See ARTICLES pages 529, 537, and 546

# Global Requirements for DNA Sample Collections: Results of a Survey of 204 Ethics Committees in 40 Countries

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**The Industry Pharmacogenomics Working Group has an interest in attaining a better understanding of global requirements for sample collections intended for pharmacogenetics research. To have adequately powered pharmacogenetics studies representative of the clinical trial population, it is important to collect DNA samples from a majority of consenting study participants under many institutional review board/ethics committee (IRB/EC) jurisdictions. A survey was distributed to gather information from local and central IRBs/ECs. The survey included questions related to the approval of pharmacogenetics studies, collection and banking of samples, and return of data to subjects. A total of 204 responses were received from global IRBs/ECs with pharmacogenetic experience. The data show that requirements for approval of pharmacogenetic research differ between IRBs/ECs within and between countries but not between regions of the United States. A better understanding of differing requirements should facilitate global sample collection of DNA for pharmacogenetics research and may provide the basis for harmonized regulations for collection of genetic samples in the future.**

Pharmacogenetics research in drug development requires special considerations and disclosures in the informed-consent process, detailing the ethical implications of the data and the potential risks for genetics-based discrimination.[1,2] Enrollment in pharmacogenetics research studies requires voluntary participation through informed consent as in any other clinical research protocol. Because informed-consent policies vary both globally and locally, and access to evolving regulations in many countries is difficult, most pharmaceutical companies have adopted a consent process separate from the main study consent.[1,2] This process enables the main study to efficiently enroll patients without being encumbered by the additional approvals that may be required for collection of genetic samples and pharmacogenetics research.

The differing requirements of local and regional institutional review boards and ethical committees (IRBs/ECs) (collectively referred to as ECs) prior to approval of pharmacogenetics research and biobanking are generally specified through regulatory guidance and local ethical principles. In most countries, an explanation of how patient privacy will be maintained, how the samples will be coded[3,4] and stored, and which personnel will be allowed access to the samples and data must be stated in the informed-consent form. Often, the scope of research work detailing the pharmacogenetic research to be performed is required to be disclosed, and occasionally a specific listing of genes must be supplied. Some countries restrict sample export, genetic testing, and biobanking because of ethical considerations, religious beliefs, or concerns about intellectual property.[5–9] The individual results generated from these exploratory studies are usually included in population-based statistical analysis designed to generate hypotheses. Nonetheless, individual results can be reported back to subjects, and this practice also has many ethical, legal, and social implications.[10,11]

Although in most countries companies have adopted processes that allow for genetic sample collection, this is an appropriate time to seek a better understanding of the varying local regulations so as to move toward developing common processes for efficient global sample collections. Cataloging the differences in

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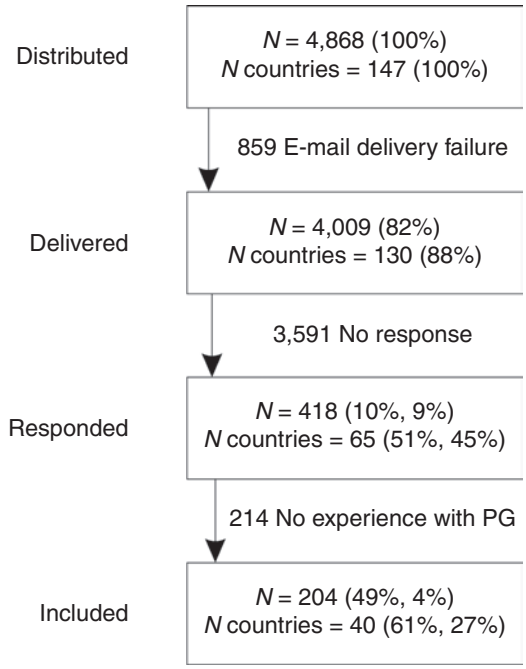


**Figure 1** Number and percentage of ethics committees that completed the survey. Response percentages are presented from one box above and from uppermost box. PG, pharmacogenetics.

requirements for pharmacogenetic research approvals will serve as a basis for information that can be used to harmonize global sample-collection practices in the future. In this context, we carried out a survey to gather information on current practices by distributing a questionnaire electronically. The questions focused on the local requirements for approval of applications for collection of genetic samples and conducting research involving such genetic data. We report the results of this survey, highlighting the differences in the approval processes within and among countries with respect to genetics research, DNA banking, and sample coding. We further investigated differences in approval processes within regions of the United States. The results reported represent the first global evaluation of EC practices with regard to evaluation of applications for collection of genetic samples, pharmacogenomics research, sample coding, and DNA banking.

