

# Appendix B:

## Elements of Established Private Clinical Trial Registries and Results Databases

<i>Criteria</i>	PhRMA <sup>1</sup> (clinicalstudyresults.org)	Thompson Centerwatch <sup>2</sup>	Amgen <sup>3</sup>	Astra-Zeneca <sup>4</sup>	Bayer <sup>5,6</sup>	Boehringer Ingelheim <sup>7</sup>	Bristol-Myers Squibb <sup>8</sup>	Eli Lilly <sup>9</sup>	Forest <sup>10</sup>	Genzyme <sup>11</sup>	GlaxoSmithKline <sup>12</sup>	Hoffman La-Roche <sup>13</sup>	Norvartis <sup>14,15</sup>	Organon <sup>16</sup>	Purdue Canada <sup>17</sup>	Sanofi-Aventis <sup>18</sup>	Takeda Pharmaceutical <sup>19</sup>	Wyeth <sup>20</sup>
<b>Clinical Trial Registries</b>																		
Clinical Trial Registry		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Accessible at No Charge*	n/a	n/a	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓
Open to All Registrants*	n/a	n/a				n/a					n/a					n/a		
Not-For-Profit*	n/a	n/a				n/a					n/a					n/a		
Verification of Registration Data*	n/a	n/a	✓			n/a	✓				n/a					n/a		
Electronically Searchable*	n/a	n/a	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓
Includes All WHO Data Elements*	n/a	n/a	✓	✓		n/a	✓	✓		✓	n/a	✓	✓			n/a	✓	✓
Conforms to ICMJE	n/a	n/a				n/a					n/a					n/a		
Registration at Inception	n/a	n/a	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓
Specifies Recruitment Status	n/a	n/a	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓
Target Sample Size	n/a	n/a				n/a	✓	✓		✓	n/a	✓	✓	✓	✓	n/a	✓	✓
Funding Source	n/a	n/a	✓	✓		n/a	✓	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓
Institutional Location	n/a	n/a				n/a	✓	✓		✓	n/a	✓	✓	✓	✓	n/a		
Contact Information	n/a	n/a	✓			n/a	✓	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓
Title of Study	n/a	n/a	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓
Technical or Lay Summary	n/a	n/a	✓	✓		n/a	✓	✓		✓	n/a	✓	✓			n/a	✓	✓
Research Ethics Review Disclosed	n/a	n/a	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓
Ethics Committee Named	n/a	n/a				n/a					n/a					n/a		
Study Hypothesis/Purpose of Study	n/a	n/a	✓	✓		n/a	✓	✓	✓	✓	n/a	✓	✓	✓		n/a	✓	
Key Inclusion and Exclusion Criteria (Eligibility Criteria)	n/a	n/a	✓	✓		n/a	✓	✓		✓	n/a	✓	✓	✓	✓	n/a	✓	✓
Study Design (e.g., Allocation to Intervention, Type of Masking, Group Assignment)	n/a	n/a	✓	✓	✓	n/a	✓	✓		✓	n/a	✓	✓	✓	✓	n/a	✓	✓
Study Type (e.g., Interventional vs. Observational, Randomized vs. Non-Randomized)	n/a	n/a	✓	✓	✓	n/a	✓	✓		✓	n/a	✓	✓	✓	✓	n/a	✓	✓
Study Phase	n/a	n/a	✓	✓	✓	n/a	✓	✓		✓	n/a	✓	✓	✓		n/a	✓	✓
Primary Outcome Variable	n/a	n/a				n/a	✓	✓		✓	n/a	✓	✓		✓	n/a	✓	✓
Secondary Outcome Variable	n/a	n/a				n/a	✓	✓		✓	n/a	✓	✓		✓	n/a	✓	✓
Phase I Trials Included*	n/a	n/a	✓			n/a	✓			✓	n/a	✓	✓			n/a	✓	✓
Phase II Trials Included	n/a	n/a	✓	✓	✓	n/a	✓	✓		✓	n/a	✓	✓			n/a	✓	✓
Observational Trials Included	n/a	n/a	✓	✓	✓	n/a	✓	✓	✓	✓	n/a	✓	✓	✓		n/a	✓	✓
Publications Listed	n/a	n/a				n/a	✓	✓			n/a	✓	✓	✓		n/a		

