**S3 Table.** Characteristics of Paediatric Trials for New Medicines Initially Authorised for Adults Only in 2010-2014

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|  | **Authorised for adults only, no. (%)** |
| Total paediatric trials, n | 203 |
| Therapeutic area |  |
| Alimentary and metabolism | 32 (15.8%) |
| Blood | 18 (8.9%) |
| Cardiovascular | 12 (5.9%) |
| Genitourinary | 9 (4.4%) |
| Anti-infective | 29 (14.3%) |
| Antineoplastic and immunomodulatory | 44 (21.7%) |
| Neurologic | 41 (20.2%) |
| Respiratory | 2 (1.0%) |
| Musculoskeletal and others | 16 (7.9%) |
| PIP opinion year |  |
| 2008 | 30 (14.8%) |
| 2009 | 42 (20.7%) |
| 2010 | 40 (19.7%) |
| 2011 | 49 (24.1%) |
| 2012 | 35 (17.2%) |
| 2013 | 7 (3.5%) |
| Study type |  |
| PK/PD only | 41 (20.2%) |
| Primarily efficacy | 115 (56.7%) |
| Efficacy and safety | 10 (4.9%) |
| Primarily safety | 37 (18.2%) |
| Planned completion after MA |  |
| Yes | 179 (88.2%) |
| No | 24 (11.8%) |
| Any extension of completion date |  |
| Yes | 104 (51.2%) |
| No | 99 (48.8%) |
| Any modification (excl. extensions) |  |
| Yes | 122 (60.1%) |
| No | 81 (39.9%) |
| Orphan drug status |  |
| Yes | 23 (11.3%) |
| No | 180 (88.7%) |