## RESULTS

Of the 4,009 potential participants (ECs) to whom the questionnaires were distributed, responses were received from 418 (**Figure 1**); A total of 214 survey participants from 26 countries were excluded because they had no previous experience in the evaluation of an application with a genetic component. In these cases, answers to the survey questions provided minimal guidance on local regulations because the responses in most cases were "I don't know." Therefore, a total of 204 ECs from 40 countries (**Table 1**) were represented in the final data set reported here. Most of the responses received were from the United States (49.5%), Canada (7.8%), and Australia (5.4%). Not all the questions were answered by the responding ECs; **Table 2** shows the total number and summary of responses to individual questions.

**Table 1 Rate of response of ethics committees by country**

| Country | Ethics committee sites | Percentage of total responses |
|---|---|---|
| United States | 101 | 49.5 |
| Canada | 16 | 7.8 |
| Australia | 11 | 5.4 |
| Germany | 7 | 3.4 |
| Belgium, Brazil | 5 Each | 2.4 (Each country) |
| Italy, United Kingdom | 4 Each | 2.0 (Each country) |
| Colombia, India, Korea (Republic of), Mexico | 3 Each | 1.5 (Each country) |
| Czech Republic, Norway, Peru, Spain, Taiwan, Thailand | 2 Each | 1.0 (Each country) |
| Argentina, Armenia, Austria, China (Mainland), Costa Rica, Ecuador, Egypt, Finland, France, Hungary, Indonesia, Israel, Kyrgyzstan, Lebanon, Liberia, Mozambique, the Netherlands, Nigeria, "other," Puerto Rico, Romania, Senegal, Slovenia, South Africa, Switzerland, Venezuela, Vietnam | 1 Each | 0.5 (Each country) |

Of the ECs with experience related to submissions including sample collection for pharmacogenetics research, seven (from 196 responses, see **Table 2**) stated that they never approve pharmacogenetics research, whereas 40 stated that they always approve pharmacogenetics research without any imposed requirements. The rest of the respondents indicated that they approve DNA analysis with some restrictions imposed. The vast majority of these respondents require that the scope of the intended research be described (alone or in combination with other requirements) (**Figure 2**).

Banking of samples requires regulatory approval, but the requirements that apply to samples collected for immediate analyses may be different from those for samples designated for banking. Of the 191 responding ECs, 15 said that they never approve DNA sample banking. Twelve committees responded that they approve DNA banking without restrictions. The remaining ECs stated that they approve DNA banking only if certain conditions are met. Generally, the scope of the intended research study is required to be described. This may be either a stand-alone requirement or in combination with a requirement for a list of candidate genes.

Samples collected for pharmacogenetics research and/or banking are generally labeled with a code. Coding categories have been described previously in much detail[3,4] and are discussed in depth elsewhere.[12] Of 155 responding ECs, 72 did not know whether they require a certain coding category when DNA samples are collected for DNA banking. Of the ECs that require a certain coding category, 31 allow single coding (**Figure 3**), 13 allow samples to be identified, 15 require anonymization, and 4 require samples to be anonymous. The committees in the latter two categories do not allow re-identification of the subject if additional clinical information is desired at a subsequent time.

