Reporting of results of interventional studies by the information service of the National Institutes of Health

Tatyana Shamliyan
Division of Health Policy and Management, University of Minnesota School of Public Health, MN, USA

Abstract: The Food and Drug Administration Amendments Act of 2007 mandated that sponsors of applicable studies must provide results within one year of study completion. We aimed to analyze the factors associated with reporting of results from interventional studies registered on ClinicalTrials.gov. On May 20, 2010, we retrieved 20 available fields from 57,233 closed studies on the website and identified 31,161 interventional studies that were required to post results. We compared the proportion of studies with results versus studies without results by age, gender, and disease status of participants, by interventions, sponsors, phase of clinical trials, and completion dates. The results of studies were reported for 4.7% of applicable studies, 8% of industry-sponsored studies, 7.5% of Phase II and 6.5% of Phase IV clinical trials, 4.9% of drug studies, and 0% of genetic studies. Withdrawn (n = 486) and suspended (n = 414) interventions did not provide results. The percentage of studies with results varied from 0% to 21% among different sponsors. The first studies with results were completed in 1992. The proportion of studies with results increased over time. Completion dates were not available for 7446 studies. The database does not have fields available to facilitate routine analysis of the rate of compliance with federal law for posting results. The analysis of accuracy of the protocols in relation to the results and publications is not possible without time-consuming evaluation of individual postings and individual publications.

Keywords: registries, research standards, access to information, clinical trials, disclosure

Introduction
Transparency in designing, conducting, and reporting of human experiments and observational studies is essential to guarantee the integrity of clinical research. Registration of clinical trials with information about study sponsors and protocols makes clinical research more transparent. In 2000, the National Institutes of Health (NIH) requested that clinical trials assessing pharmacologic treatments for serious or life-threatening diseases be registered in the ClinicalTrials.gov online database. This website was developed by the National Library of Medicine as an information service for the NIH and the US Department of Health and Human Services. However, at that time, NIH policy did not require mandatory registration of all human studies. In 2005, the World Association of Medical Editors started to require mandatory registration of all clinical studies as a condition of publication. Sponsors must now provide the World Health Organization (WHO) with a minimum dataset of information, including details of study design, recruitment activities, ethics review of research, target sample size, conditions of eligibility for subjects to participate in the study, and primary and secondary outcomes. Stakeholders can find detailed information about study
Shamliyan protocols on ClinicalTrials.gov, but study results are not yet consistently available online.

Selective publication of positive results and outcomes\(^5\)–\(^7\) led to further scrutiny and called for public disclosure of study results. The Food and Drug Administration Amendments Act (FDAAA) of 2007 mandated that sponsors of applicable studies must provide study flow, baseline subject characteristics, and outcomes after active and control interventions within one year of study completion.\(^8\) The FDAAA regulations defined the following clinical trials as needing to adhere to the requirements: Phase II–IV interventional studies, studies involving any drugs, biological products, or medical devices regulated by the FDA, studies having at least one site in the US or which are conducted under an investigational new drug application or investigational device exemption; and studies initiated or ongoing as of September 27, 2007, or later.\(^9\)–\(^12\) Results can be posted within three years of completion of the study for trials investigating off-label use of previously approved drugs.

Registration of clinical trials on ClinicalTrials.gov improved the transparency of clinical research tremendously.\(^13\)–\(^15\) Stakeholders can find the WHO minimum dataset for the design of 92,385 studies.\(^16\) Harvard University has recognized the achievement of this website with their Innovations in American Government Award.\(^17\) The degree of sponsor compliance with federal law in providing results of studies on ClinicalTrials.gov has not been examined as yet.

We aimed to examine the completeness of the posted study designs and factors associated with reporting study results.

