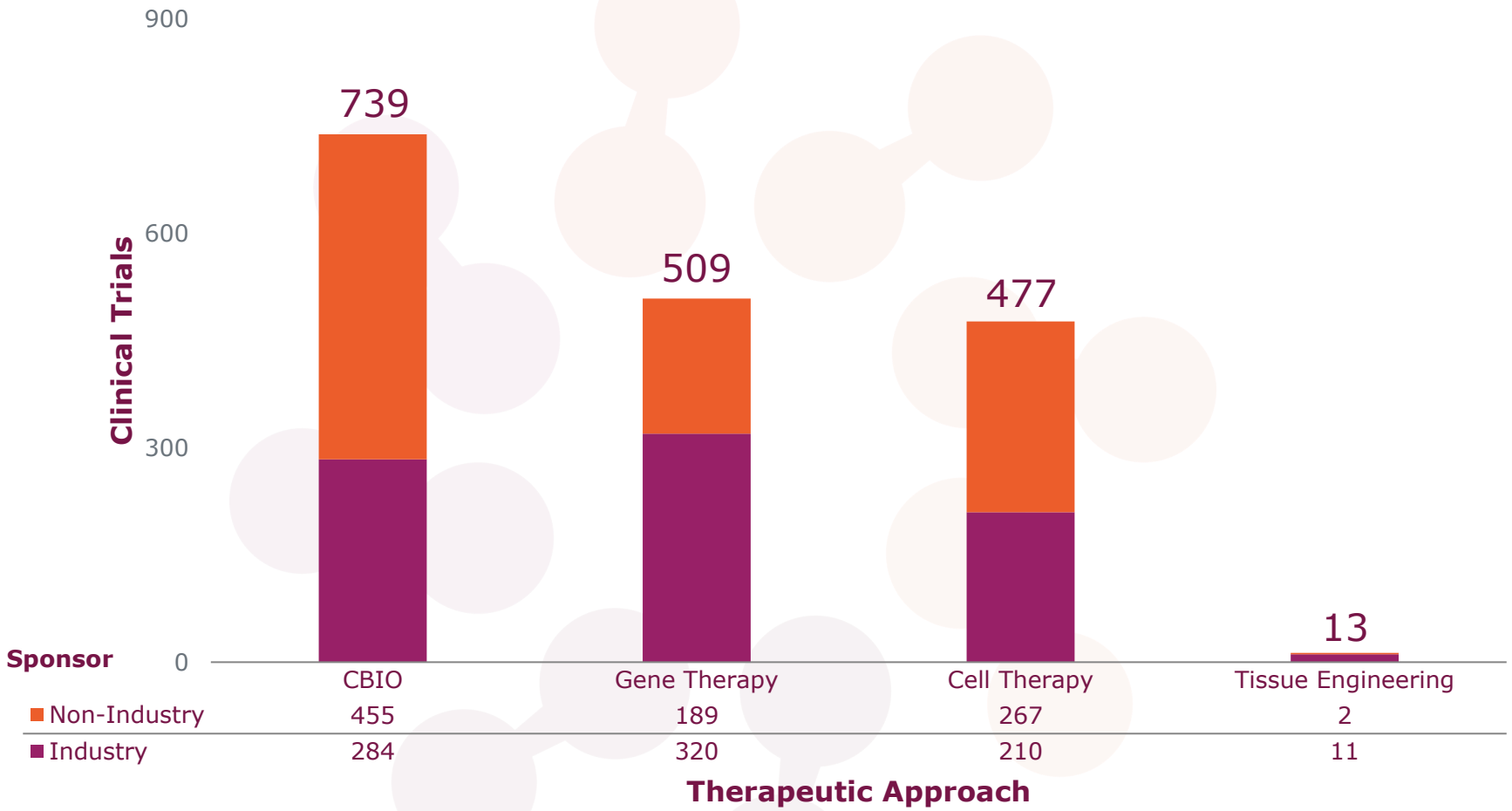
Ongoing Clinical Trials by Therapeutic Approach and Region



	CBIO	Gene Therapy	Cell Therapy	Tissue Engineering
Total	739	509	477	13
Other Regions	14	30	35	
Europe	96	145	85	3
Asia Pacific	349	127	169	3
North America	356	338	215	8