**Table 2 Condensed list of questions included in the survey of global ethics committees**

| | Number of ECs responding | Summary of country responses |
|---|---|---|
| *Demographics and experience-related questions* | | |
| Is your IRB/EC central, regional, local, other? Please specify. | 202 | Central (9%), regional (11%), local (77%), other (3%) |
| Have you been involved in conducting of genetic studies? | 203 | No (21%), yes but not directly (47%), yes, direct involvement (32%) |
| Has your committee evaluated pharmacogenetics study applications? | 204 | Filtering question. Included only if answered "yes."<br>Yes, fewer than 10 applications (43%), yes, at least 10 applications (57%).<br>The 214 responses that were not included had the following distribution of responses: no ($n = 194$), I do not know,[11] missing[9] |
| *Questions related to informed consent* | | |
| Does your committee require a separate ICF for pharmacogenetics studies? (I cannot say, no, yes) | 201 | 101 (50%) Committees require a separate ICF in all studies, 53 (26%) require a separate ICF for some studies, and 47 (23%) do not require a separate ICF |
| For what pharmacogenetics studies does your committee require a separate ICF? (For biobanking, exploratory studies, other) | 40 | 30 (75%) Committees require a separate ICF for biobanking, eight (20%) require a separate ICF for biobanking and exploratory studies, and two (5%) require a separate ICF for exploratory studies |
| *Questions related to result reporting* | | |
| Does your committee require that individual genotypes be reported back? | 196 | More than 50% of the ECs do not require results to be reported back to study participants |
| In what cases does your committee require that individual genotypes be reported back? (For valid biomarkers, probably valid biomarkers, other) | 32 | 15 ECs require result reporting for all cases (countries include Brazil, Ecuador, Italy, Kyrgyzstan, Liberia, Peru, Puerto Rico, Romania, and United States). Some ECs require reporting in selected cases (for valid biomarkers: Australia, Brazil, Canada, Czech Republic, Egypt, Mexico, Palestinian Authority, South Africa, and United States) |
| When genotypes are reported back, does your committee require a certain level of assay validation? | 46 | Of the ECs with reporting requirements, half require approval by a regulatory body for result reporting, and the others require CLIA/GLP validation of test method |
| Specify the level of validation that is required when genotypes are reported back. (CLIA/GLP, approval by regulatory body (FDA, EMEA, other)) | 24 | Some ECs specified CLIA/GLP or other methods of validation required prior to reporting results to individuals |
| When genotypes are reported back, select who they are reported back to (individual, the investigator, the committee, other) | 44 | Most ECs require results to be given to the investigator or the individual. Nine ECs require that results be reported to the EC |
| When genetic results are reported back to individuals, does your committee require genetic counseling? | 46 | 37 Of responding ECs require that genetic counseling be provided when results are reported back to individuals |
| *Questions related to DNA analysis* | | |
| What requirements are imposed by your committee to approve analysis of DNA. (I cannot say, gene list, scope of the genetic analysis, no imposed requirements, our committee never approves DNA analysis) | 196 | Seven ECs never approve genetics research (United States (California, Florida, Massachusetts, Virginia), Liberia, Kyrgyzstan, India)<br>40 ECs always approve genetics research (United States (28 sites), Australia (two sites), Belgium, Canada, China, Costa Rica, Germany, Indonesia, Korea, the Palestinian Authority, Puerto Rico, and South Africa (one site each))<br>Other ECs impose restrictions (see **Figure 2**) |
| Please provide the reason for the practice not to approve analysis of DNA? (Open text) | 5 | 1. We do not have the mechanism to do analysis<br>2. There has never been a request for a researcher to analyze DNA<br>3. Lack of internal expertise in this area<br>4. A committee is currently being formed to evaluate these proposals<br>5. No answer supplied |
| Our committee approves DNA analysis only if the following conditions are met: (I cannot say, a gene list, scope of genetic analysis, sample destruction following testing, results must be reported back, our committee never approves analysis of DNA) | 122 | See **Figure 2** |
| *Questions related to biobanking* | | |
| What requirements are imposed by your committee to approve DNA sample biobanking? (I cannot say, a gene list, scope of genetic analysis, sample destruction following testing, results must be reported back, our committee never approves banking of DNA) | 191 | 15 ECs never approve DNA sample banking (United States (five sites), Belgium, Brazil, Colombia, India, Mexico, Thailand, Ecuador, Finland, Liberia, and the Palestinian Authority);12 ECs always approve DNA sample banking (Australia, Canada, China, Kyrgyzstan, and Puerto Rico (one site each), Korea (two sites), and United States (five states))<br>Other ECs approve DNA banking if certain conditions are met (research scope was the most common requirement) |