**Methods**

We retrieved all closed studies from ClinicalTrials.gov as of May 20, 2010. We retrieved all 20 available fields, including

**Table 1** Distribution of the studies closed in www.clinicaltrials.gov on 20 May 2010

| Category            | Frequency | Percentage |
|---------------------|-----------|------------|
| **Age**             |           |            |
| Adult               | 10,254    | 17.92      |
| Adult/senior        | 32,678    | 57.1       |
| Child               | 3428      | 5.99       |
| Child/adult         | 2544      | 4.44       |
| Child/adult/senior  | 8158      | 14.25      |
| Senior              | 171       | 0.3        |
| **Gender**          | Frequency missing (n = 393) |
| Both                | 48,224    | 84.84      |
| Female              | 5408      | 9.51       |
| Male                | 3208      | 5.64       |
| **Funding sources** |           |            |
| Industry            | 22,288    | 38.94      |
| Industry with other funding sources | 4835 | 8.45 |
| **Recruitment**     |           |            |
| Active, not recruiting | 13,751   | 24.03      |
| Approved for marketing | 16      | 0.03       |
| Completed           | 36,992    | 64.63      |
| Enrolling by invitation | 1330    | 2.32       |
| No longer available | 24        | 0.04       |
| Suspended           | 587       | 1.03       |
| Temporarily not available | 7  | 0.01 |
| Terminated          | 3554      | 6.21       |
| Withdrawn           | 685       | 1.2        |
| Withheld            | 287       | 0.5        |
| **Study types**     | Frequency missing (n = 287) |
| Expanded access     | 47        | 0.08       |
| Interventional      | 48,859    | 85.8       |
| Observational       | 8040      | 14.12      |
| **Recruitment**     |           |            |
| Active, not recruiting | 13,751   | 24.03      |
| Approved for marketing | 16      | 0.03       |
| Completed           | 36,992    | 64.63      |
| Enrolling by invitation | 1330    | 2.32       |
| No longer available | 24        | 0.04       |
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| Terminated          | 3554      | 6.21       |
| Withdrawn           | 685       | 1.2        |
| Withheld            | 287       | 0.5        |
| **Study results**   | Frequency missing (n = 16,589) |
| Has results         | 1793      | 3.13       |
| No results available | 55,440   | 96.87      |
| **Phases**          | Frequency missing (n = 16,589) |
| Phase 0             | 176       | 0.43       |
| Phase I             | 7163      | 17.62      |
| Phase II            | 12,775    | 31.43      |
| Phase III           | 10,657    | 26.22      |
| Phase II–III        | 1182      | 2.91       |
| Phase IV            | 6488      | 15.96      |
| Phase I–II          | 2203      | 5.42       |

(Continued)
### Table 2 Age and gender distribution of the interventional, active, not recruiting studies applicable to reporting the results (Phase 0–I excluded)

| Age            | Gender | Has results | No results available | n   | Percentage with results |
|----------------|--------|-------------|----------------------|-----|------------------------|
| Adult          | Both   | 151         | 3807                 | 3958| 3.82                   |
|                | Female | 39          | 876                  | 915 | 4.26                   |
|                | Male   | 6           | 410                  | 416 | 1.44                   |
|                | Total  | 196         | 5093                 | 5289| 3.71                   |
| Adult/senior   | Both   | 787         | 15,719               | 16,506| 4.77                  |
|                | Female | 46          | 1348                 | 1394| 3.30                   |
|                | Male   | 28          | 708                  | 736 | 3.80                   |
|                | Total  | 861         | 17,775               | 18,636| 4.62                  |
| Child          | Both   | 157         | 1951                 | 2108| 7.45                   |
|                | Female | 6           | 34                   | 40  | 15.00                  |
|                | Male   | 0           | 31                   | 31  | 0.00                   |
|                | Total  | 163         | 2016                 | 2179| 7.48                   |
| Child/adult    | Both   | 30          | 1066                 | 1096| 2.74                   |
|                | Female | 10          | 151                  | 161 | 6.21                   |
|                | Male   | 1           | 23                   | 24  | 4.17                   |
|                | Total  | 41          | 1240                 | 1281| 3.20                   |
| Child/adult/senior | Both  | 113         | 2987                 | 3100| 3.65                   |
|                  | Female | 12          | 385                  | 397 | 3.02                   |
|                  | Male   | 4           | 119                  | 123 | 3.25                   |
|                  | Total  | 129         | 3491                 | 3620| 3.56                   |
| Senior         | Both   | 4           | 82                   | 86  | 4.65                   |
|                | Female | 0           | 8                    | 8   | 0.00                   |
|                | Male   | 0           | 0                    | 0   |                        |
|                | Total  | 4           | 90                   | 94  | 4.26                   |

