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| [Screen 0](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=1_C_1) [1\_C\_1](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=1_C_1)  | Scientific Research OverviewClick the forward arrow to begin. |  |
| [Screen 1](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=2_C_2) [2\_C\_2](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=2_C_2)  | Whether exploring a promising new therapy, developing a pioneering technology, or just helping people live longer healthier lives, scientific research is an essential part of our success as a company.This course will look at the different types of research we support and will explain how laws and regulations, along with our own internal policies and procedures, have been put in place to protect the integrity of this research. It will also provide you with some practical advice on how to ensure that we continue doing research not only in the right way, but also for the right reasons. |  |
| [Screen 2](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=3_C_3) [3\_C\_3](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=3_C_3)  | Upon completion of this course, you will be able to:* Explain why Abbott conducts and supports scientific research;
* Distinguish between the different types of research Abbott conducts and supports;
* Explain the reasons for some of the key laws, regulations, and standards that govern scientific research;
* State the requirements that Abbott has put in place to govern the way in which we conduct research;
* Describe the roles and responsibilities of scientific personnel as opposed to sales, marketing, and other non-scientific personnel; and
* Know where to go for help and support.
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| [Screen 3](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=4_C_4) [4\_C\_4](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=4_C_4)  | 1 | Advancing ScienceHere you will learn about the different kinds and levels of scientific research we support.6 MinutesSection 1 | Advancing ScienceWhy We Conduct ResearchThe Types of Research We SupportReview2 | Scientific IntegrityHere you will learn how laws, regulations, and our internal requirements govern how we conduct research.12 MinutesSection 2 | Scientific IntegrityLaws, Regulations and StandardsAbbott’s Internal RequirementsReview3 | Playing Your PartHere you will learn how to ensure Abbott’s research activities remain focused on the legitimate advancement of science.6 MinutesSection 3 | Playing Your PartWhat to Do – Non-Scientific FunctionsWhat to Do – Research and Scientific FunctionsWhere to Go for SupportReview4 | Knowledge CheckAssess your understanding of the key concepts and principles of this course.5 MinutesSection 4 | Knowledge CheckAssessmentClick the panel to get started.Click the yellow play button to begin.This content is not yet available. You must complete Section{a} {b}. |  |
| [Screen 4](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=5_C_8) [5\_C\_8](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=5_C_8)  | Scientific research helps us determine if a product is effective.In other words, it tells us if a product works. And if it does work, how well. |  |
| [Screen 5](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=6_C_9) [6\_C\_9](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=6_C_9)  | Scientific research provides us with the evidence that is required for regulatory approvals and market access decisions around the world.It serves as the basis for promotional claims once a product is approved. |  |
| [Screen 6](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=7_C_10) [7\_C\_10](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=7_C_10)  | Scientific research helps us to gain knowledge about product safety both before and after we launch a product.It helps to answer the question: is the product safe and effective? |  |
| [Screen 7](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=8_C_11) [8\_C\_11](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=8_C_11)  | Scientific research answers many other questions as well. In doing so, it helps us to produce products that are not only safe and effective, but also:* Easier to use,
* More cost effective, and
* More reliable.

As we make our way through this course, you will learn more about the benefits of scientific research, and more importantly, about the role each of us has to play in safeguarding its integrity. |  |
| [Screen 8](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=9_C_12) [9\_C\_12](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=9_C_12)  | There are many different kinds and levels of scientific research that Abbott supports.Generally, this research breaks down into two broad categories: Abbott-sponsored clinical research, and Investigator-sponsored Studies (ISS) (also known as Investigator Initiated Studies (IIS)). |  |
| [Screen 9](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=10_C_13) [10\_C\_13](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=10_C_13)  | Abbott-sponsored clinical research are studies that are designed and managed by Abbott.These studies typically include one or more participating medical centers (institutions), with properly qualified physicians or other healthcare professionals (investigators) conducting the study. |  |
| [Screen 10](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=11_C_14) [11\_C\_14](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=11_C_14)  | Before a new product is approved for treatment or use, Abbott conducts a trial or series of trials to prove that the product is safe and effective, and to ultimately understand the extent of effectiveness.They generally provide the evidence to support regulatory approvals required to market our products in jurisdictions around the world. |  |
| [Screen 11](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=12_C_15) [12\_C\_15](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=12_C_15)  | Once a product or treatment is approved, Abbott sometimes conducts additional research.Its aim is to help us better understand product performance over its lifecycle. These trials are sometimes even required as a condition of product approval. |  |
| [Screen 12](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=13_C_16) [13\_C\_16](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=13_C_16)  | What is most important to understand is that while there may be third-party institutions and investigators participating in the conduct of clinical trials, Abbott is responsible for company-sponsored clinical research. |  |
| [Screen 13](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=14_C_17) [14\_C\_17](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=14_C_17)  | Investigator-sponsored studies (ISS) are studies that are initiated, designed, and conducted by external investigators and institutions.That is to say, the investigator or institutional sponsors are responsible for the conduct of such studies. |  |
| [Screen 14](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=15_C_18) [15\_C\_18](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=15_C_18)  | ISS studies can include, for example:* Additional research into approved uses of marketed products,
* Comparisons with other therapies, and
* Investigations into potential new uses of existing products.
