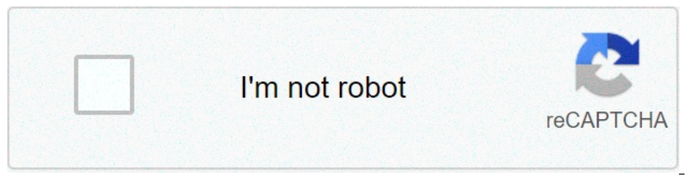

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Sample internal audit report executive summary

Antibacterial resistance is a growing global problem. According to the most recent statistics from the Centers for Disease Control and Prevention (CDC), at least 2 million people acquire serious infections with bacteria that are resistant to one or more of antibacterial drugs designed to treat those infections in the United States alone. Of these, approximately 23,000 die as a result of drug-resistant infections. Even though estimates vary widely, the economic cost of antibacterial resistance in the United States could be as high as $20 billion and $35 billion a year in excess direct healthcare costs and lost productivity costs, respectively (U.S. Centers for Disease Control and Prevention, 2013). Despite the potential of new antibacterial products to reduce the social burden associated with resistant infections, some of the large companies have been exiting the markets for antibacterial drugs and vaccines in recent years and have also failed to respond to the possible social value of opportunities in production of rapid diagnostic products. These market exits have been driven by the most basic of reasons: insufficient return to capital invested in development of these products. Consequently, governments across the globe are looking to identify ways to stimulate the development of antibacterial products. This study, conducted by Eastern Research Group, Inc. (ERG) under contract to the U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Planning and Evaluation (ASPE) and partly funded by FDA, develops an analytical decision-tree model framework that can be used to assess the impacts of different possible market incentives on the private and social returns to product development of new antibacterial products (in contrast to those already under development). Using the model developed, we evaluate the private and social returns associated with the following types of antibacterial products for a hypothetical developer at the beginning of pre-clinical research phase: Antibacterial drugs for oral or intravenous (IV) administration designed to treat: Acute bacterial otitis media (ABOM); Acute bacterial skin and skin structure infections (ABSSSI); Community acquired bacterial pneumonia (CABP); Complicated intra-abdominal infections (CIAI); Complicated urinary tract infections (CUTI); and Hospital acquired/ventilator associated bacterial pneumonia (HABP/VABP). A new vaccine effective in preventing acute bacterial otitis media (ABOM), and A new rapid point-of-care diagnostic designed to identify methicillin-resistant Staphylococcus aureus (MRSA) that can cause serious infections, such as skin or wound infections, pneumonia, or infections of the blood The study also considers the level needed to reach a private value of $100 million at the start of pre-clinical research for a hypothetical developer for the following four categories of incentives that encompass the majority of strategies that have been proposed in the policy literature: Intellectual property (IP) extensions; Tax incentives; Modifications to the clinical trial process and approval standards aimed at shortening the drug development process; and Private grants, awards, and prizes for antibacterial product research and development. For antibacterial drugs (see Table E - 1), we find that the average value to the developer considering whether to start pre-clinical research ranges from a low of -$4.5 million for HABP/VABP to a high of $37.4 million for CABP, falling short of the $100 million threshold. However, when parameter uncertainty is considered, the lower bound of private returns could potentially range from -$23.5 million (HABP/VABP) to -$15.8 million (ABSSSI), substantially lower than the $100 million threshold, and the upper bound from $126.7 (HABP/VABP) to $330.0 million (CABP), considerably above the $100 million threshold. The primary drivers for the observed wide range of results are attributable to, in order of importance, the total market size, the real opportunity cost of capital, and the total time to market model parameters. Value of the incentives to the developers would be higher at later stages of development, meaning that once a drug successfully reaches certain milestones, incentives to further develop it increase. However, we focus on the value at the point the developer is considering whether to start the pre-clinical stage. Table E - 1: Antibacterial Drug Private Returns (Figures are in $ Million) Note that this study considers the developer's private value from the point of the current state of science. Assessing advancements in translational research and basic pathogen biology were outside the scope of this project. However, we note that such advancements have the potential to impact private value of a drug at the start of pre-clinical studies. For example, improved understanding of pathogen biology can cut pre-clinical research time and can yield compounds with higher average efficacy entering human trials. To assess the extent to which these private values fall short of the societal importance of drugs, we estimate the potential social value for these antibacterial drugs. Similar to private returns, we find that there is wide variation in the estimated social values across the different indications (see Table E - 2). The primary drivers for the observed wide range of social EPV results are attributable to, in order of importance, the model parameters for the percentage in disease duration for patients that do not respond to commonly used antibacterial drugs; phase 1 clinical trial success probability; pre-clinical R&D success probability, and the real annual social rate of discount. Despite the high degree of variability, even the lower bounds of these social values (see Table E - 2) are greater than the estimated private ENPVs by orders of magnitude across all of the indications. Moreover, for CABP, CUTI, and HABP/VABP, the 90 percent lower bounds of social values are greater than the 90 percent upper bounds of private values for the same indications. Table E - 2: Antibacterial Social Returns (Figures are in $ Million) Using the decision-tree framework developed, we estimate the private and social value for a new ABOM vaccine at $515.1 million (which is greater than the $100 million threshold) and $2.281 billion, respectively. Similarly, the private and social value for new rapid point-of-care diagnostic designed to identify methicillin-resistant Staphylococcus aureus (MRSA) that can cause serious infections is estimated at $329.0 million and $22.1 billion, respectively. The gap between the current private and public values of drug development suggest that incentives are desirable to stimulate the development of drugs to treat the six indications considered, whether through