CLINICAL TRIALS WATCH

In this factsheet, trials that were registered in 2011 and 2012 on the registry CTR-I have been analysed. Data for 2011 were collated up to November 2011 and up to November 2012 for 2012. 644 trials and 787 trials were found to be registered in 2011 and 2012 respectively up to the cut off date.

We found 2,905 trial sites for 2011, and 3,114 trial sites for 2012. This implies a dominance of multi-sited trials. The number of ethics committees is slightly less than the number of trials: 2,620 in 2011 and 2,778 in 2012. This implies that in some cases, one ethics committee is issuing approvals for more than one trial site.

A preliminary classification on study type for both the years is given below

Study type	**Number of trials**	
	2011	**2012**
Non-randomised, placebo-controlled trial	2	2
Single arm trial	90	152
Non-randomised, active-controlled trial	10	11
Non-randomised, multiple arm trial	14	10
Randomised parallel group trial	79	125
Randomised, parallel group, placebo-controlled trial	134	147
Randomised, parallel group, active-controlled trial	151	124
Randomised, parallel group, multiple arm trial	41	45
Randomised, crossover trial	23	29
Cluster randomised trial	5	8
Randomised factorial trial	3	5
Other	92	129
Total	**644**	**787**

It is quite clear that the gold standard for evidence generation, the randomised controlled trial (RCT) design is the favourite study design. There are 431 out of 644 trials in 2011, and 475 out of 787 trials in 2012 which employ this design. Use of a placebo in study design is extensive, with 134 trials in 2011 and 149 trials in 2012. Comparing the study molecule with an existing treatment -- the active control -- is also equally used, with 161 trials in 2011 and 135 trials in 2012. Please note that multiple arm trials which might employ both the active control and placebo controls are not counted in this. Single arm trials are also quite preferred with 90 trials for the year 2011 and 152 trials for 2012. It is quite intriguing to see 92 (2011) and 129 (2012) trials specified as other in study design.

An analysis of different phases of these trials is given in the table below.

Phase	**Number of trials**	
	2011	**2012**
1	13	34
2	81	112
3	174	191
4	113	91
1/2	16	13
2/3	29	22
3/4	15	10
Post-market surveillance	10	26
NA	193	288
Total	**644**	**787**

Phase 3, where there is a necessity to recruit a maximum number of patient-participants, has the maximum number of trials (174 for 2011 and 191 for 2012). Phase 4 also has a large number of trials. It was found that a large number of trials (193 for 2011 and 288 for 2012) are marked as "Phase not applicable". A preliminary analysis of this section of trials was done. There were 46 (2011) and 41 (2012) treatment trials in which a molecule was being tested. These also included a few safety and efficacy trials, comparison of treatments etc. 37(2011) and 23 (2012) trials were found to be testing treatment which employs devices, surgeries, invasive techniques, etc.

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