 |  |
| [Screen 15](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=16_C_19) [16\_C\_19](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=16_C_19)  | In some cases, Abbott may choose to provide funding and/or other support for ISS.For example, the Company may provide Abbott product to be used in the study. |  |
| [Screen 16](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=17_C_20) [17\_C\_20](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=17_C_20)  | However, it is important to keep in mind that as we are not the study sponsor and are not responsible for conduct of the ISS, our involvement is generally limited:* We do not have regulatory responsibilities for the ISS.
* We do not initiate ISS.
* We are not responsible for design of the protocol.
* We do not conduct or supervise the research.
* We are not responsible for analyzing the data from the study.
 |  |
| [Screen 17](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=18_C_21) [18\_C\_21](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=18_C_21)  | Limiting our involvement in the conduct of ISS is necessary so there’s no misunderstanding around who is responsible for the study, and to help maintain the integrity and independence of the study results. |  |
| [Screen 18](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=19_C_22) [19\_C\_22](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=19_C_22)  | Click the arrow to begin your review.ReviewTake a moment to review some of the key concepts in this section.Why We Conduct ResearchScientific Research helps us to produce products that are not only safe and effective, but also:* Easier to use;
* More cost effective; and
* More reliable.

Abbott-sponsored clinical researchAbbott conducts clinical research to prove that a product is safe and effective, and to ultimately understand the extent of effectiveness. Additional research may be conducted to help us better understand product performance over its lifecycle.Investigator-sponsored studies (ISS)These are studies that are initiated, designed, and conducted by external investigators and institutions. Abbott has no regulatory responsibilities associated with these studies.Funding and Support for ISSAbbott may choose to provide funding and/or other support for Investigator-Sponsored Studies. However, we are not the study sponsor, and our involvement is limited.To check your progress, click the Menu button.You have completed section 1 of 4Click the forward arrow to continue learning |  |
| [Screen 19](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=20_C_24) Activity: Dialogue[20\_C\_24](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=20_C_24)  | Government agencies and regulatory authorities around the world set out laws, regulations, and standards governing many aspects of the research process from clinical trial design to the selection of investigators, from research funding to the timely reporting of meaningful study results. |  |
| [Screen 19](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=21_C_24) [21\_C\_24](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=21_C_24)  | In the case of Abbott-sponsored clinical research, Abbott has the regulatory responsibilities of a sponsor, and is responsible for ensuring the research is conducted consistent with these local laws, regulations, and industry standards. |  |
| [Screen 19](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=22_C_24) [22\_C\_24](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=22_C_24)  | In the case of Investigator Sponsored Studies (ISS), the research is independent from Abbott. The investigator conducting the research has the regulatory responsibilities of a sponsor and investigator and must ensure the research is conducted consistent with these local laws, regulations, and standards. |  |
| [Screen 20](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=23_C_26) [23\_C\_26](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=23_C_26)  | The question of why we conduct or support research is of particular interest to regulators and government agencies.Government agencies want to ensure that research funding is never used as a reward for buying, using, influencing the use of, or recommending our products, or as a means to promote an unapproved or off-label use of a product. |  |
| [Screen 21](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=24_C_28) Activity: Scenario[24\_C\_28](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=24_C_28)  | Imagine . . .You work in Research and Development. You set up a robust post-marketing trial for the purpose of comparing the long-term safety of Abbott’s drug-eluting stents with that of a competitor’s. You recruit a group of highly qualified vascular surgeons (some of whom currently use Abbott stents and some who use a competitor’s technology) solely on the basis of their qualifications and expertise, and pay them fair market value compensation for their services.That's not correct!That's correct!That's partially correct! |  |
| [Screen 21](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=26_C_28) Activity: Questions[26\_C\_28](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=26_C_28)  | Is there anything in this arrangement that you think might raise a red flag with government regulators?[1] Yes.[2] No.Submit |  |
| [Screen 21](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=25_C_28) Activity: Feedback[25\_C\_28](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=25_C_28)  | * The trial design is robust.
