Financial Reporting Insights

REVENUE RECOGNITION IN THE LIFE SCIENCES INDUSTRY

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TABLE OF CONTENTS

1. Introduction

In 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606),* to provide a robust framework and comprehensive principles for addressing revenue recognition issues. Additionally, the guidance on accounting for certain costs related to a contract with a customer in the scope of ASC 606 was codified in ASC 340-40, *Other Assets and Deferred Costs – Contracts with Customers*.

While virtually all aspects of ASC 606 and ASC 340-40 are relevant to life sciences entities, this white paper highlights aspects of the guidance that are particularly pertinent for these entities. For additional information about all of the revenue recognition guidance, including those aspects discussed in this white paper, as well as numerous examples illustrating how to apply the guidance, refer to our revenue recognition guide.

2. Scope

In general, ASC 606 applies to revenue from contracts with customers. Revenue is defined in the Master Glossary of the ASC as "Inflows or other enhancements of assets of an entity or settlements of its liabilities (or a combination of both) from delivering or producing goods, rendering services, or other activities that constitute the entity's ongoing major or central operations."

It is not uncommon for entities in the life sciences industry to enter into collaborative agreements. Guidance on the accounting for such agreements exists in ASC 808, *Collaborative Arrangements*. One of the challenges in accounting for collaborative agreements is determining whether they give rise to revenue, which depends on whether the counterparty to the agreement is a customer. If so, the agreement is a contract with a customer that falls within the scope of ASC 606. Customer is defined in ASC 606-10-15-3 as "a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration." As such, contracts with a counterparty other than a customer, or that generate income other than revenue, do not fall within the scope of ASC 606. Certain guidance in ASC 808 is helpful in clarifying the interaction between ASC 606 and ASC 808 by:

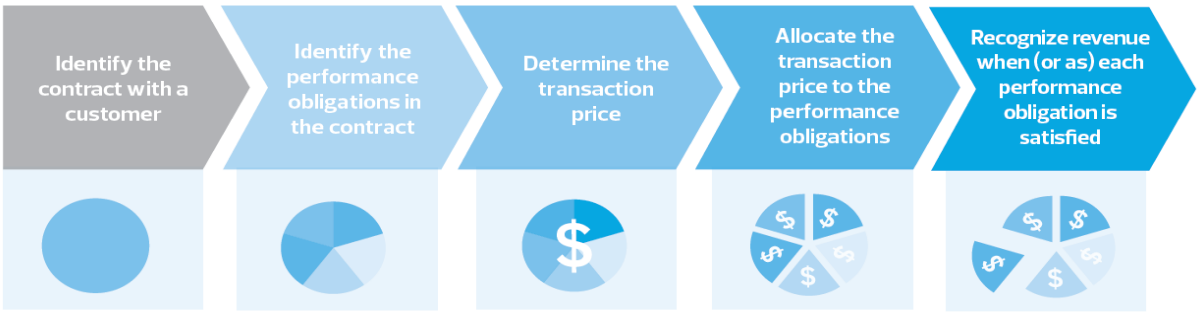
- Noting that certain transactions between collaborative participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In these situations, all of the guidance in ASC 606 should be applied, including recognition, measurement, presentation and disclosure requirements.
- Precluding presenting a transaction with a collaborative arrangement participant that is not directly related to sales to third parties together with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer.

Finally, in evaluating whether an arrangement is in the scope of ASC 606, if an entity is providing medical equipment at a customer's location under a multi-year agreement, the entity should first consider whether the arrangement meets the definition of a lease under ASC 842, *Leases*.

3. Core principle and key steps

To put the specific aspects of the revenue recognition guidance discussed in this white paper into proper context, it is important to know that the core principle included in the guidance (ASC 606-10-10-2) is to "recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services."

