Practical Guidance

Geographic Considerations in International Clinical Trials

A Practical Guidance® Practice Note by
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This practice note discusses drug, medical device, and biologics clinical trials conducted outside the United States. It covers U.S. and foreign rules, regulations, and guidance that manufacturers should consider when designing and conducting them. Among the topics addressed are data use, export control, and clinical trial approval and conduct rules.

For additional information about legal and regulatory considerations for clinical trials, see Clinical Trials Resource Kit.

Benefits of Conducting Clinical Trials outside of the U.S.

The U.S. Food and Drug Administration (FDA) requires manufacturers of drugs, medical devices, and biologics to prove the safety and effectiveness of their products. Most often, safety and effectiveness are established by well-controlled clinical trials.

Conducting clinical trials outside of the U.S. (OUS) offers many benefits to researchers, including the opportunity to access different populations with varying levels of treatment naïveté, potentially less burdensome regulatory requirements, and additional funding sources. OUS clinical trials also can present lower operational costs for study sponsors, such as lower investigator salary requirements, cheaper consumables, and lower overhead; a greater availability of study participants and motivated investigators, and therefore faster recruitment rates; fewer competing trials; and the ability to study diseases not prevalent in the U.S. In addition, some nations are actively trying to attract clinical research, lowering barriers to studies with foreign sponsors.

A robust industry of contract research organizations (CROs) with expertise in OUS regions can make it easier for a U.S. study sponsor to take advantage of foreign study sites and populations by navigating institutional and local regulatory requirements on behalf of the sponsor.

For information about CROs, see Contract Research Organization Agreements and Clinical Trial Agreement Considerations for Pharmaceutical Sponsors.

It is important to note that many of the benefits of conducting OUS clinical trials abroad have countervailing ethical or legal challenges that must be considered and addressed, especially in clinical trials taking place in low- and middle-income countries, where there is often less oversight of clinical trials s than in high-income countries.

Although OUS clinical trials may cost less, this is often because standards of living and medical care in foreign jurisdictions are lower and the incentives to participate can be perceived as coercive. Fewer competing trials often means that researchers are inexperienced, which can result in data integrity challenges or compliance shortcuts, and that local populations are unfamiliar with clinical research, which makes informed consent more difficult. Where there are treatment-naïve patients, care after the trial ends or for the control group population presents ethical quandaries.

FDA Requirements for Accepting Data from OUS Clinical Trials

The FDA will accept data from OUS clinical trials in two ways: (1) an investigational new drug (IND) application or investigational device exemption (IDE) (either as direct support for the application, or as additional support for the application) or (2) adherence to international good clinical practice (GCP) guidelines.

Using OUS Clinical Trial Data to Support Drugs and Biologics Research, Licensing, and Marketing Applications

OUS clinical trials can be used to support an FDA application for an IND, a new drug application (NDA), an abbreviated new drug application (ANDA), or a biologics license application (BLA). FDA guidance indicates that OUS clinical trials can, but are not required to be, conducted under an IND. If the OUS clinical trial is conducted pursuant to an IND, the sponsor must adhere to all applicable IND clinical trial requirements regardless of the location of the study. See 21 C.F.R. pt. 312 (IND applications).

When not conducted under an IND, the FDA can still accept an OUS clinical trial as support for an IND, NDA, ANDA, or BLA, but the trial must comply with the requirements of 21 C.F.R. § 312.120. Under these requirements, a study must be conducted in accordance with GCP. GCP is defined as "a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected," including the use of an independent ethics committee (IEC) and procedures related to obtaining informed consent.

Additionally, a sponsor must provide a description of actions that it took to ensure that the research complied with GCPs, including specific supporting information identified by regulation. The FDA can waive these additional non-IND requirements under certain circumstances if the waiver is justified and in the interest of public health. And although the FDA will not accept as support for an IND or application for marketing approval a study that does not meet these regulatory requirements, the FDA may nonetheless consider the data.