* The endpoint (comparing the long-term safety of Abbott’s stents with that of a competitor’s) is clear.
* The selection of investigators has been properly based on qualifications and expertise.
* Payment is based on fair market value compensation.
 |  |
| [Screen 22](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=27_C_29) Activity: Scenario[27\_C\_29](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=27_C_29)  | Now imagine . . .You set up exactly the same trial: same endpoint, same group of doctors, same compensation. The only difference is that this time the trial is being driven by the Xience marketing group, who see it as a great opportunity to introduce their stents to a new group of doctors.That's not correct!That's correct!That's partially correct! |  |
| [Screen 22](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=29_C_29) Activity: Questions[29\_C\_29](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=29_C_29)  | Do you think government regulators would still view this clinical trial as okay?[1] Yes.[2] No.Submit |  |
| [Screen 22](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=28_C_29) Activity: Feedback[28\_C\_29](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=28_C_29)  | Even though on the surface it's the same exact trial – same endpoint, same group of doctors, same compensation – something fundamental has changed.What's changed is the reason why the research is being conducted. It is now clear that the real intent of the study isn’t to test the long-term safety of two technologies side-by-side, but rather to familiarize some of the vascular surgeons with Abbott’s stents. |  |
| [Screen 23](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=30_C_31) [30\_C\_31](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=30_C_31)  | In fact, any trial that is used for the purpose of improperly inducing or rewarding someone to use or recommend a company’s products, or to improve access to, or relationships with, Health Care Professionals (HCPs) or Investigators, may be considered illegal based on anti-corruption or anti-kickback laws.CLICK THE OTHER LAWS BUTTON TO LEARN MORE. |  |
| [Screen 23](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=31_C_31) [31\_C\_31](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=31_C_31)  | OTHER LAWSOther laws that target kickbacks and corrupt and fraudulent practices in the clinical research context, include:* The U.S. Anti-kickback Statute
* The Foreign Corrupt Practices Act
* The U.K. Bribery Act
* The Prevention of Corruption Law in India
* The Countermeasures Against Corruption Law in Russia
 |  |
| [Screen 24](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=32_C_32) [32\_C\_32](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=32_C_32)  | The bottom line is that it is illegal to make research payments or provide other items of value in order to improperly induce or reward investigators and HCPs to use or recommend the company’s products. |  |
| [Screen 25](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=33_C_33) [33\_C\_33](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=33_C_33)  | It is also illegal to conduct scientific research as a “disguised” means of promoting unapproved uses of Abbott products.For example, supporting a research study that has little or no scientific value in order to get a product used in an unapproved manner would likely be viewed as off-label promotion of the product which is prohibited by Abbott policies and is illegal in many jurisdictions. |  |
| [Screen 26](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=34_C_34) [34\_C\_34](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=34_C_34)  | How we conduct or support research is also of interest to regulatory authorities. |  |
| [Screen 27](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=35_C_35) [35\_C\_35](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=35_C_35)  | In most trials, government agencies and regulatory authorities specify requirements for nearly every aspect of the research process.For Abbott-sponsored clinical research, Abbott and the Investigator/Site has a shared regulatory responsibility to assure the requirements.For ISS, the Investigator is solely responsible for these regulatory requirements, but Abbott assesses Investigator ability to comply as part of a support decision to fund an ISS. |  |
| [Screen 28](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=36_C_35b) [36\_C\_35b](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=36_C_35b)  | Authorities specify requirements relating to:* The design of the clinical trial;
* The selection and funding of investigators and study sites;
* The monitoring of the trial;
* The reporting of serious adverse events and safety issues;
* Patient authorization and informed consent;
* Patient privacy; and
* The reporting of study results.