**Table 2 Continued on next page**

**Table 2 (Continued)**

| | Number of ECs responding | Summary of country responses |
|---|---|---|
| Please provide the reason for the practice not to approve DNA biobanking | 14 | 1. Cultural and religious issues (other): only certain IRBs/ECs are allowed to recognize biobanking (Belgium)<br>2. No specific DNA research studies (Colombia)<br>3. To protect the genetic material of our population (Ecuador)<br>4. Biobanking cannot be part of a drug trial; must be separate and focused research proposal (Finland)<br>5. Rules are not made yet (India)<br>6. We have an institutional biobanking system (Korea)<br>7. No resources to do biobanking (Liberia)<br>8. Little or no benefit to the individuals that donated samples (Mexico)<br>9. No reason, have not had a protocol for biobanking approval yet (Thailand)<br>10. Not what we do (United States)<br>11. Catholic Directives (United States)<br>12. Our IRB had only one genetic study submitted (United States)<br>13. It has not been requested (United States) |
| Our committee approves DNA sample biobanking only if the following conditions are met: (a gene list, scope of genetic analysis, sample destruction following testing, results must be reported back) | 115 | 94 ECs approve biobanking if the scope of research is provided. Four ECs require that a list of genes be provided. 17 ECs require both |
| Does your committee require certain coding categories for DNA sample biobanking? (I cannot say, our committee does not allow biobanking, allows with a condition) | 155 | 72 ECs did not know whether there are regulations for coding samples<br>31 ECs allow single coding, 13 allow samples to be identified, 15 require anonymization (Australia, Canada, Czech Republic, France, Germany, India, Indonesia, Italy, the Netherlands, and United States), and 4 require anonymous coding (from Brazil, Mozambique, and United States) |
| Our committee allows DNA biobanking if samples are: (identified, single coded, double coded, anonymized, anonymous) | 80 | See above |
| Indicate the geographical limitations specified by your committee for DNA biobanking. (No limitation, limited to storage within my country, limited to other locations) | 155 | 104 ECs have no geographical limitations, 34 limit to certain locations, 17 did not know |
| Biobanking is limited to locations within: (in European Union, EEA, in United States, other) | 35 | 31 ECs limit banking most commonly within their own country or zone |
| *Questions related to storage limitations* | | |
| Does your committee limit the storage duration of DNA samples? | 156 | ECs in Australia, Canada, Colombia, Italy, Kyrgyzstan, Mozambique, Peru, Romania, Senegal, South Africa, Switzerland, Taiwan, and United States (Arizona, District of Columbia, New York, North Carolina, and Texas) have storage limitations |
| Your committee limits the storage duration of DNA samples for how many years? | 18 | |

Options are in parentheses, where appropriate. The number of responding ECs consists of only those with experience in evaluating applications with a pharmacogenetics research component. CLIA/GLP, clinical laboratory improvement amendments/good laboratory practice; EC, ethics committee; EMEA, European Medicines Agency; FDA, US Food and Drug Administration; ICF, informed-consent form; IRB/EC; institutional review board/ethics committee.

For the most part, samples collected for pharmacogenetics research can be exported and stored at various locations without any restrictions. Surprisingly, 34 of 155 responding ECs do limit specimen banking to certain locations (**Figure 4**), most commonly within their own country or zone (e.g., European countries to the European Union). In countries where storage limitations are imposed, the majority of respondents specified that samples are required to be destroyed after 10 or 20 years. Four ECs (one each in Canada, Colombia, Taiwan, and the United States) impose a 20-year storage limitation, three ECs (one each in Australia, Germany, and the United States) have a 15-year storage limitation, six ECs (one each in Canada, Kyrgyzstan, Mozambique, Romania, Senegal, and Switzerland) have a 10-year limitation, and other ECs in Australia, Peru, South Africa, Italy, and the United States have limitations of 7, 5, 5, 3, and 2 years, respectively.