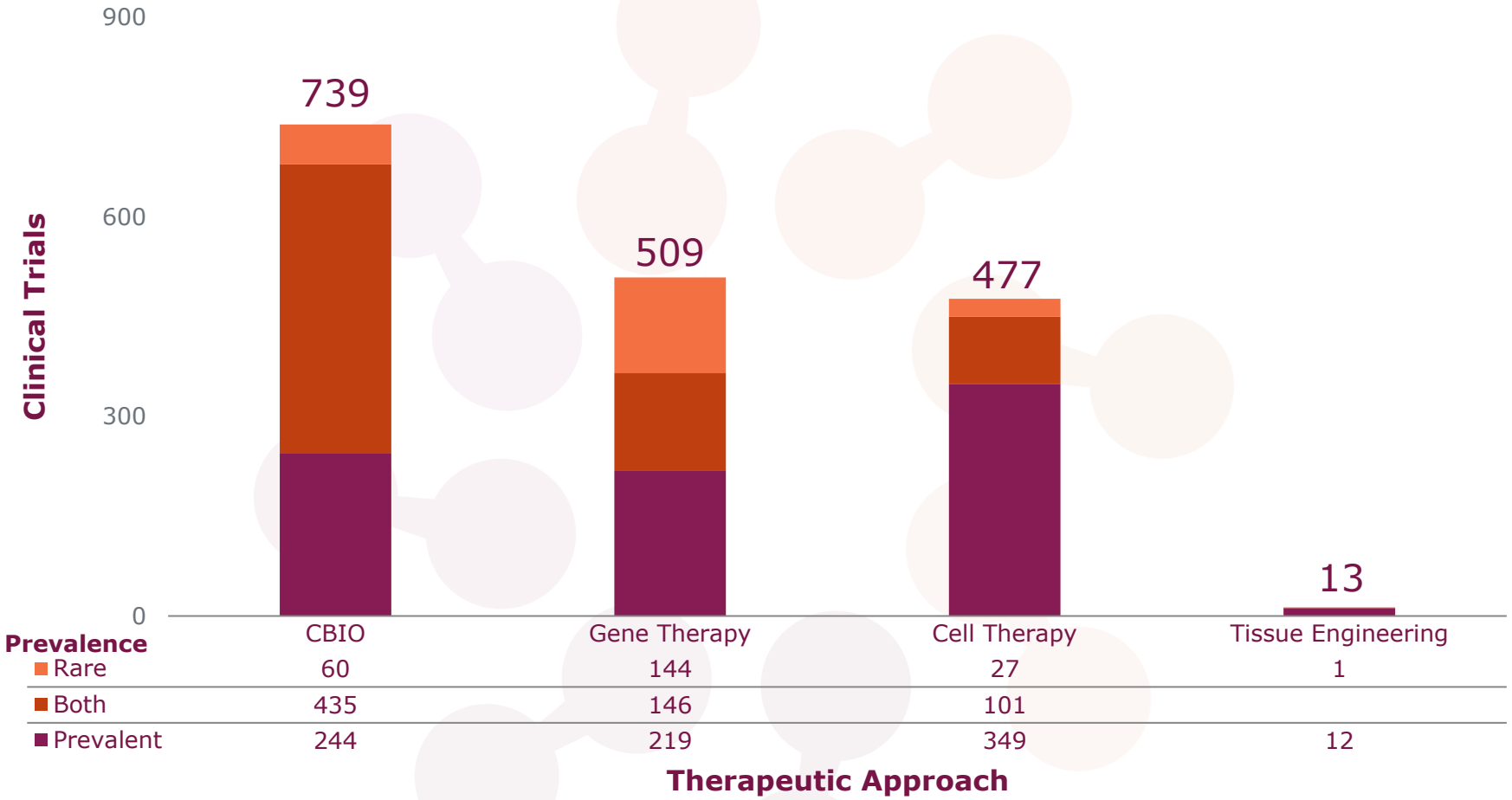
1. Within-graph labels represent therapeutic approach totals
2. Clinical trials take place in multiple regions; sum of regional totals will not be equivalent to therapeutic approach totals