 |  |
| [Screen 29](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=37_C_36) [37\_C\_36](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=37_C_36)  | In addition to local laws and regulations, voluntary standards (which describe Good Clinical Practice (GCP) and Good Scientific Practice (GSP)) set out further guidelines.Such as, but not limited to, standards by International Standards Organization (ISO) and International Committee and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).These guidelines help to ensure both the integrity of the scientific method, as well as patient safety and consent. |  |
| [Screen 30](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=38_C_37) [38\_C\_37](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=38_C_37)  | Let’s now take a look at some of the internal requirements that help ensure we comply with these laws, regulations, and standards. |  |
| [Screen 31](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=39_C_38) [39\_C\_38](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=39_C_38)  | First and foremost, Abbott ensures that all Abbott-sponsored clinical research fills a legitimate need.That means that before any research begins, Abbott reviews researchers’ proposals and determines if Abbott will support it. Research Protocols are developed, reviewed, and approved by appropriate scientific/medical/clinical staff. The Research Protocols are reviewed to determine whether or not it:* Follows appropriate clinical or scientific practices,
* Has a clear hypothesis or end point, and
* Has the legitimate goal of advancing clinical or scientific understanding.
 |  |
| [Screen 32](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=40_C_39) [40\_C\_39](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=40_C_39)  | Once approved, Abbott selects investigators and sites based on relevant criteria, such as:* Training and experience;
* Access to relevant patient or consumer populations;
* Appropriate research facilities; and
* History of conducting research in accordance with all applicable legal, regulatory, and other requirements.
 |  |
| [Screen 33](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=41_C_40) [41\_C\_40](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=41_C_40)  | Abbott never bases its selection decisions on marketing objectives, such as the desire to gain or improve access to particular customers or to reward customers for the value or volume of their business.Abbott also has requirements to ensure that investigators and sites selected to conduct research are not debarred, restricted, or otherwise disqualified from conducting research by any relevant regulatory authority or governing body. |  |
| [Screen 34](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=42_C_41) [42\_C\_41](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=42_C_41)  | Compensation paid to investigators or sites is always reasonable and based on fair market value for the country where the research is conducted.Compensation and other terms reflective of materials, overhead and any other support provided is documented in a contract with the investigator or site conducting the research. And, under no circumstances is compensation ever to be tied to the outcome of the study. |  |
| [Screen 35](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=43_C_42) [43\_C\_42](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=43_C_42)  | Once the study results are available, Abbott requires timely reporting in an objective, accurate, and complete manner.CLICK THE DOWN ARROW TO LEARN MORE.Abbott-Sponsored Clinical ResearchIn the case of Abbott-sponsored clinical research where Abbott has control and full responsibility for the study and is required to register and post results, Abbott ensures that these studies are registered, and meaningful study results are shared through scientific posters, medical journals, and publicly accessible clinical trial registries such as clinicaltrials.gov and Eudamed.There are even guidelines, such as the International Committee of Medical Journal Editors (ICMJE), that set out criteria for who can and should be named as authors on scientific research publications.Investigator-Sponsored StudiesIn the case of investigator-sponsored studies, where research is initiated, designed, and conducted by external investigators and institutions, Abbott has less control but still uses reasonable effort to encourage disclosure of the study results in a timely and reasonable manner. |  |
| [Screen 36](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=44_C_43) [44\_C\_43](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=44_C_43)  | Abbott also has additional requirements in place to ensure the safe and appropriate conduct of scientific research.For example, Clinical Research is conducted with Human Subject Protection considerations, such as Ethics Committee review and oversight to ensure safety and independent oversight, informed consent and following applicable laws to protect rights and confidentiality of personal and medical information.These checks and balances help to ensure our scientific research activities comply with the laws, regulations, and standards that have been put in place to protect the interests of the people who use and recommend our products. |  |