According to the responses, sample collections for pharmacogenetics research always require informed consent; some of the ECs require that this be a document separate from the consent form related to the main clinical research study. Once consent has been obtained from patients, sample collection and analyses can be carried out. More than 50% of the ECs surveyed do not require results to be reported to the individual; however, 15 of 196 responding ECs require result reporting in all cases (see **Table 2**). Some of the ECs surveyed require reporting in selected cases, such as the reporting of valid biomarker results after approval by a regulatory body or method validation by clinical laboratory improvement amendments/good laboratory

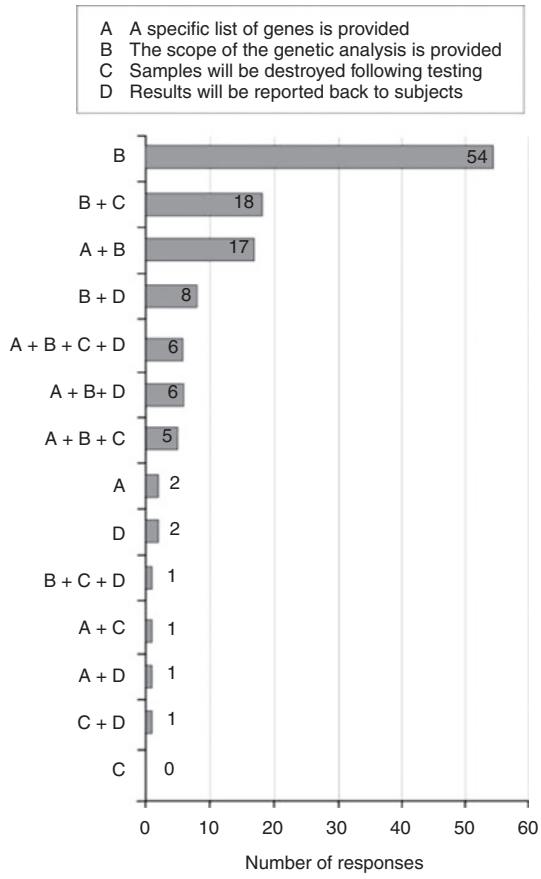


**Figure 2** Ethics committee requirements for approval of applications for DNA analyses.

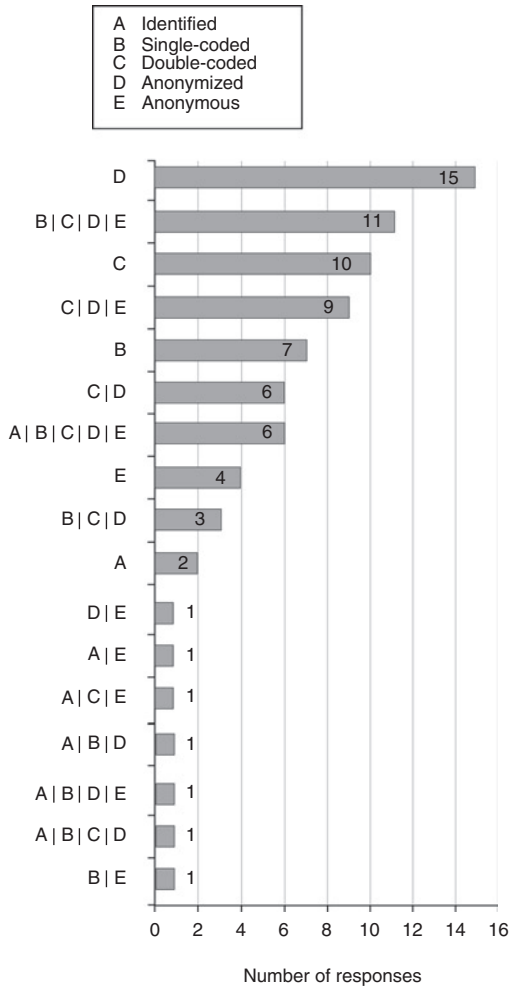


**Figure 3** Number of ethics committees that accept different coding categories for DNA banking.

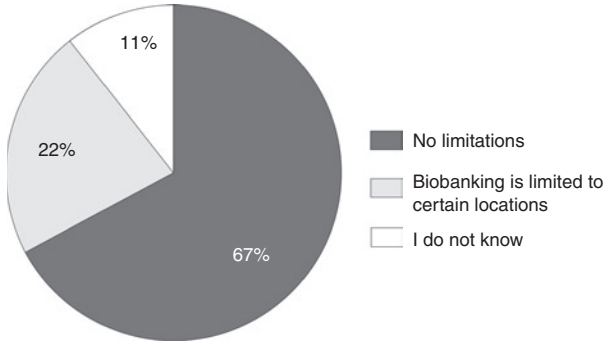


**Figure 4** Geographical limitations for DNA sample biobanking.

practice[13] or by other means. Incidentally, two ECs require that data be reported to the individual yet allow anonymization of samples. This would not be possible, given that the links to identify individual patients are destroyed when samples are anonymized. With respect to the reporting of results, most ECs require that reports be given directly to the investigator or to the individual; however, 9 of the 44 ECs that responded require reporting to the EC itself. Of the 46 ECs that responded, 37 require that, if genetics results are reported back to individuals, genetic counseling also be offered.

With the exception of those from the United States, the data collected in the survey (**Table 1**) was not sufficient to perform countrywise statistical analyses. For ECs in the continental United States, regional differences in practices for approval of genetic testing and DNA banking were assessed by grouping survey responses according to the location of the respective ECs—West, Southwest, Midwest, Northeast, and Southeast—and testing using Fisher's exact test. No statistically significant differences were identified in regional requirements for genetic testing approval ($P = 0.41$) and DNA banking approval ($P = 0.77$). The ECs located in all these regions either imposed requirements for genetic