Specific regulations allow for OUS clinical trials not conducted under an IND to be the sole basis for marketing approval for NDAs or ANDAs, provided that the clinical trials otherwise comply with 21 C.F.R. § 312.120, and (1) "the foreign data are applicable to the U.S. population and U.S. medical practice"; (2) "the studies have been performed by clinical investigators of recognized competence"; and (3) "the data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means." 21 C.F.R. § 314.106(b) (NDA and ANDA). "Failure of an application to meet any of these criteria will result in the application not being approvable based on the foreign data alone," though the agency indicates that this policy will be applied "in a flexible manner according to the nature of the drug and the data being considered." 21 C.F.R. § 314.106(b)(3).

Using OUS Clinical Trial Data for Medical Device Research, Licensing, and Marketing Applications

OUS clinical trials can be used to support an FDA application for an investigational device exemption (IDE), a premarket approval (PMA), a 510(k), or a De Novo classification, among other forms of approval. 21 C.F.R. § 812.28. FDA guidance does not make a distinction between OUS clinical trials conducted under an IDE and OUS clinical trials not conducted under an IDE. To be accepted, however, the sponsor must demonstrate that the trial was conducted in accordance with GCPs.

Additionally, a sponsor must provide a description of the actions the sponsor took to ensure that the research conformed to GCP, including specific supporting information identified in 21 C.F.R. § 812.28(b). These requirements can be waived by the agency under certain circumstances if the waiver is justified and in the interest of public health. Independent of the waiver option, "FDA may accept the information from such clinical investigations to support an IDE or a device marketing application or submission if FDA believes that the data and results from such clinical investigation are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected."

OUS clinical trials can also be the sole basis for an IDE or marketing approval but note that FDA regulations are specific to the type of approval. For an IDE, the sponsor must comply with 21 C.F.R. § 812.28 (acceptance of data from clinical investigations conducted outside the United States). FDA guidance suggests that an IDE may be based solely on OUS clinical trials.

OUS clinical trials can be the sole support for a PMA so long as the investigations meet the requirements of 21 C.F.R. § 812.28, and (1) "the foreign data are applicable to the U.S. population and U.S. medical practice"; (2) "the studies have been performed by clinical investigators of recognized competence"; and (3) "the data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means." 21 C.F.R. § 814.15.

For 510(k) applications, which in part may rely on existing medical device and safety data, the sponsor must comply with both 21 C.F.R. § 812.28, and "If any such investigation was not conducted in accordance with GCP as described in § 812.28(a) of this chapter," the sponsor must "include either a waiver request in accordance with § 812.28(c) of the chapter or a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected." 21 C.F.R. § 807.87(j)(2) (510(k)).

Other U.S. Laws Implicated by OUS Clinical Trials

In addition to adhering to the FDA's regulations related to the use of OUS clinical trial data to support an IND or IDE application, a sponsor must consider other U.S. laws when they apply to the type of activity being carried out abroad.

The Common Rule

OUS clinical trials must also comply with the Common Rule, 45 C.F.R. § 46.101 et seq., if the trials receive funding from a Common Rule agency. As of December 2022, 20 federal agencies were Common Rule signatories, including the Department of Health & Human Services (HHS) (excluding the FDA), Department of Defense, U.S. Agency for International Development, the Environmental Protection Agency, the National Science Foundation, and some offices in the Department of Veterans Affairs.

Significantly, the FDA is not a Common Rule agency and the Common Rule differs from the FDA's IRB and informed consent regulations (pending harmonization efforts required by the 21st Century Cures Act).

The Common Rule requires any organization engaged in federally funded or federally sponsored research, regardless of location, to maintain a Federalwide Assurance—a written commitment to compliance with human research protection regulations—with the federal Office for Human Research Protections (OHRP) and to adhere to the Common Rule's provisions governing informed consent, IRB review, and protection of vulnerable populations, among other things. See 45 C.F.R. § 46.103(d).

Clinical trials generally will not qualify for a Common Rule exemption. However, some forms of research, including survey research and research using existing data or biospecimens, are exempt from some, or all, of the Common Rule reporting requirements.