### Table 3 Funding distribution, phases, and completion status of the interventional, active, not recruiting studies applicable to reporting of results (Phase 0–I excluded)

| Funding source                      | Has results | No results available | n   | Percentage with results |
|-------------------------------------|-------------|----------------------|-----|------------------------|
| Total                               | 1394        | 29,767               | 31,161| 4.47                   |
| Industry                            | 1126        | 12,789               | 13,915| 8.09                   |
| Industry with other sources         | 72          | 2644                 | 2716 | 2.65                   |
| National Institutes of Health       | 23          | 2214                 | 2237 | 1.03                   |
| Other/National Institutes of Health | 19          | 1367                 | 1386 | 1.37                   |
| Other/unknown                       | 15          | 840                  | 855  | 1.75                   |
| Network/National Institutes of Health| 2           | 665                  | 667  | 0.30                   |
| US Federal                          | 5           | 444                  | 449  | 1.11                   |
| National Institutes of Health/other | 0           | 366                  | 366  | 0.00                   |
| **Phases**                          |             |                      |     |                        |
| Total                               | 1268        | 23,268               | 24,536| 5.17                   |
| Phase I–II                          | 26          | 1444                 | 1470 | 1.77                   |
| Phase II                            | 283         | 8788                 | 9071 | 3.12                   |
| Phase II–III                        | 19          | 798                  | 817  | 2.33                   |
| Phase III                           | 613         | 7555                 | 8168 | 7.50                   |
| Phase IV                            | 327         | 4683                 | 5010 | 6.53                   |
| Frequency missing (n = 6625)        |             |                      |     |                        |
| **Completion status**               |             |                      |     |                        |
| Completed                           | 1243        | 25,390               | 26,633| 4.67                   |
| Enrolling by invitation             | 0           | 768                  | 768  | 0.00                   |
| Suspended                           | 0           | 414                  | 414  | 0.00                   |
| Terminated                          | 151         | 2709                 | 2860 | 5.28                   |
| Total                               | 1394        | 29,767               | 31,161| 4.47                   |
| Withdrawn                           | 0           | 486                  | 486  | 0.00                   |
the ClinicalTrials.gov identifier, age group, gender, disease status of the eligible subjects, and examined interventions, recruitment status, study sponsors, study type and design, phase of clinical trials, start and completion dates, and posting of study results. Field locations were as described online at http://prsinfo.clinicaltrials.gov/definitions.html. We used the exact data provided by the sponsors. We further categorized interventions as behavioral, biological, device, dietary supplements, disease management, drug, education, genetic, procedural, and exercise. We also redefined

Table 4 Distribution of conditions of subjects in closed interventional, active, not recruiting studies applicable to reporting of results (Phase 0–1 excluded)