testing (Midwest ($n = 12$), Northeast ($n = 15$), Southeast ($n = 8$), Southwest ($n = 7$), and West ($n = 9$)) or did not impose such requirements (Midwest ($n = 9$), Northeast ($n = 9$), Southeast ($n = 1$), Southwest ($n = 4$), and West ($n = 4$)). Additionally, ECs that never permitted DNA testing were present in the Northeast ($n = 1$), Midwest ($n = 1$), West ($n = 1$), and Southeast ($n = 2$). The small number of responses was insufficient for further statistical analysis of specific regional requirements for genetic testing imposed by ECs. With respect to DNA banking, some ECs imposed requirements (Midwest ($n = 17$), Northeast ($n = 24$), Southeast ($n = 9$), Southwest ($n = 10$), and West ($n = 11$)), whereas other ECs did not impose such requirements (Midwest ($n = 2$), Northeast/Southwest/West ($n = 1$ each),

**Table 3 Key issues to consider when selecting sites for global studies involving pharmacogenetics research: survey responses and authors' experience**

| Limitation | Survey response | Authors' experience |
|---|---|---|
| No DNA banking allowed | United States, Belgium, Brazil, Colombia, Mexico, Thailand, Ecuador, Finland, Liberia, and the Palestinian Authority | Many ECs in the United States, Colombia, and Finland allow DNA banking<br>Brazil requires a separate protocol to be submitted[20]<br>Some ECs in Thailand allow DNA banking and some do not<br>Taiwan does not allow banking at some sites but does allow it at other sites<br>Malaysia does not allow banking |
| No sample exportation allowed | No limitations | Sample exportation from China has been extremely difficult |
| Sample coding restrictions are imposed | 15 ECs require anonymization (Australia, Canada, Czech Republic, France, Germany, India, Indonesia, Italy, the Netherlands, and United States) and four require anonymous coding | Samples from Brazil and Italy cannot be anonymized or anonymous |
| Banking restricted to designated locations | 34 ECs restrict banking to designated locations. United States (13 sites), Canada (four sites), Australia (one site), Germany (two sites), Belgium (one site), Brazil (one site), Italy (two sites), United Kingdom (one site), Colombia (one site), Norway (one site), Peru (one site), Spain (one site), Taiwan (one site), France (one site), Puerto Rico (one site), Senegal (one site), and Venezuela (one site) | China, Sweden, and Iceland restrict sample banking to their respective countries |