| [Screen 37](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=45_C_44) [45\_C\_44](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=45_C_44)  | Click the arrow to begin your review.ReviewTake a moment to review some of the key concepts in this section.Inducements and RewardsIt is illegal to make research payments or provide other items of value in order to improperly induce or reward investigators and HCPs to use or recommend the company’s products.Off-Label PromotionIt is illegal to conduct scientific research as a “disguised” means of promoting unapproved uses of Abbott products.Legitimate NeedAll research must fill a legitimate need.Selection of InvestigatorsInvestigators and sites must be selected based on relevant criteria.CompensationCompensation paid to investigators or sites must be reasonable and based on fair market value for the country where the research is conducted.Reporting of Study ResultsStudy results must be reported in a timely, objective, accurate, and complete manner.SafetyAll Scientific research must be conducted in a safe and appropriate manner.To check your progress, click the Menu buttonYou have completed section 2 of 4Click the forward arrow to continue learning |  |
| [Screen 38](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=46_C_45) [46\_C\_45](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=46_C_45)  | In scientific research, the roles and responsibilities of medical and research personnel differ from those of their sales, marketing, and other non-scientific colleagues. |  |
| [Screen 39](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=47_C_46) Activity: Dialogue[47\_C\_46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=47_C_46)  | | Senior Sales Representative I work in sales. What are some of the key things that I need to keep in mind? |  |
| [Screen 39](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=48_C_46) [48\_C\_46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=48_C_46)  | For sales, marketing, and other functions not responsible for conducting or managing research, here are three important things to remember. |  |
| [Screen 39](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=49_C_46) [49\_C\_46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=49_C_46)  | Leave scientific research activities to the research-related functions.Sales, marketing, and similar non-research functions may provide input on strategic priorities for scientific research, but may not direct, control, or unduly influence decisions relating to research activities. |  |
| [Screen 39](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=50_C_46) [50\_C\_46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=50_C_46)  | Limit your input into investigator or site selection to what is permitted in your policies or procedures.Never lobby research colleagues on behalf of particular investigators or sites. And never demand that a site or investigator be included in a study. |  |
| [Screen 39](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=51_C_46) [51\_C\_46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=51_C_46)  | Finally, always refer scientific research questions to an appropriate research representative or resource in your division. This includes:* Requests for support of ISS
* Requests from investigators or sites to participate in Abbott-sponsored clinical research
* Questions about research involving unapproved products or unapproved uses of approved products
 |  |
| [Screen 40](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=52_C_47) Activity: Dialogue[52\_C\_47](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=52_C_47)  | | Senior R&D Manager I work in R&D. What are the important things I need to do in order to remain compliant? |  |
| [Screen 40](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=53_C_47) [53\_C\_47](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=53_C_47)  | If you are part of Abbott’s scientific, medical, or research team responsible for initiating, designing, and/or managing Abbott-sponsored clinical research, here is what you need to do. |  |
| [Screen 40](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=54_C_47) [54\_C\_47](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=54_C_47)  | Always ensure that the trial or study fills a legitimate scientific need and has a clear goal of advancing clinical or scientific understanding.For example, if you are reviewing a proposed ISS, ensure that* There is a need for the research,
* The study has clear scientific value, and
* The study can be conducted in accordance with applicable requirements.
 |  |
| [Screen 40](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=55_C_47) [55\_C\_47](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=55_C_47)  | Only select investigators and sites for research based on objective criteria relevant to the research itself. |  |
| [Screen 40](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=56_C_47) [56\_C\_47](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=56_C_47)  | Make sure that all payments for research reflect fair market value.Ensure that payments are only made for actual research performed, and always based on fair market value for the services being performed. |  |
| [Screen 40](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=57_C_47) [57\_C\_47](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=57_C_47)  | Always ensure the appropriate and timely reporting of meaningful study results in an objective, accurate, and complete manner as required by Abbott policies and procedures.Regardless of outcome, never suppress or prohibit the publication of study results. |  |
| [Screen 40](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=58_C_47) [58\_C\_47](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=58_C_47)  | Be fully transparent regarding involvement in the research and publication process.Always ensure that Abbott’s involvement (including your own personal involvement) is disclosed in accordance with applicable requirements. |  |
| [Screen 40](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=59_C_47) [59\_C\_47](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=59_C_47)  | Always respect the independent nature of ISS research by following applicable requirements regarding Abbott involvement. That means:* Not taking responsibility for design of the protocol;
* Not helping to conduct or supervise research; and
* Not taking responsibility for data analysis or manuscript development.
