

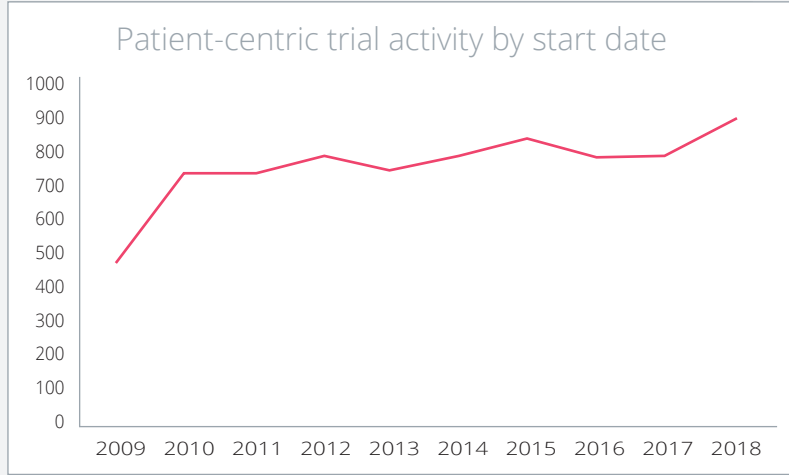
Snapshot of the patient-centric trial landscape

As the volume of the patient voice continues to grow within drug development, learn how **patient-centricity** has been playing out in clinical trial activities through Trialtrove

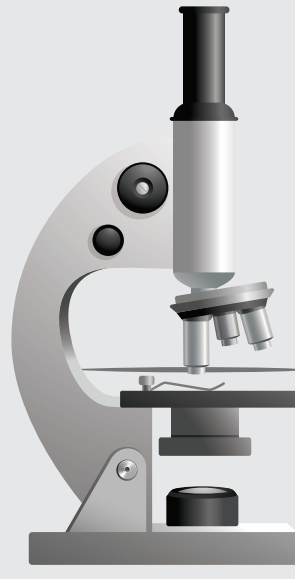
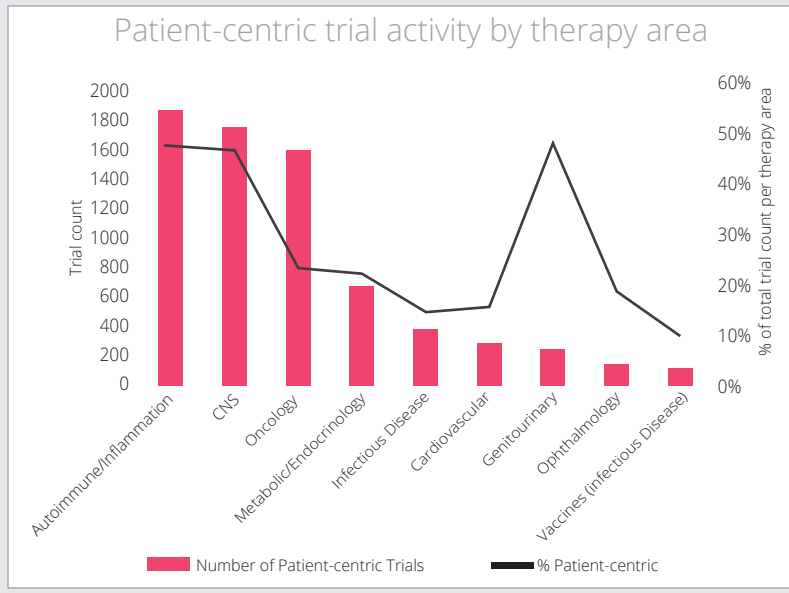
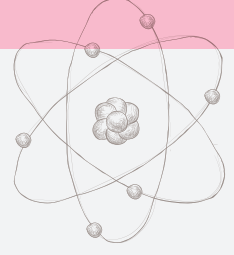


Overview of trends in Phase I/II – Phase III industry-sponsored clinical trials

In 2009, the FDA issued final guidance on the use of patient-reported outcome measures in clinical trials and how sponsors can use these tools to support labeling claims. Since then, patient-centric trial activity has been fairly stable and consistent.



The uptick in 2010 is also observed among non-patient centric trials, and likely reflects increased reporting of clinical trial activity across the board.



By **trial count**, Autoimmune/Inflammation, CNS, and Oncology lead the patient-centric pack.