EC, ethics committee.

and Southeast ($n = 0$)). Moreover, some of the ECs in each of the regions never approved DNA banking. As before, the small number of responses precluded additional statistical assessment of regional differences in specific DNA banking requirements. A small number of ECs were aware of sample coding restrictions in the United States regions, but the sample sizes were too small for formal statistical testing within the coding categories. There were also no significant regional differences ($P = 0.074$) in sample storage restrictions.

## DISCUSSION

The results of this study demonstrate that ECs differ in their approach to approval of sample collections intended for pharmacogenetic research—as initially expected. Attempts were made to group ECs with similar experiences; however, given the limited numbers of ECs from each individual country (except the United States), it was not possible to find statistical associations within country-level responses. No statistically significant differences were found in the practices for approval of genetic testing and banking of specimens when the results were examined by regions of the United States (West, Southwest, Midwest, Northeast, and Southeast) although different ECs had different requirements for approval within each of the regions. These results should be interpreted with caution, given the small sample sizes. The majority of the ECs in the United States were local (77%), and the others were regional (11%), central (9%), or other (3%); however, additional information regarding the categorywise classification of ECs was not collected in the survey. Therefore, our discussion focuses on key issues that should be considered when selecting sites for pharmacogenomics research in global studies. The issues are identified in **Table 3**, and survey responses are compared and contrasted with our experiences.

We have found that it is possible to both conduct research and bank samples in many of the countries surveyed. Contrary to expectations, several sites within the surveyed countries reported that they do not allow pharmacogenetics research or banking even though they knew of no country-level regulations preventing these activities. At the other extreme, several ECs, including one in China, stated that they allow both pharmacogenetics research and DNA sample banking without restrictions. In China, we have encountered restrictions on both sample exportation and analysis. The data related to the requirements for reporting of genetic testing results, as derived from this survey, are consistent with our experience in this regard; however, data related to banking of specimens is somewhat inconsistent. In practice, we have encountered fewer restrictions on banking than are suggested by the survey results, except in countries, such as China and Sweden, that have in-country sample banks. In the United States, restrictions are usually from sites that already have an extensive bank, such as the Veterans Association and the Mayo Clinic. The overall findings of this study show that differences exist between ECs in the way they implement country regulations in combination with local or institutional policies. Although this is consistent with the philosophy that IRBs/ECs protect local populations according to their interpretation of regulations and ethical conduct of research, it demonstrates the complexity that industry faces when attempting to streamline sample collection.

To accommodate these restrictions, a separate informed-consent form is recommended, containing information related to how the samples will be collected, coded, and stored; what type of research will be conducted; whether the results will be reported back to individuals; and, if so, under what circumstances. It is also recommended that the study be located in countries and sites that allow the described research and or banking of samples. In the case of countries with restrictions, it is anticipated that delays in approvals of the research application

will occur, and this should be considered when the overall timelines for the study are compiled.