 |  |
| [Screen 41](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=60_C_48) [60\_C\_48](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=60_C_48)  | If you are unsure or have questions about your role and responsibilities in respect to scientific research, it is usually best to speak to your manager first.The Office of Ethics and Compliance (OEC) and Legal are also resources that can help you analyze the situation and brainstorm alternatives. |  |
| [Screen 42](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=61_C_49) [61\_C\_49](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=61_C_49)  | If you have concerns about the research practices of a colleague or third-party partner, talk to the OEC or Legal, or voice your concerns via the OEC Helpline at speakup.abbott.com.(The OEC Helpline is available 24 hours a day 7 days a week and allows you to submit concerns online or by calling an operator who speaks your language.) |  |
| [Screen 43](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=62_C_50) [62\_C\_50](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=62_C_50)  | Click the arrow to begin your review.ReviewTake a moment to review some of the key concepts in this section.Sales, Marketing, and Other Similar FunctionsAlways leave scientific research activities to the research-related functions.Legitimate NeedAll research must fill a legitimate need.Selection of InvestigatorsInvestigators and sites must be selected based on relevant criteria.CompensationCompensation paid to investigators or sites must be reasonable and based on fair market value for the country where the research is conducted.Reporting of Study ResultsStudy results must be reported in a timely, objective, accurate, and complete manner.TransparencyBe fully transparent regarding involvement in the research and publication process.IndependenceAlways respect the independent nature of ISS research by following applicable requirements regarding Abbott involvement.To check your progress, click the Menu buttonYou have completed section 3 of 4Click the forward arrow to continue learning |  |
| [Screen 44](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=63_C_51) [63\_C\_51](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=63_C_51)  | Where to Get HelpManagerIf you have questions about scientific research or have concerns about research practices of a colleague or a third-party, the best place to start is with your manager.Written Standards* Code of Business Conduct – For our company’s fundamental set of expectations of every employee, consult our [Code of Business Conduct](https://abbott.sharepoint.com/sites/abbottworld/EthicsCompliance/cobc/Pages/Code-eBook-and-PDF.aspx).
* Global Policy Portal – For our corporate policies and procedures applicable companywide, visit the [Global Policy Portal](https://abbott.sharepoint.com/sites/abbottworld/GlobalPolicy/Pages/Home.aspx).

Office of Ethics and Compliance (OEC)* OEC Website – Refer to the [OEC website](https://abbott.sharepoint.com/sites/abbottworld/EthicsCompliance/Pages/Home.aspx) for answers to a variety of compliance questions, including questions about Abbott’s support of scientific research. Our company’s global and country-specific OEC policies and procedures can also be accessed from the website.
* OEC Contacts – You are encouraged to contact the OEC at any time with any ethics and compliance questions, or to discuss concerns about possible violations of our written standards, laws, or regulations:
* Corporate OEC – Call 1-224-667-5210 or email oec@abbott.com with any questions related to ethics and compliance at Abbott.
* Divisional or Country OEC – Your divisional or country [OEC representative](https://icomply.abbott.com/Apps/ComplianceContacts/) can provide additional guidance on divisional or country-specific OEC policies, procedures, and guidelines.
* OEC Helpline – Visit our multilingual OEC Helpline at [speakup.abbott.com](http://speakup.abbott.com/) to voice your concerns about a potential violation of our company’s values and standards of conduct. The OEC Helpline is available 24 hours a day 7 days a week and allows you to submit concerns online or by calling an operator who speaks your language.
* iComply – Visit [iComply](http://icomply.abbott.com/) to access compliance-related applications and resources geared towards interactions with Health Care Professionals and Health Care Organizations.