<b>Criteria</b>	<b>PhRMA<sup>1</sup></b> <b>(clinicalstudyresults.org)</b>	<b>Thompson Centerwatch<sup>2</sup></b>	<b>Amgen<sup>3</sup></b>	<b>Astra-Zeneca<sup>4</sup></b>	<b>Bayer<sup>5,6</sup></b>	<b>Boehringer Ingelheim<sup>7</sup></b>	<b>Bristol-Myers Squibb<sup>8</sup></b>	<b>Eli Lilly<sup>9</sup></b>	<b>Forest<sup>10</sup></b>	<b>Genzyme<sup>11</sup></b>	<b>GlaxoSmithKline<sup>12</sup></b>	<b>Hoffman La-Roche<sup>13</sup></b>	<b>Norvartis<sup>14,15</sup></b>	<b>Organon<sup>16</sup></b>	<b>Purdue Canada<sup>17</sup></b>	<b>Sanofi-Aventis<sup>18</sup></b>	<b>Takeda Pharmaceutical<sup>19</sup></b>	<b>Wyeth<sup>20</sup></b>	
Independent Verification of Results	n/a	n/a				n/a	✓				n/a								
Protocol for Online Submission	n/a	n/a				n/a					n/a								
Text Search Specific to Clinical Trials	n/a	n/a				n/a	✓		✓		n/a	✓							✓
Search by Recruitment Status	n/a	n/a			✓	n/a					n/a								
Search by Sponsor/Institutional Location	n/a	n/a			✓	n/a					n/a								
Search by Disease	n/a	n/a			✓	n/a	✓	✓		✓	n/a	✓	✓	✓			n/a		✓
Results	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Link to Results	n/a	n/a			✓	n/a					n/a	✓			✓		n/a		
<b>Clinical Trial Results Databases</b>																			
Clinical Trial Results Database	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Open to All Registrants	✓	✓	n/a																
Results Disclosed	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Results Posted Within 12 Months <sup>†</sup>	✓	n/a	✓	✓		n/a				✓		✓	✓	✓			n/a	n/a	n/a
Results Reporting Standardized		✓	n/a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			n/a	✓	✓
Funding Source	✓	✓	n/a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Institutional Location	✓		n/a	✓		✓	✓	✓			✓	✓					✓		
Contact Information			n/a							✓		✓							✓
Title of Study	✓	✓	n/a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓
Technical or Lay Summary	✓	✓	n/a	✓	✓	✓	✓	✓		✓		✓	✓	✓			✓	✓	✓
Safety Data/Adverse Events	✓	✓	n/a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓
Detailed Outcome Information <sup>‡</sup>	✓		n/a	✓				✓	✓		✓		✓						
FDA Approval Status	✓		n/a						✓	✓			✓				✓		✓
Attrition Rate	✓		n/a	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓					✓
Study Hypothesis/Purpose of Study	✓	✓	n/a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓
Study Design	✓	✓	n/a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓
Publications	✓		n/a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓
Link to FDA Label	✓		n/a						✓	✓			✓						✓
Description of the Patient Population	✓	✓	n/a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓
Stipulates Essential Data Elements		✓	n/a	✓	✓			✓	✓			✓				✓		✓	
Study Phase	✓	✓	n/a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓
Phase I Trials Included	✓	✓	n/a	✓			✓	✓	✓	✓	✓	✓					✓		
Phase II Trials Included	✓	✓	n/a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓
Observational Trials Included	✓	✓	n/a	✓	✓	✓		✓	✓	✓	✓		✓	✓			✓		✓
Independent Verification of Results			n/a					✓											
Text Search Specific to Clinical Trials	✓		n/a	✓				✓		✓		✓	✓						
Search by FDA Approval			n/a						✓										
Search by Phase			n/a			✓													

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Search by Name of the Drug	✓	✓	n/a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Search by Sponsor/Institutional Location			n/a																	
Search by Disease	✓	✓	n/a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Posts on PhRMA Web site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