incentives described in this report or public research investment. However, given the degree of uncertainty associated with different model parameters and the limited scope of this project, it is difficult to ascertain the necessary levels of such incentives. The size of the social benefits from developing a new antibacterial drug is also highly uncertain and based on the improvement in outcomes from a hypothetical new drug. It is also important to note that simultaneous institution of conservation mechanisms, such as education campaigns to promote prudent use, and other stewardship programs, along with the types of antibacterial drug production incentives considered are likely to alter the incentive levels identified in this study. Conservation incentives, by their very nature, tend to reduce the potential market size for new antibacterial drugs thereby necessitating higher production incentive levels to boost private returns to the $100 million threshold. Any publicly listed company in the U.S. is required to have its financial statements audited. This process improves internal controls and assesses a company's performance. Finance leaders need to understand the different types of audit reports so they can make confident decisions and optimize their processes. The main types of audit reports are unmodified opinion reports, qualified opinions, adverse opinions and disclaimers. Unmodified opinion reports are given when the auditors are able to access all the data they need in the proper formats. Qualified opinions are given when there are parts of financial records missing or not conforming to the proper standards. Adverse opinions are made when the company's financial situation as a whole is unreliable or unconfirmed. Disclaimers are made when the auditor isn't able to finish the report. Each type of audit report has a distinctive role and provides valuable insights into your company's financial performance. An audit report is an official evaluation of an entity's financial status, combined with the auditor's opinions and collected data on the entity's financial transactions and situation. This is a common process for companies to use when examining their own records and releasing financial information to investors or potential investors. Audits may occur within or outside of the company in question. An internal audit is performed by accountants who work inside the company. These audits are usually easier to perform and do not take as long since the auditors are familiar with company records and have experience in making reports. However, investors and official agencies do not have the same trust in internal audits, and many companies do not have the resources to perform them, so external audits are also practiced. In this case, a company will hire a firm to perform audits on its behalf. There are four distinct types of audits that can be produced, whether internal or external. The unmodified opinion report is the purest type of auditing report. It is unmodified by any caveats the accountant writing the report may have, meaning that they have been able to access all needed financial information and that the information was in conformity with GAAP (generally accepted accounting procedures). This makes it much easier for the accountant to perform the audit, but there are several qualifications the auditors are required to mention, such as whether other accountants besides the writer worked on the audit or whether there are concerns about the company's financial status. A qualified opinion report is given when the auditors were not able to fully satisfy themselves on all aspects of the company's financial status. Specific records may be missing, or some parts of information may not be up to GAAP. In some cases, the auditor may be able to access data but not fully confirm it. All these problems are documented and make the auditor's evaluation more negative. An adverse opinion report is a negative response that occurs only when the auditor finds the company's records as a whole are uninformative and not in line with GAAP, or if the financial records have been falsified or are in other ways erroneous. The accountants add paragraphs explaining these problems and giving their opinions as to how the records differ from GAAP. The disclaimer report is issued only when the auditors are unable to perform their work. When not enough time or information is available, a disclaimer of opinion report is issued. This is rare. An auditor will often only make this report if the company refuses to reveal specific information or if the auditing firm and the company break their contract. There are other influences auditors must consider when making their report, usually concerning the state of the company. If the company is being investigated for a specific crime, or if it is expected to be sold or dissolved within the next year, the auditors take this into consideration and alter their report because of it. Though a difficult task, conducting an audit is a necessity for organizations in highly regulated industries, as well as those that wish to make improvements to process productivity and efficiency. Writing the report often makes up the most difficult portion of the audit process; while you want a comprehensive report, you also want to make it user-friendly so management and others looking at your audit can make the best decisions based on its findings. Include a front page with the name of the organization, project title, audit lead and date. For reports longer than 5 pages, include a table of contents. Start with an executive summary relating your findings with a brief abstract of the issues, state of the findings and conclusions. Include a background summary. This should provide the background for why you conducted the audit. Discuss how your organization assembled audit team and why it made the audit a priority. Provide objectives and standards. The objectives detail the project's goals, and standards inform the reader what format you used to conduct the audit. If you conducted the audit with the goal of setting standards, state this here. Include a section on methodology. This should provide the reader with the population for the sample, rationale for how you chose the sample, the size of the audit and the time period in which you conducted it. End with results and conclusions. Use charts and percentages to help readers to visualize your findings. Put the conclusion in terms anyone in the organization can understand, and make sure the conclusion directly ties back to audit objectives. Most businesses prepare a lot of documents, reports and analyses when deciding whether to move in a strategic direction or which steps to take with a project. Since it would be unreasonable to expect all interested parties to read every single document, most businesses will summarize their findings in an executive report. An