The information gathered in this survey should provide the basis for future discussions aimed at harmonizing regulations and practices for sample collections intended for pharmacogenetic research. From this survey, it appears that many ECs view country-level requirements as minimum requirements and impose additional restrictions as they deem appropriate to ensure compliance with institutional policy and to ensure the protection of patients. Alternatively, considering some of the individual responses, there may be an inadequate understanding of the country-level requirements or lack of experience with this particular type of research (see **Table 3**). It is clear from these data that educational efforts should be made that target ECs and emphasize the value of pharmacogenetics research and DNA banking. These data also suggest that education is needed with respect to sample-coding categories[3,4] because a high proportion of the ECs surveyed did not know whether coding restrictions were imposed on samples collected for banking. Furthermore, some ECs that called for anonymization required results to be reported which, as explained earlier, is not possible. It is interesting that one EC each in Puerto Rico and Romania said that they allow identified samples to be banked. When samples are identified, the patient's personal information, such as name or initials and date of birth, is available on the sample label. However, the practice of collecting identified samples for pharmacogenetics research as part of a clinical trial is generally avoided by the pharmaceutical industry. The holding of a summit meeting is recommended to bring together all the stakeholders involved—both those who approve applications for pharmacogenetics research studies and those who conduct them—as a first step toward a better understanding of the goals and views of individual researchers and regulators. Open discussion in multiple forums should facilitate development and adoption of harmonized processes and regulations for future sample collection. This is one of the main goals of the Industry Pharmacogenomics Working Group, whose members are actively working toward achieving this goal.[14–17]

Herein, we have tried to identify and discuss the requirements imposed by multiple ECs; however, this study has several limitations. Despite significant efforts to collect representative data from a large number of ECs from many different countries, there was a low response rate even after repeated reminders. The questionnaire was presented in English, which may have contributed to the limited response from countries in which English is not an official language. In view of the insufficient sample size, we cannot generalize the overall findings of this study. The practices of the ECs that responded to the survey are presented and discussed. In addition, we contrast these responses with company experiences that provide valuable information to parties involved in global pharmacogenetics research.

The pharmaceutical industry as well as regulatory agencies recognize that collection of DNA samples from most, if not all, subjects taking part in clinical trials is key to success in this research field[14,18] and that significant efforts should be made to harmonize practices for sample collection in the near future.

## METHODS

The Industry Pharmacogenomics Working Group (http://www.i-pwg.org) initiated this study to gather information to facilitate future harmonization of practices for global collection of genetic samples intended for pharmacogenetics research. As a first step toward this goal, a subteam identified, from their own experience, the restrictions that most commonly impede genetic sample collection. A survey was then developed with questions aimed at identifying countries and regions with specific regulations for genetic sample collection, for both prospective research and DNA sample banking. Additionally, questions related to sample handling and processing, sample storage location, sample coding, and sample testing and reporting were included. The majority of the questions and summarized answers can be found in **Table 2**. However, this is not a comprehensive listing involving individual ECs because the survey utilized logic branching.

The survey questionnaire was developed and conducted using an online survey system (http://www.SurveyMonkey.com). It contained a total of 27 questions; however, because the survey used logic branching, responses were not necessarily required for all questions, depending on how a preceding question was answered. The ECs were identified from a comprehensive listing of sites supplied by the US Food and Drug Administration through the Freedom of Information Act. Invitations to participate in the survey were distributed on 16 February 2009 to 4,868 ECs and redistributed to nonresponding sites on 9 March 2009. Responses were included in the analysis if they were received on or before 21 March 2009 and contained a response to at least one of the questions. A total of 418 responses were received (10% of the delivered invitations; **Figure 1**); 214 survey participants from 26 countries were excluded from the analysis because they had no previous experience in the evaluation of an application with a genetic component. Ultimately, a total of 204 ECs from 40 countries (**Table 2**) were represented in the final data set reported here.

With the exception of those from the United States, the data collected from various countries (**Table 1**) in this survey were not sufficient to perform statistical analyses. In the continental United States, responses were received from the following regions: West, 17 ECs; Southwest, 12 ECs; Midwest, 26 ECs; Northeast, 29 ECs; and Southeast, 14 ECs). Responses related to approvals for genetics research, sample coding, and DNA biobanking were stratified according to the regions. Regional differences in response to these survey questions were evaluated with Fisher's exact test, using the R software package.[19]

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## CONFLICT OF INTEREST

The authors declared no conflict of interest. All the authors are employed by pharmaceutical companies that are actively engaged in pharmacogenetics research, including the collection, analysis, and storage of DNA samples from subjects participating in clinical trials.



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