\* Criteria required for ICMJE acceptance  
† Applies to trial completion or termination date (not time after FDA approval)  
‡ The presence, in tabular format, of efficacy data in sufficient detail to permit the calculation of risk ratios

<sup>1</sup> Clinicalstudyresults.org. Available at: [www.clinicalstudyresults.org](http://www.clinicalstudyresults.org). 7/14/07.  
<sup>2</sup> CenterWatch Clinical Trials Listing Service: Available at: <http://www.centerwatch.com/>. Accessed: 7/14/07.  
<sup>3</sup> Amgen-Patients-Clinical Trials. Available at: <http://www.amgentrials.com/>. Accessed: 7/14/07.  
<sup>4</sup> AstraZeneca Clinical Trials. Available at: <http://www.astrazenecaclinicaltrials.com>. Accessed: 7/14/07.  
<sup>5</sup> Bayer Health Care-Trial Finder. Available at: [http://www.bayerhealthcare.com/scripts/pages/en/research\\_development/clinical\\_trials/trial\\_finder/index.php](http://www.bayerhealthcare.com/scripts/pages/en/research_development/clinical_trials/trial_finder/index.php). Accessed: 7/14/07.  
<sup>6</sup> Clinical Trials-Bayer Schering Pharma. Available at: <http://www.bayerscheringpharmaclinicaltrials.de/scripts/pages/en/index.php>. Accessed: 7/14/07.  
<sup>7</sup> Boehringer Ingelheim Global Clinical Trials Website. Available at: <http://trials.boehringer-ingelheim.com/>. Accessed: 7/14/07.  
<sup>8</sup> Bristol-Myers Squibb-Clinical Trials Disclosure. Available at: <http://ctr.bms.com/ctd/start.do>. Accessed: 7/14/07.  
<sup>9</sup> Lilly Clinical Trial Register. Available at: [www.lillytrials.com](http://www.lillytrials.com). Accessed: 7/14/07.  
<sup>10</sup> Forest Clinical Trial Registry. Available at: <http://forestclinicaltrials.com>. Accessed: 7/14/07.  
<sup>11</sup> Genzyme Clinical Research. Available at: <http://www.genzymeclinicalresearch.com/>. Accessed: 7/14/07.  
<sup>12</sup> GlaxoSmithKline Clinical Trials Register. Available at: <http://ctr.gsk.co.uk/welcome.asp>. Accessed: 7/14/07.  
<sup>13</sup> Roche Clinical Trial Protocol Registry and Results Database. Available at: [www.roche-trials.com](http://www.roche-trials.com). Accessed 7/14/07.  
<sup>14</sup> Clinical Trials at Novartis. Available at: <http://www.novartisclinicaltrials.com/webapp/etrial/home.do>. Accessed: 7/14/07.  
<sup>15</sup> Novartis Clinical Trial Results. Available at: <http://www.novartisclinicaltrials.com/webapp/clinicaltrialrepository/public/main.jsp>. Accessed: 7/14/07.  
<sup>16</sup> Organon. Available at: [http://www.organon.com/clinical\\_trials/index.asp](http://www.organon.com/clinical_trials/index.asp). Accessed: 7/14/07.  
<sup>17</sup> Clinical Trials (Purdue Pharma). Available at: [http://www.purdue.ca/research/research\\_clinical.asp](http://www.purdue.ca/research/research_clinical.asp). Accessed: 7/14/07.  
<sup>18</sup> Sanofi-Aventis. Available at: <http://www.sanofi-aventis.us/live/us/en/layout.jsp?scat=E7C27A86-08F4-4798-8241-710051CE000A>. Accessed: 7/14/07.  
<sup>19</sup> Clinical Study Protocol Summaries-Takeda Pharmaceutical Company. Available at: <http://www.takeda.com/c-t/>. Accessed: 7/14/07.  
<sup>20</sup> Clinical Trial Listings-Wyeth.com. Available at: <http://www.wyeth.com/ClinicalTrialListings>. Accessed: 7/14/07.