| Conditions                        | Has results | No results available | n     | Percentage with results |
|-----------------------------------|-------------|----------------------|-------|-------------------------|
| Total                             | 1394        | 29,763               | 31,157| 4.47                    |
| **Largest number with results**   |             |                      |       |                         |
| Diabetes                          | 99          | 1378                 | 1477  | 6.70                    |
| Hypertension                      | 35          | 435                  | 470   | 7.45                    |
| Human immunodeficiency virus      | 33          | 1165                 | 1198  | 2.75                    |
| Asthma                            | 30          | 513                  | 543   | 5.52                    |
| **Largest number closed studies** |             |                      |       |                         |
| Breast cancer                     | 16          | 490                  | 506   | 3.16                    |
| Schizophrenia                     | 18          | 431                  | 449   | 4.01                    |
| Pain                              | 13          | 342                  | 355   | 3.66                    |
| Obesity                           | 4           | 351                  | 355   | 1.13                    |
| Leukemia                          | 4           | 319                  | 323   | 1.24                    |
| Lymphoma                          | 2           | 320                  | 322   | 0.62                    |
| Prostate cancer                   | 12          | 301                  | 313   | 3.83                    |
| Osteoarthritis                    | 13          | 245                  | 258   | 5.04                    |
| Influenza                         | 25          | 232                  | 257   | 9.73                    |
| Cardiovascular disease            | 3           | 233                  | 236   | 1.27                    |
| Colorectal cancer                 | 2           | 233                  | 235   | 0.85                    |
| Rheumatoid arthritis              | 12          | 219                  | 231   | 5.19                    |
| Major depression                  | 13          | 206                  | 219   | 5.94                    |
| Lung cancer                       | 3           | 216                  | 219   | 1.37                    |
| Depression                        | 3           | 210                  | 213   | 1.41                    |
| Anemia                            | 12          | 192                  | 204   | 5.88                    |

Frequency missing (n = 4)
conditions into larger diagnostic categories with the first disease stated. For example, when the condition was defined as “arthralgia, pain assessment”, we analyzed it under the category of “arthralgia”. The available data do not have a single field to define the studies that are applicable to the US Public Law 110-85 (FDAAA), Title VIII, Section 801 for mandatory reporting of results. Therefore, we defined closed not-recruiting interventional trials, excluding Phase 0–I trials, as applicable to comply with FDAAA regulations.

We calculated descriptive frequency statistics without formal hypothesis testing because we did not sample the data but rather analyzed all closed studies available. We then compared the proportions of studies having results with the proportions of studies without results in categories of age, gender, disease status, interventions, study sponsorship, types, and completion dates. All calculations were performed with frequency procedure using SAS 9.1 software (SAS Institute Inc., Cary, NC).

Results

We retrieved 57,299 records but eliminated 66 records with misplaced fields, leaving a total of 57,233 records for analysis. We analyzed the completeness of the minimum dataset and found that 393 studies did not provide the gender for eligible subjects, 287 studies did not specify the type of study, and 5908 did not specify intervention or exposure (Table 1). We noticed a marked inconsistency in the classification and reporting of