Note that in addition to the Common Rule, federal funding also requires compliance with detailed administrative requirements, cost principles, audit requirements, and other public policy requirements—some of which are challenging in the context of OUS clinical trials—that are beyond the scope of this practice note.

For information about the Common Rule, see Privacy and Confidentiality in Clinical Research, Institutional Review Boards, and Special Populations in Clinical Trials.

HIPAA

The privacy regulations issued pursuant to the Health Insurance Portability and Accountability Act (HIPAA) may impact an OUS clinical trial if identifiable health information from foreign sites passes through certain types of U.S. entities.

HIPAA requires "covered entities," which include most healthcare providers but generally exclude medical device or drug manufacturers, to adhere to various requirements related to protected health information (PHI). See 45 C.F.R. § 160.103. HIPAA also governs the relationship of covered entities and "business associates," or contractors that perform certain functions for the covered entity involving the use or disclosure of PHI.

Accordingly, HIPAA may apply if a U.S. healthcare provider conducts an OUS clinical trial, a U.S. physician serves as an investigator on an OUS clinical trial, or a covered entity de-identifies PHI or performs data aggregation for a covered entity conducting an OUS clinical trial. If no PHI passes through a covered entity, then HIPAA will likely not apply.

For information about HIPAA, see HIPAA Resource Kit.

FCPA

The Foreign Corrupt Practices Act (FCPA) creates significant risks for study sponsors because most hospitals and universities in many countries are government-owned, and conducting studies in some countries requires substantial interaction with other foreign officials. Moreover, violation of the FCPA can result in substantial civil and criminal penalties.

The Foreign Corrupt Practices Act (FCPA) generally prohibits the payment of anything of value to foreign officials or entities to improperly assist in obtaining or retaining business. See 15 U.S.C. § 78dd-1(a). The definitions of "payment" and "foreign official" are quite broad, and the Department of Justice has taken the position that employees of government-owned hospitals and universities are "foreign officials" for purposes of the FCPA.

Federal scrutiny is generally focused on operations in countries with poor transparency and corruption ratings. As a result, sponsors and investigators should be particularly attuned to the political environment of a trial site and work to minimize any FCPA risks that may otherwise arise.

Sponsors that choose to conduct OUS clinical trials should maintain robust FCPA compliance programs.

For information about the FCPA, see Foreign Corrupt Practices Act (FCPA) in the Capital Markets & Corporate Governance practice area.

Additional U.S. Laws

Export control laws may impact OUS clinical trials that require items or information, such as software, technology, or other commodities, to be sent from the U.S. to a location abroad. For example, these materials can include technology used to administer trials, encrypted software used to facilitate trials, and biological agents or laboratory equipment.

Additionally, there may be nation- or region-specific limitations that a sponsor should consider. These export laws and regulations, administered by the U.S. Departments of State, Commerce, and Treasury, regulate the export of sensitive technologies, equipment, software, biological agents, and other data and services.

Violating export control laws can result in sanctions or even criminal penalties.

For a civil violation, a violating sponsor may be subject to a fine of $300,000 or twice the value of the illicit transaction; revocation of its license to export, re-export, or transfer controlled items in the United States; and a prohibition on the sponsor's ability to export, re-export, or transfer in-country any controlled item.

If the violation was willful, the sponsor can be fined at most $1,000,000, and the responsible individual could spend up to 20 years in prison. For an OUS clinical trial that involves any controlled items or technologies, diligent site selection is essential to avoid running afoul of the U.S. export control system.

The following three key export control regulatory frameworks must be considered by study sponsors: the Export Administration Regulations (Department of Commerce), the International Traffic in Arms Regulations (Department of State), and the Office of Foreign Asset Control (OFAC) (Department of Treasury).

In addition to the agencies noted above, the FDA also regulates the export of investigational drugs and medical devices.

Investigational drugs can only be exported if:

- An IND is already in effect and the drug complies with the laws of the importing country and each person receiving the drug is an approved investigator under the IND –or–
- No IND is in effect, but other requirements are met

To export an investigational medical device, a sponsor must obtain the FDA's prior approval through a Certificate of Exportability. The statutory authority and requirements for a certificate are based on the type of medical device being exported. Class I medical devices must comply with Section 801(e) of the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. § 381(e); and Class II and Class III devices

must comply with Section 802, 21 U.S.C. § 382. Additional nation-specific requirements may also apply.