executive report gives the reader a clear summary of original documents without having to read them. An executive report is a concise version of a lengthier document or documents. Write it in a way that summarizes those other documents, and convinces the audience to keep reading. Most businesses have a ton of reports, analyses, project documents, case studies, financial models and other information sitting on the desks. As useful as this information is, you're never going to get a lender, investor or busy executive to read it all. Even if they did, they might overlook important issues due to the sheer volume of information. That's where an executive report comes in. This short document gets straight to the nuts and bolts of the matter and summarizes all the main points in the larger document suite. The idea is to condense and synthesize the key points of all those other documents so readers can quickly see what you're doing and what the status of your project is. You should think about preparing an executive report whenever you need someone to rapidly become acquainted with a large body of information. For example, you might prepare an executive report to: Summarize the company's business plan for lenders. Collate the results of multiple research studies for decision-makers. Start a conversation with investors. Communicate with management and customers. The best way to think of an executive report is like a business card for your project. It should provide a brief and succinct summary of the information and leave a decisive impression on the reader. Once they've read the executive report, the reader can decide whether she would like to go deeper into the other project documents. The exact format will depend on the nature of the project and what it is you're trying to summarize. An executive summary of your business plan, for example, is going to look very different from an executive summary of your process or workflow for customers. If your organization has a house style or an executive report template, then you should follow this to ensure consistency in your business communications. Otherwise, consider the following elements when writing your report. The report should be as concise as you can make it while covering the key points. As a rule of thumb, make sure the report is no longer than 10 percent of the length of the document(s) you're summarizing. The report should strike the right tone for the audience you are reaching out to. It should begin with a summary of the project. It should systematically answer a question or questions, backed up by evidence and data points. It may involve making recommendations, but will definitely involve synthesizing and evaluating information. The report should have a clear conclusion. It should be readable independently of the main document(s). It should consist of short, concise paragraphs or bullet points. It should only include material that is present in the main project documents. This is not the place to introduce new material or go off on a frolic of your own. The first question to ask is, who is your audience? A senior leader within the organization probably will need different information and recommendations than a potential investor, for example. Understanding who your audience is allows you to organize your thoughts and write persuasively. The second question to ask is, what problem are you trying to solve for your audience? For example, are you providing a status overview of a project for senior management? In this case, you'll need to think about the problems and successes you've encountered, work in progress and upcoming milestones. Have you performed research on the possibility of moving your production abroad, in which case, you need to give decision-makers all the data they need to make the final decision? Once you know what problem you're solving and who you are solving it for, you can start pulling out the relevant information. Keep the content tightly focused on the problem. The report should follow a logical structure: introduction, meat of the report, recommendations and conclusion. The introduction sets out the purpose and scope of the report – why are you writing this document? What do you hope to achieve? The reason for writing almost any executive report is a problem or a need, and you need to name it. This provides a clear context for the rest of the report. The body of the report should be well-organized, with each pointing leading logically to the next. Describe what you're doing to solve the problem. An executive report should be well-referenced and well-researched, so refer to core materials where the reader can find the source information. Include charts, graphs and other visuals to support the key arguments you're making within the main body of the text. The recommendations section should clearly define your next steps. Make sure the information you are presenting leads logically toward this section. Are your recommendations for possible action clearly supported by the previous sections of the report? Do they mirror what the main project documents are recommending? The conclusion should be clearly stated with no ambiguity about what the reader needs to do next. Do not introduce new material in this section. There's an old adage for speechmakers, that you should, "Tell 'em what you're going to tell 'em; then tell 'em; then tell 'em what you told 'em." This is the "tell them what you told them" part of the report. There's no need to go over old ground, but you need to make sure the reader is on exactly the same page as you. The format of an executive summary is unregulated, so you can choose whatever font, margin size and layout suits you best. However, form follows function as they say, and there are a few style choices that can enhance the reader's experience. These are set out in the do's and don'ts section below. As you write, choose words that can easily be understood by your audience. Industry leaders may feel comfortable with technical terms, but investors are financial experts, not industry insiders. This audience will respond better to everyday language that requires no special knowledge of the industry you're working in. Download an executive report example, or look at reports your colleagues have prepared, for guidance on the style and layout. Use headings and subheadings so a busy reader can flip to the parts of interest. Rock the numbers, which often speak louder than words. Use illustrations, charts and graphs to highlight relevant points. Use blank lines between paragraphs and "white space" to improve the reading experience. Use a tone and language your audience will not understand. Make recommendations that are unrealistic or unsupported. Include information that doesn't exist in the main project documents. Waffle on. Copy and paste from the larger documents. You're synthesizing the information, not regurgitating it.