| Table 5 Sponsors of the closed interventional, active, not recruiting studies applicable to reporting of results (Phase 0–I excluded) |
|---------------------------------------------------------|
| Sponsors | Has results | No results available | n | Percentage with results |
|---------------------------------------------------------|
| **Total** | 1394 | 29,767 | 31,161 | 4.47 |
| **Largest number with the results** | | | | |
| GlaxoSmithKline | 115 | 728 | 843 | 13.64 |
| Pfizer | 99 | 604 | 703 | 14.08 |
| Merck | 93 | 412 | 505 | 18.42 |
| Eli Lilly and Company | 76 | 283 | 359 | 21.17 |
| Schering-Plough | 43 | 220 | 263 | 16.35 |
| Boehringer Ingelheim Pharmaceuticals | 37 | 181 | 218 | 16.97 |
| Sanofi-aventis | 36 | 590 | 626 | 5.75 |
| Alcon Research | 35 | 131 | 166 | 21.08 |
| UCB Inc. | 33 | 135 | 168 | 19.64 |
| Abbott | 25 | 163 | 188 | 13.30 |
| Bayer | 23 | 206 | 229 | 10.04 |
| Wyeth | 23 | 241 | 264 | 8.71 |
| Takeda Global Research and Development Center Inc. | 21 | 85 | 106 | 19.81 |
| **Results number of closed applicable studies** | | | | |
| Novartis Pharmaceuticals | 5 | 694 | 699 | 0.72 |
| AstraZeneca | 17 | 422 | 439 | 3.87 |
| National Institute of Allergy and Infectious Diseases | 8 | 386 | 394 | 2.03 |
| National Heart, Lung, and Blood Institute | 6 | 337 | 343 | 1.75 |
| Department of Veterans Affairs | 1 | 324 | 325 | 0.31 |
| National Institute of Mental Health | 4 | 239 | 243 | 1.65 |
| National Cancer Institute | 0 | 208 | 208 | 0.00 |
| Memorial Sloan-Kettering Cancer Center/National Cancer Institute | 0 | 190 | 190 | 0.00 |
| Hoffmann-La Roche | 4 | 183 | 187 | 2.14 |
| Bristol-Myers-Squibb | 17 | 168 | 185 | 9.19 |
| Johnson and Johnson Pharmaceutical Research and Development, LLC | 7 | 163 | 170 | 4.12 |
| Novo Nordisk | 12 | 155 | 167 | 7.19 |
| National Institute of Diabetes and Digestive and Kidney Diseases | 2 | 159 | 161 | 1.24 |
| Amgen | 3 | 150 | 153 | 1.96 |
| National Center for Complementary and Alternative Medicine | 2 | 132 | 134 | 1.49 |
| Astellas Pharma Inc | 1 | 121 | 122 | 0.82 |
| North Central Cancer Treatment Group/National Cancer Institute | 0 | 114 | 114 | 0.00 |
| National Institute on Drug Abuse | 1 | 109 | 110 | 0.91 |
For example, “non small cell lung cancer” was reported variously as “non-small cell lung cancer”, “non small cell lung carcinoma”, or “NSCLC”. More than 50% of the studies included adult subjects, and 85% of all studies recruited both genders. Children and seniors were included in a very small proportion of studies. More than 60% of closed studies were completed, and more than 65% of closed studies examined the effects of pharmacologic treatments. A total of 39% of all studies were sponsored by industry. Most of the studies (97%) did not have their results posted on the website.

Of 31,161 applicable closed interventional studies, 4.5% had results available. Proportions of studies with results contained similar age and gender groups (Table 2). Studies with children as subjects tended to report results more frequently. Industry-sponsored studies reported results more often (8.1%) than nonindustry-funded studies (Table 3). Phase III and IV clinical trials reported results more often (total 14%) compared with Phase II trials (3%, Table 3). Suspended interventions (n = 414) and withdrawn interventions (n = 486) did not provide results or reasons for the cause of suspension or withdrawal (Table 3). The first studies containing results (n = 3) were sponsored by Merck and added to the database in 2009. These three studies are listed as NCT00882440, NCT00886600, and NCT00887250, and were completed in 1992. Among the applicable closed interventional studies, 7446 did not provide a completion date. The proportion of the studies with results increased over time (see Figure 1).

Among the applicable 31,161 closed interventional studies, the studies of hypertension and influenza reported results more
Table 8 Patient conditions in withdrawn and suspended interventions applicable to reporting of results by type of treatment (shown if ≥10 interventions). The results are not available for all studies

| Withdrawn interventions | Biological | Device | Drug | Procedure | Radiation | Total |
|-------------------------|------------|--------|------|-----------|-----------|-------|
| Total                    | 20         | 47     | 341  | 45        | 2         | 486   |
| Breast cancer            | 3          | 0      | 12   | 0         | 0         | 16    |
| Diabetes                 | 1          | 0      | 9    | 2         | 0         | 12    |
| Asthma                   | 1          | 1      | 7    | 2         | 0         | 11    |
| Human immunodeficiency   | 4          | 0      | 0    | 0         | 0         | 11    |

| Suspended interventions  | Biological | Device | Drug | Procedure | Radiation | Total |
|--------------------------|------------|--------|------|-----------|-----------|-------|
| Total                    | 50         | 43     | 254  | 41        | 1         | 414   |
| Prostate cancer          | 1          | 0      | 8    | 1         | 0         | 11    |
| Brain and central nervous system tumors | 2          | 0      | 8    | 0         | 0         | 10    |
| Human immunodeficiency   | 1          | 0      | 8    | 1         | 0         | 10    |
| Leukemia                 | 3          | 0      | 6    | 1         | 0         | 10    |
| Melanoma                 | 6          | 0      | 4    | 0         | 0         | 10    |