In addition to import and export controls, a sponsor should also be aware of restrictions and licensing requirements associated with selling or exporting products to companies and countries sanctioned by the U.S. government. OFAC maintains a list of sanction programs specific to countries; and a list of sanctioned individuals and companies associated with the targeted countries. Generally, U.S. persons are prohibited from engaging in business with these individuals, entities, or nations.

For information about U.S. export rules, see Export Compliance Programs in the Commercial Transactions practice area.

Foreign Laws Implicated by OUS Clinical Trials

Data Protection Laws

The European Union's General Data Protection Regulation (GDPR) is perhaps the most prominent foreign data protection regime impacting the processing and transfer of clinical trial data.

GDPR has become a template on which other countries have based their national data protection laws. GDPR's reach is extensive in that it applies to any entity that processes the personal data of a European resident located in a European Union single market country, whether or not that entity has an established presence in the European Union. GDPR impacts the processing of personal data for research, consent to data processing, secondary uses, storage, and data subjects' rights (e.g., to access, rectification, to be forgotten, and to object).

For information about the GDPR, see General Data Protection Regulation (GDPR) Overview Resource Kit in the Data Security & Privacy practice area.

Many other nations have passed data protection laws in recent years. For example, Brazil's Lei Geral de Proteção de Dados Pessoais came into effect in August of 2018, South Africa's Protection of Personal Information Act came into effect in July of 2020, and China's Personal Information Protection Law of the People's Republic of China came into effect in November of 2021.

Laws Governing the Approval and Conduct of Clinical Trials

In addition to applicable U.S. law and foreign data protection laws, OUS clinical trials are subject to study-related laws and regulations of the country in which the research is conducted. Laws and regulations specifically applicable to clinical research may include requirements for approval by an ethics committee or a regulating body, registration of the clinical trial in a public database, sponsor responsibilities in the event of a research injury, and laws governing human biological materials.

For information about state regulation of clinical trials, see Clinical Research State Law Survey.

For information about U.S. data protection laws, see the Data Security & Privacy State Law Comparison Tool.

IEC Review and Review by a Governmental or Regulating Body

Many countries require approval by an independent ethics committee and/or a governmental or regulating body prior to conducting research on human subjects.

For example, Argentina requires research projects in human health to be submitted for evaluation, guidance, and approval by a research ethics committee that is independent of the sponsor, before the project starts and during its development. Further, the provincial health authorities are responsible for registering and supervising research ethics committees. In South Africa, health research that involves human participants must undergo independent review by a registered health research ethics committee and where applicable, the Medicines Control Council.

Even where a U.S.-based IRB has reviewed the trial and where that IRB meets local requirements, sponsors should carefully consider whether having a local ethics committee review the trial as well may offer additional insights or protections.

Informed Consent

Most countries require that researchers obtain informed consent from study subjects. Informed consent that is voluntary is also a cornerstone of ethical clinical research in human subjects trials. However, cultural and regional norms and literacy rates affect how consent is practically given. The International Council for Harmonisation (discussed in more detail below) has specific GCP guidance related to informed consent in E6, and sponsors and researchers generally seek consent even if local law does not require it.

For example, Israel requires obtaining prior informed consent before conducting a clinical trial with human subjects unless an exception applies. Egypt requires investigators to comply with the ethical principles originating in the Declaration of Helsinki in obtaining and documenting informed consent, which must be approved by

the institutional review board and subject to ongoing review if any changes are subsequently made. Specific guidelines for informed consent must likewise be followed in Thailand.

Biospecimens

Many countries have rules regarding the secondary use of biospecimens in research. Issues regarding the use of biospecimens are often tied to subjects' informed consent or waiver thereof, depending on the circumstances and proposed use of the biospecimens.