But **by proportion**, Genitourinary has the highest percentage of patient-centric trials, followed by Autoimmune/Inflammation and CNS. This is driven by the nature of the diseases within these therapy areas, which have a high impact on overall patient quality of life and tap heavily into patient-reported outcomes

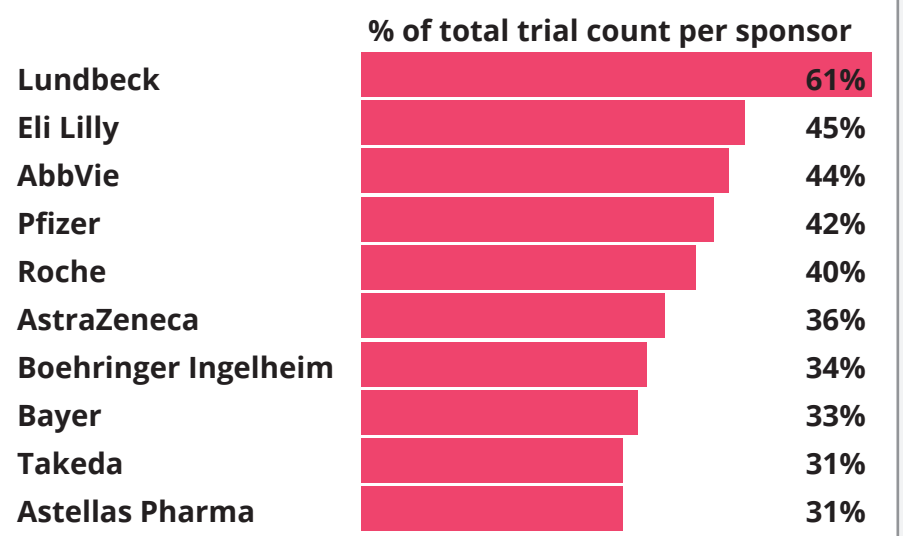
Diseases contributing to high proportion of patient-centric trials by therapy area

Therapy Area	Key Diseases
Genitourinary	Overactive Bladder, Benign Prostatic Hyperplasia, Menopausal Symptoms
Autoimmune/Inflammation	Rheumatoid Arthritis, Asthma, Osteoarthritis
CNS	Nociceptive Pain, Neuropathic Pain, Depression

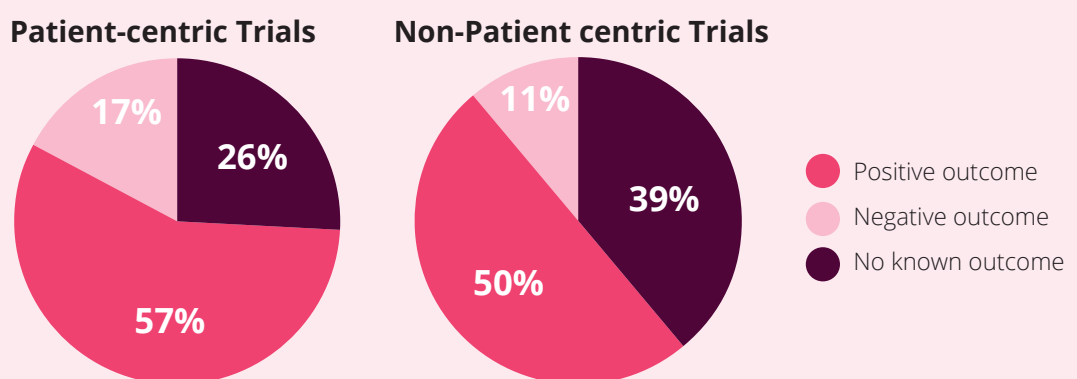
Top 10 industry sponsors for patient-centric trials (% of total trial count)

Lundbeck is the leading sponsor due to the company's investment in CNS indications, such as depression and schizophrenia.

Top sponsors list is also driven by the nature of the diseases targeted by these companies.



Does patient centricity improve trial outcomes?



A slightly higher percentage of patient-centric trials fall into the positive outcome category. A higher percentage of trials also fall into the negative outcome category for patient-centric trials. A much higher percentage of unreported outcomes is observed for non-patient centric trials. This could suggest that sponsors conducting patient-centric trials are doing a better job of getting trial data and final conclusions out into the public domain and to the patients.

Top 5 diseases areas reporting highest % of positive outcomes

Top diseases for patient-centric trials hovered around 80%, while non-patient centric trials had lower proportions in the 60th percentile.

Some differences in the distribution of diseases types are observed, but notably Type 2 Diabetes was in the top 5 for both trial cohorts.

Patient-centric Trials	
Disease	% Positive Outcome
Hemostasis/Hemophilia	82%
Uterine fibroids	81%
Type 2 Diabetes	79%
Anemia	76%
Hyperuricemia/Gout	75%

Non-patient centric Trials	
Disease	% Positive Outcome
COPD	64%
Type 2 Diabetes	63%
Intra-abdominal Infections	62%
Osteoporosis	60%
Respiratory Vaccines	60%

Source: Trialtrove® May 2019