Legal DivisionIf you have questions about laws and regulations that govern scientific research, the [Legal Division](https://abbott.sharepoint.com/sites/abbottworld/Legal/Pages/Home.aspx?icid=AW_MN_ORG_Legal) can assist you.Vendor CredentialingMany hospitals are now requesting specific documentation that indicates a company representative is qualified to gain access to the Health Care Organization. If you receive such a request, go to [hcir.oneabbott.com](http://hcir.oneabbott.com/) for information and guidance.Course ResourcesTRANSCRIPTClick [here](http://dummy.com/reference/Transcript.pdf) for a full transcript of the course. |  |
| [Screen 45](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=64_C_53) Activity: Introduction[64\_C\_53](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=64_C_53)  | The Knowledge Check consists of 10 questions. You must score 80% or higher to successfully complete this course.When you are ready, click the Knowledge Check button to begin. |  |
| [Screen 46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=65_C_54) [65\_C\_54](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=65_C_54)  | [1] You should talk to the OEC or Legal if you have concerns about the:[1] Research practices of a colleague.[2] Involvement of sales and marketing personnel in ISS activities.[3] Research activities of third-party partners.[4] All of the above.NextIf you have concerns about the research practices of a colleague or third-party partner, talk to the OEC or Legal, or voice your concerns via the OEC Helpline at speakup.abbott.com. |  |
| [Screen 46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=66_C_54) [66\_C\_54](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=66_C_54)  | [2] Abbott selects investigators and sites to perform research based on criteria such as:[1] Qualifications and expertise.[2] Ability to gain or improve access to customers.[3] Both 1 and 2.NextAbbott’s selection decisions are never based on marketing objectives, such as the desire to gain or improve access to particular customers or to reward customers for the value or volume of their business. Abbott selects investigators and sites based only on criteria relevant to the research itself. |  |
| [Screen 46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=67_C_54) [67\_C\_54](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=67_C_54)  | [3] Abbott ensures that Company-sponsored clinical research protocols are developed, reviewed and approved by appropriate scientific/ medical/clinical staff in order to confirm that the research:[1] Follows appropriate clinical or scientific practices.[2] Has a clear hypothesis or end point.[3] Has the legitimate goal of advancing clinical or scientific understanding.[4] All of the above.NextAbbott’s scientific or medical personnel review and confirm that all research fills a legitimate scientific need or interest and has a clear and legitimate goal of advancing clinical or scientific understanding. For example, research is assessed to confirm it follows appropriate clinical or scientific practice and has a clear hypothesis or end point. |  |
| [Screen 46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=68_C_54) [68\_C\_54](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=68_C_54)  | [4] Studies that have the objective of introducing a new product or therapy to physicians:[1] Are permitted for new indications of already approved products.[2] Can be conducted only in markets where there is a lot of competition between companies trying to sell similar products.[3] Could be considered illegal if the payment is intended to reward or induce investigators to use or recommend a particular product.NextStudies, where the intended objective is to introduce a new product or therapy to physicians, spur sales of the product, or reward physicians for using a product – rather than test a scientific hypothesis or collect data to fill a legitimate need could be considered illegal, if the payment is intended to reward or induce investigators to use or recommend a particular product. |  |
| [Screen 46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=69_C_54) [69\_C\_54](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=69_C_54)  | [5] Sales, marketing, and other similar functions may only respond to a scientific research question if it is unsolicited.[1] True.[2] False.NextSales, marketing, and other similar functions should refer all scientific research questions to an appropriate research representative or resource in their division. |  |
| [Screen 46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=70_C_54) [70\_C\_54](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=70_C_54)  | [6] Scientific and medical personnel involved in providing support for an Investigator-Sponsored Study may provide assistance in designing the protocol.[1] True.[2] False.NextScientific, medical, or research teams involved in providing support for Investigator-Sponsored Studies must always respect the independent nature of the research by following applicable requirements regarding Abbott involvement.That means:* Not taking responsibility for design of the protocol;
* Not helping to conduct or supervise research; and
* Not taking responsibility for data analysis or manuscript development.