The use of human tissue samples for retrospective studies in Thailand requires following several requirements; in certain situations, the ethics committee may agree to waive the tissue owners' informed consent by taking into account a list of consideration such as the modes of obtaining the tissue samples (e.g., from pathology storage, a blood bank). In India, informed consent, confidentiality, privacy, and re-consent are largely influenced by the degree of identifiability, whether the biospecimens and data are anonymized or not. As a general principle, research must be conducted on least identifiable data.

Clinical Trial Registries

Clinical trial registries are databases of research in a particular area, usually a country. In Switzerland, authorized clinical trials must be recorded in a public registry, with specifications indicated by the Federal Council. In Brazil, all clinical trials involving investigators and participants from different countries must be registered after approval from a national ethics committee and before enrollment of the first patient.

Research/Subject Injury

Countries vary on the issue of how research-related injuries are handled. Medicines Australia recommends (but does not require) that a sponsor of a clinical trial pay compensation to participants suffering personal injury, including death, if attributable to participation in the trial. In China, sponsors must ensure that participants and researchers can be compensated. The sponsor must bear the cost of diagnosis and treatment for damage or death of a participant, in addition to the corresponding compensation.

Note that OHRP provides a summary of international human research laws. You may also consult with local counsel or CROs familiar with the markets where OUS trials will operate.

Clinical Trial Agreement Templates

Some countries have adopted model or template clinical trial agreements.

For example, the United Kingdom's National Health Service issued the National Directive on Commercial Contract Research Studies, which sets out provider requirements for commercial contract research. A commercial contract research study is a research project that is fully sponsored and fully funded by a commercial company, regardless of its National Institution for Health Research Clinical Research Network portfolio status, except for investigator-initiated trials and other industry collaborative studies not solely sponsored by a commercial entity.

In France, sponsors that set up clinical trials with a French hospital must use the updated "La Convention Unique" issued by the Ministry of Health and Prevention. The template includes key updates to conform with GDPR and the European Union's Clinical Trial Regulation, fee structures for services, handling of biological materials, confidentiality, and electronic versions of the contract.

International Codes/Standards

ICH GCP

With roots in the Declaration of Helsinki, the International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use – Guidelines for Good Clinical Practice (GCP) was issued in 1996 as an internationally agreed standard to ensure ethical and scientific quality in designing, conducting, recording, and reporting human subjects clinical trials. The purpose of GCP is to facilitate the mutual acceptance of clinical data by regulatory authorities in the European Union, Japan, and the United States.

According to the FDA, GCP is consistent with the FDA's good guidance practices regulation at 21 C.F.R. § 10.115 and reflects the FDA's current thinking on good clinical practices, but GCP is not binding on the FDA or the public.

In April of 2021, ICH released a draft of GCP E6(R3), which is meant to be aligned with the principles of ICH's E8(R1) Revision of General Considerations for Clinical Studies. ICH's E8(R1) includes a framework for designing quality into clinical trials, stakeholder engagement, trial design, proportionate trial management, and focus on factors critical to the quality of trials.

ICH recognizes that since the development of E6(R2), clinical trials have continued to evolve with new designs and technological innovations. ICH is developing E6(R3) to provide guidance that is applicable to different clinical trial designs and to focus on key principles and objectives. E6(R2) focused on a proportionate, risk-based approach to design and conduct of clinical trials and E6(R3) will further advance this concept and encourage relevant parties to

utilize this approach. For additional information, see ICH Final Business Plan, ICH E6(R3): Guideline for Clinical Practice.

Declaration of Helsinki

The Declaration of Helsinki (the Declaration) was developed in 1964 by the World Medical Association and it is regarded as a foundational document on human subject research ethics. Several revisions have been made to the Declaration (most recently in 2013) and it is currently under consideration for further revision.

In 2008, the FDA made a switch at 21 C.F.R. § 312.120 from the Declaration to GCP with respect to the acceptance of foreign clinical studies not conducted under an IND. Specifically, the FDA required these studies to be conducted according to the ethical principles of the GCP instead of the Declaration. One reason for the change was that the evolving standard for human subject protections are better addressed in the GCP. Additionally, the FDA believed that the Declaration did not provide sufficient guidance on how to ensure proper conduct of clinical trials. Practically, the FDA believed that the switch from the Declaration to GCP would reduce confusion about which revisions of the Declaration would apply to these studies.