Discussion

We found that a statistical analysis of compliance with mandatory reporting of results was difficult to perform. Missing or inconsistently reported study details, including patient diseases, study completion dates, and reported interventions may lead to wrong conclusions about a sponsor’s compliance with federal law regarding study registration and reporting of outcomes. We could not identify a single well-defined field that has applicability status of individual studies to provide results. One variable provides information about the posting of the results. The changes in protocols and deviations from the planned presentation of the primary provided results for more than 20% of applicable sponsored studies. Several sponsors did not provide results for funded studies. For instance, the National Cancer Institute sponsored 208 closed interventions without results and Memorial Sloan-Kettering Cancer Center sponsored 190 closed interventions without results. Genetic treatments were examined in 48 closed studies. None of the genetic studies provided results (Table 6). The studies of several drug, including zidovudine, risperidone, and vildagliptin, did not report their results.

Of 31,161 applicable closed interventional studies, 2860 were terminated and 5.3% of 2860 reported results (Table 7). In terminated studies, the most common diseases involved were diabetes and human immunodeficiency virus. Of the terminated studies in prostate cancer, anemia, asthma, and rheumatoid arthritis, more than 10% reported results. The terminated studies of subjects with lymphoma, pain, obesity, heart failure, and colorectal cancer did not provide results. The majority of interventions that were suspended or withdrawn examined the effects of drugs (Table 8). Breast cancer and prostate cancer were among the most common conditions for trials which were suspended or had interventions withdrawn.

Table 7 Terminated interventional, active, not recruiting studies applicable to reporting of results (Phase 0–i excluded) by type of condition (shown for ≥20 total studies)

| Conditions                          | With results | No results | n     | Percentage with results |
|-------------------------------------|--------------|------------|-------|-------------------------|
| Total                               | 151          | 2709       | 2860  | 5.28                    |
| Diabetes                            | 13           | 135        | 148   | 8.78                    |
| Human                               | 5            | 94         | 99    | 5.05                    |

Note: The table is truncated for brevity. The full table includes more conditions and data points.
outcomes and safety outcomes were not easy to analyze without time-consuming evaluation of each study. Reporting of studies completed before September 2007 was available in a small proportion of the interventions, when the sponsors decided to comply.

Both clinicians and the general public need complete and accurate information about study protocols and results.9 Stakeholders should be able to find a clear description of interventions, including prior FDA approvals, off-label evaluations, investigational new drug applications and numbers, and investigational device exemptions, as well as the applicability of reported results.18–20 Critical appraisal of the protocols and investigational device exemptions, as well as the applicability of studies without evaluation of the market status of the tested interventions. Finally, our analysis found that none of the suspended or withdrawn studies reported either the baseline characteristics of enrolled subjects or the exact reasons for terminating the study. Posting the results of a study should be mandatory for all trials, regardless of prior FDA approval.9,11

Our study had several limitations. We defined the applicability of studies without evaluation of the market status of individual studies. We did not analyze deviations from the protocols when reporting the results. We did not analyze whether the sponsors posted the study results in a timely manner according to the expected date. Future research should analyze time intervals between completion of the study, posting of results, and publication of the results in peer-reviewed journals.

We conclude that compliance with the requirements to post results of closed studies is low for both industry- and nonindustry-sponsored studies. The need for studies to report the results should be identified in the database during the registration of the studies.

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