The corresponding authors originated from 28 countries, but most were located in the United States (70/218; 32%) and Germany (43/218; 20%).

Medical devices

Most of the medical devices reported were instruments (86/218; 39%) or implants (79/218; 36%) (table 1). Devices were developed by industry alone (140/218; 64%), academia alone (46/218; 21%), or both (32/218; 15%).

Regulatory approvals

Of the 218 devices described in clinical studies, 99 (45%) ultimately received regulatory clearance or approval (table 2). These included 510(k) clearance (78/99; 79%), premarket approval (17/99; 17%), and humanitarian device exemption (4/99; 4%).

Regulatory clearance or approval was granted between April 1997 and September 2014. The median lag between publication of the clinical study and regulatory clearance or approval was 2 months (interquartile range −10.8 to 26.3 months). Of these, 43 devices (43/99; 43%) were actually cleared or approved before a clinical study was published; the median lag in these devices was −12.5 months (interquartile range −23.3 to −6.3 months).

Published clinical studies of devices that received regulatory clearance or approval were mostly case series' comprising level 4 evidence (89/99; 90%).

Statistical analysis

Devices were more likely to receive regulatory clearance or approval if developed by industry alone compared with academia alone (58% *v* 11%; P<0.001), or by both industry and academia compared with academia alone (41% *v* 11%; P=0.003). There was no significant difference in clearance or approval between devices developed by industry alone compared with both industry and academia (58% *v* 41%; P=0.114).

There was no significant difference in the proportion of 510(k) clearance and other approvals that were awarded to industry alone, industry and academia, or academia alone (P>0.1 in all cases).

Discussion

We identified a multitude of new medical devices in clinical studies, almost half of which received regulatory approval. The 510(k) pathway was most commonly used, and devices often received regulatory clearance before the first published clinical study. The corollary is that many devices cleared for use in patients had no clinical data accessible in the literature to support their use. Published clinical studies were mostly case series' comprising level 4 evidence. Without high quality clinical data available, informed shared decision making on the use of new medical devices is difficult if not impossible.

The 510(k) pathway is a fast track system that allows the regulatory approval of a device that is "substantially equivalent" to a predicate device. A device is considered substantially equivalent if it has the same intended use as the predicate device and it has the same technological characteristics, or, if it has different technological characteristics, information is provided that demonstrates that it is at least as safe and effective as the predicate device. Clinical studies are therefore not usually required.

The introduction of a device after it has been cleared through the 510(k) pathway is usually unstructured and variable.[2] A device may be introduced in the form of a research study but, more often, may be published as a non-comparative trial without special institutional board review. Although many such devices are safe and effective, the dangers of this process are obvious and have been reported.[10-13] The Balliol Collaboration has proposed the IDEAL model for safe innovation to deal

Table 1 | Characteristics of new medical devices, and whether they ultimately received regulatory clearance or approval, or not

Characteristics	Total (n=218)	Clearance or approval (n=99)	No clearance or approval (n=119)
Type of device:			
Imaging	31	11	20
Implant	79	37	42
Instrument	86	47	39
Laboratory analysis	3	1	2
Monitor	10	3	7
Physiotherapy	7	0	7
Other	2	0	2
Target specialty:			
Anesthesiology	5	2	3
Cardiovascular	67	40	27
Clinical chemistry	2	0	2
Clinical toxicology	1	0	1
Dental	2	0	2
Ear, nose, and throat	12	3	9
Gastroenterology and urology	19	7	12
General and plastic surgery	22	11	11
General hospital	8	2	6
Haematology	2	1	1
Neurology	15	6	9
Obstetrics and gynaecology	11	6	5
Ophthalmology	11	5	6
Orthopaedics	22	10	12
Physical medicine	6	0	6
Radiology	13	6	7

Table 2 | Development of new medical devices, and whether they ultimately received regulatory clearance or approval, and regulatory pathway used

Developer	Total (n=218)	Clearance or approval (n=99)	510k (n=78)	Premarket approval (n=17)	Humanitarian device exemption (n=4)
Academia alone	46	5	5	0	0
Academia and industry	32	13	10	1	2
Industry alone	140	81	63	16	2