It is worth noting that the United States also objected to certain revisions made to the Declaration between 2000 and 2004 and these objections appear to have motivated the FDA's decision to switch to GCP. Specifically, the United States objected to paragraphs 29 and 30. Paragraph 29 required: "The benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists." Paragraph 30 stated: "At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study." Sponsors that agree to comply with the Declaration of Helsinki, either by contract or by conducting trials in countries that mandate compliance with it, should be cognizant of where these requirements differ from what is required in the U.S.

OHRP recognizes in its Federalwide Assurance that an institution's human subjects research activities, which are required to be guided by a statement of principles, may rely on an existing statement of principles. In other words, foreign institutions can choose among several options for both ethical principles (e.g., Declaration of Helsinki) and research standards (e.g., ICH GCP E6, Common Rule, etc.).

CIOMS

The Council for International Organizations of Medical Sciences (CIOMS) is an international, nongovernmental, nonprofit organization established by the World Health Organization (WHO) and UNESCO in 1949. WHO and UNESCO established CIOMS to facilitate the exchange of views and scientific information in the medical sciences by securing continuity and coordination between international organizations of medical sciences, by making their work known, and by providing them with material aid where necessary. That purpose has expanded to accommodate other forms of international collaboration in the medical sciences. CIOMS issues publications on topics such as ethics, pharmacovigilance, and international nomenclatures of diseases. CIOMS guidelines are particularly salient when contracting with foreign entities in low- and middle-income countries.

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Clint Hermes draws on his deep experience as general counsel at two teaching hospitals to advise clients on regulatory, accreditation, and corporate governance matters in academic medicine. In addition, Clint also offers clients practical advice and insights on all regulatory and contracting aspects of human and animal research.

Clint's accomplishments on behalf of academic medical centers have been as varied as negotiating complex academic affiliation agreements; implementing enterprise risk management programs; securing dismissal of a *qui tam* action involving federal grant compliance; preparing clients for Joint Commission, AAHRPP, and ACGME reviews; lobbying HHS for changes to a PREP Act declaration; obtaining a favorable OIG Advisory Opinion; and establishing healthcare and humanitarian programs overseas.

Clint has extensive experience with the regulation of human and animal research, clinical trial registration and transparency, conflicts of interest, federal grants, biospecimens, data sharing, and expanded access to investigational products. His work on behalf of the research missions of academic medical centers and life sciences companies has taken him throughout Africa, Asia, the Middle East, and South America. He has served on numerous Institutional Review Boards (IRBs) in the United States and abroad, including as Vice Chair of a Harvard-affiliated IRB and of a biobank IRB abroad, and as science policy advisor to a foreign government.

Clint has authored numerous articles and book chapters (including one published by Cambridge University Press) in the areas of international health projects and biomedical research and has been quoted in publications such as MIT's *Technology Review*, *Bloomberg Law*, *Modern Healthcare*, *STAT News* and *Canada's Globe and Mail*.

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Before law school, Heather was a public health analyst at RTI International, focusing on program evaluation and health system financing for the Centers for Medicare & Medicaid Services (CMS). During law school, she summered at the Center for Health Law & Policy Innovation at Harvard Law School and in the Office of the Chief Counsel at the Food & Drug Administration (FDA). Before joining the firm, she served as a term law clerk for the Honorable Damon R. Leichty of the United States District Court for the Northern District of Indiana and the Honorable Carol Hooten of the Minnesota Court of Appeals. Heather earned a law degree from the University of Notre Dame Law School and an undergraduate degree in biomedical anthropology from Wellesley College.

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Angelique earned her law degree from The University of Chicago Law School where she also earned a Graduate Program in Health Administration and Policy (GPHAP) Certificate and was awarded the Erikson Fellowship for her work at a Chicago-area hospital. Angelique is a member of the American Health Law Association (AHLA) and served on the Hospitals and Health Systems practice group in the Leadership Development Program from 2020-2021.