 |  |
| [Screen 46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=71_C_54) [71\_C\_54](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=71_C_54)  | [7] Sales and marketing personnel may:[1] Provide input into investigator or site selection as permitted by applicable policies and procedures.[2] Lobby research colleagues on behalf of investigators.[3] Demand that a site or investigator be included in a study.[4] All of the above.NextSales and marketing personnel may provide input into investigator or site selection as allowed by applicable policies or procedures. However, they may never lobby research colleagues on behalf of particular investigators or sites, or demand that a site or investigator be included in a study. |  |
| [Screen 46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=72_C_54) [72\_C\_54](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=72_C_54)  | [8] Abbott is solely responsible for the conduct of:[1] Company-sponsored clinical research.[2] Investigator-sponsored studies.[3] Both 1 and 2.NextAbbott is only responsible for the conduct of company-sponsored clinical research. While we may in some cases choose to provide funding and/or other support for investigator-sponsored studies, we are not the study sponsor and are not responsible for conduct of the study. |  |
| [Screen 46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=73_C_54) [73\_C\_54](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=73_C_54)  | [9] Compensation paid to investigators or sites must be based on fair market value for the country where:[1] The protocol is designed.[2] The research is conducted.[3] The trial is managed.NextCompensation paid to investigators or sites must be based on fair market value for the country where the research is conducted. |  |
| [Screen 46](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=74_C_54) [74\_C\_54](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=74_C_54)  | 10Compensation paid to an investigator may be tied to the outcome of an Investigator-Sponsored Study.[1] True.[2] False.SubmitUnder no circumstances can compensation ever be tied to the outcomes of a study. |  |
| [Screen 47](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=75_C_55) Activity: Overall Feedback[75\_C\_55](http://www.learnex.co.uk/test/AbbottEnterpriseCyber/courses/EN-US/course/index.html?showScreen=75_C_55)  | No results are available, as you have not completed the Knowledge Check.Congratulations! You have successfully passed the Knowledge Check and completed the course.Please review your results below by clicking on each question.Once you are done, you must click the EXIT [X] icon in the course title bar before closing your browser window or browser tab.Sorry, you did not pass the Knowledge Check. Take a few minutes to review your results below by clicking on each question.When you are done, click the Retake Knowledge Check button. |  |
| 76\_toc\_1 | Introduction |  |
| 77\_toc\_2 | Welcome |  |
| 78\_toc\_3 | Objectives |  |
| 79\_toc\_4 | Menu |  |
| 80\_toc\_5 | Advancing Science |  |
| 81\_toc\_6 | Why We Conduct Research |  |
| 82\_toc\_7 | The Types of Research We Support |  |
| 83\_toc\_8 | Review |  |
| 84\_toc\_9 | Scientific Integrity |  |
| 85\_toc\_10 | Laws, Regulations, and Standards |  |
| 86\_toc\_11 | Abbott’s Internal Requirements |  |
| 87\_toc\_12 | Review |  |
| 88\_toc\_13 | Playing Your Part |  |
| 89\_toc\_14 | Overview |  |
| 90\_toc\_15 | What to Do – Non-Scientific Functions |  |
| 91\_toc\_16 | What to Do – Research and Scientific Functions |  |
| 92\_toc\_17 | Where to Go for Support |  |
| 93\_toc\_18 | Review |  |
| 94\_toc\_19 | Knowledge Check |  |
| 95\_toc\_20 | Introduction |  |
| 96\_toc\_21 | Knowledge Check |  |
| 97\_toc\_22 | Assessment |  |
| 98\_toc\_23 | Feedback |  |
| 99\_string\_1 | The Course cannot contact the LMS. Click 'OK' to continue and review the course. Note, Course Certification may not be available. Click 'Cancel' to exit  |  |
| 100\_string\_2 | All questions remain unanswered |  |
| 101\_string\_3 | Questions |  |
| 102\_string\_4 | Question |  |
| 103\_string\_5 | not answered |  |
| 104\_string\_6 | That's correct! |  |
| 105\_string\_7 | That's not correct! |  |
| 106\_string\_8 | Feedback:  |  |
| 107\_string\_9 | Scientific Research Overview |  |
| 108\_string\_10 | Knowledge Check |  |
| 109\_string\_11 | Submit |  |
| 110\_string\_12 | Retake Knowledge Check |  |
| 111\_string\_13 | Course Description: Scientific research helps us produce products that are not only safe and effective, but also easier to use, more cost effective, and more reliable. The aim of this course is to explain Abbott’s commitment to safeguarding the integrity of scientific research, and to provide practical advice on how to conduct and support research not only in the right way, but also for the right reasons. |  |
| 112\_string\_14 | Table of Contents |  |
| 113\_string\_15 | Where to Get Help |  |
| 114\_string\_16 | Reference Material |  |
| 115\_string\_17 | Audio |  |
| 116\_string\_18 | Exit |  |
| 117\_string\_19 | Close |  |