Ongoing Clinical Trials by Therapeutic Approach and Sponsor



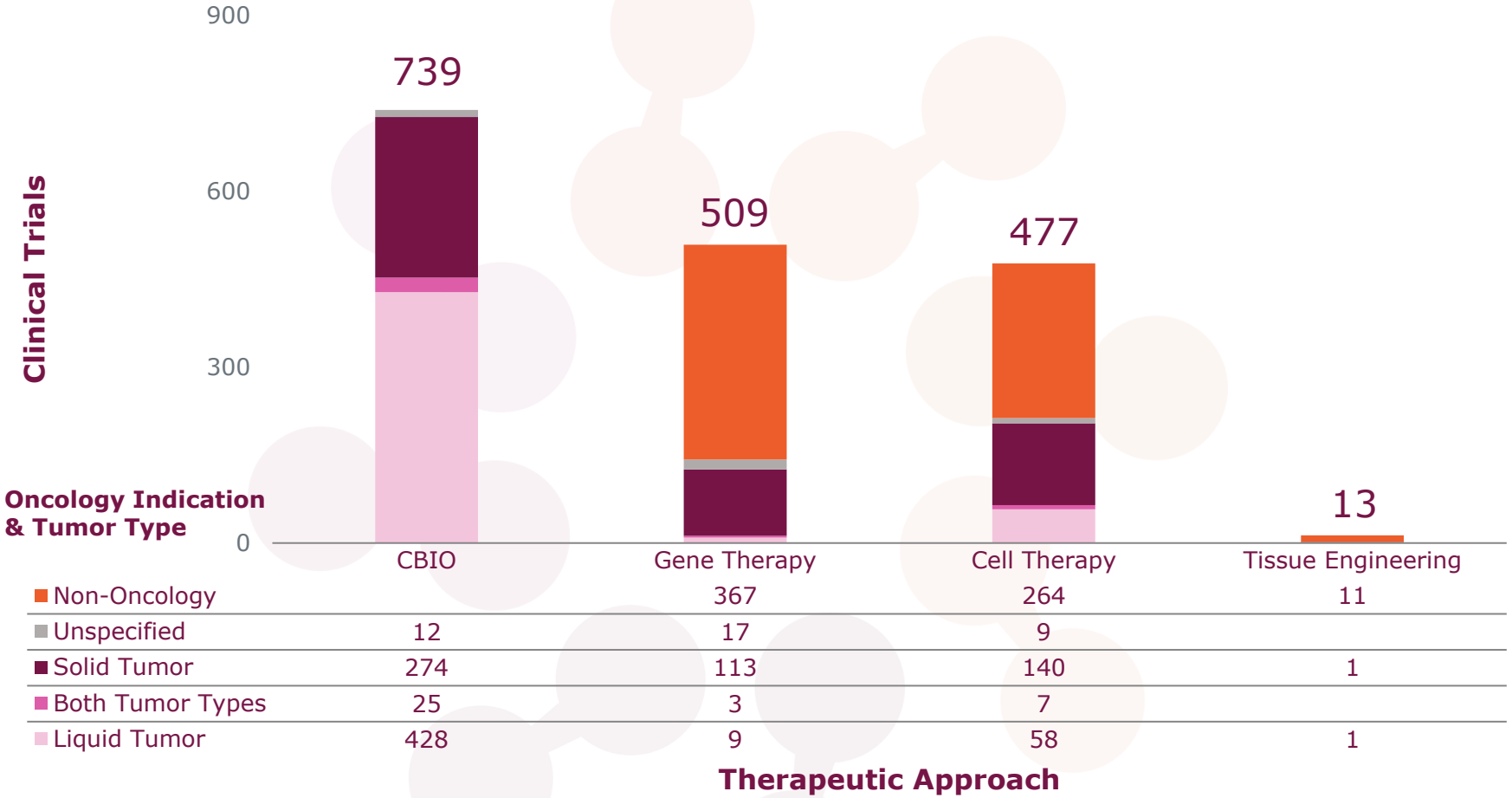
1. Within-graph labels represent therapeutic approach totals
2. Non-industry includes academic and governement sponsors

Ongoing Clinical Trials by Therapeutic Approach and Prevalence



1. Within-graph labels represent therapeutic approach totals

Ongoing Clinical Trials by Therapeutic Approach and Oncology Indication & Tumor Type



Oncology Indication & Tumor Type	CBIO	Gene Therapy	Cell Therapy	Tissue Engineering
Non-Oncology		367	264	11
Unspecified	12	17	9	
Solid Tumor	274	113	140	1
Both Tumor Types	25	3	7	
Liquid Tumor	428	9	58	1

1. Within-graph labels represent therapeutic approach totals

Methodology Notes for Clinical Trial Data

Methodology Notes

1. Clinical trial data represent a snapshot in time; this snapshot was taken in June 2023.

2. Clinical trials include trials in phases 1-3, active at any point in the calendar year.

3. Clinical trial regions are based on known site locations, which may change over time.

4. Clinical trials may have multiple site locations which may reside in a single region or span across multiple regions; the sum of clinical trials across regions will not be equivalent to the total number of trials.

5. *Trial sponsorship is based on GlobalData's categorization of entities: Industry = public or private entities; Nonindustry = government entities or institutions such as hospitals, medical centers, and facilities funded by not-for-profits.

6. *Oncology and prevalence classifications are based on GlobalData indentification of trial indications; many trials have multiple indications.

7. GlobalData's clasification of 'rare' indications or populations is based on US FDA and HIG Genetic and Rare Diseases Information Center (GARD) definitions (affecting <200,000 people in the US); 'rare' may not reflect different regional prevalences.

*Updated in 2023