In addition, the guidance sets out the following steps for an entity to follow when applying the core principle to its revenue-generating transactions:



4. Step 1: Identifying the contract with a customer

A contract is defined in ASC 606-10-25-2 as "an agreement between two or more parties that creates enforceable rights and obligations." To account for a contract in accordance with the guidance, the following five contract existence criteria must be met:

- Approvals have been obtained and a commitment to perform exists on the part of both parties
- Rights of both parties are identifiable
- Payment terms are identifiable
- Commercial substance exists
- Collection of substantially all of the amount to which the entity will be entitled in exchange for the goods or services that will be transferred to the customer is probable (i.e., likely to occur)

When all of the contract existence criteria are met, the remaining steps in the five-step revenue recognition model are applied to the contract. When all of the contract existence criteria are not met, revenue is deferred and the contract existence criteria continue to be evaluated to determine whether they are subsequently met. Absent meeting the contract existence criteria, revenue is only recognized under very limited circumstances as discussed in Section 4.1.

4.1 Evaluating collectibility and price concessions

To meet the collectibility criterion, an entity must be able to conclude that collection of substantially all of the amount to which it will be entitled in exchange for the goods or services that will be transferred to the customer is probable (i.e., likely to occur). For this purpose, only the customer's ability and intention to pay is considered. However, before an entity can determine whether the collectibility criterion is met, it must determine the amount that should be evaluated for collectibility. To do so, there are two primary considerations:

- *Transaction price.* As discussed in Chapter 6, the transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer. An entity considers a number of factors in estimating the transaction, including whether the entity intends to offer the customer a price concession and whether the customer has a valid expectation of receiving a price concession based on the entity's customary business practices, published policies or specific statements. In general, the entity does not take the customer's credit risk into consideration when estimating the transaction price. It is not uncommon for certain entities in the life sciences industry to offer price concessions or extended payment terms to customers or to sell goods or services to customers that do not have a proven ability to pay the entire contract price. As a result, the transaction price could be less than the contractually stated price.

- *Ability to mitigate credit risk.* An entity should take into consideration its ability to mitigate credit risk related to the transaction price (and, if so, to what extent). This is consistent with the focus of the collectibility criterion on the amount the entity expects to be entitled to for the goods or services that will be transferred to the customer, which may not be all of the promised goods or services in the contract.

Life sciences entities should be particularly diligent when determining the transaction price, as price concessions are more common when an entity is trying to establish itself and its product. For example, a price concession can take the form of extended payment terms that are subsequently renegotiated to reduce annual payments in later years. Determining whether an amount that is not expected to be collected from a customer results from a price concession or the customer's inability to pay may be difficult. However, this determination could significantly affect the timing and amount of revenue recognized.

- *Price concession.* The amount that is not expected to be collected due to a price concession is not included in the transaction price (which is the amount ultimately recognized as revenue)
- *Inability to pay.* When one or more of the contract existence criteria is not met (e.g., the entity cannot conclude that collection of substantially all of the amount to which it will be entitled in exchange for the goods or services that will be transferred to the customer is probable), revenue is deferred and the contract existence criteria continue to be evaluated to determine whether they are subsequently met. Absent meeting the contract existence criteria, revenue only is recognized when the amounts paid by the customer are nonrefundable and one of the following is true:
  - The entity has no remaining performance obligations and it has received all, or substantially all, of the amounts promised by the customer
  - The contract has been terminated
  - The entity has transferred control of the goods or services to which the nonrefundable consideration relates, stopped transferring additional goods or services to the customer and is under no obligation to transfer any additional goods or services

Application of this guidance could result in the initial deferral of revenue for what may be a significant period of time, even if nonrefundable cash has been received.

All entities in the life sciences industry need to have processes in place to evaluate collectibility (e.g., credit checks, assessing the operating and payment history of the customer) to ensure compliance with ASC 606, particularly as it relates to determining whether amounts not expected to be collected from a customer result from a price concession or the customer's inability to pay and accounting for nonrefundable cash received when the collectibility criterion has not been met. In doing so, an entity needs to understand the contractual terms as well as its customary business practices and knowledge of the customer. For example, sales to top wholesalers operating within the biotechnology and pharmaceuticals industry may require unique considerations regarding collectibility, as these wholesalers will often short-pay due to chargebacks submitted back to the pharmaceutical manufacturer. A chargeback arises when, as part of their contracts with wholesale customers, pharmaceutical companies agree to reimburse wholesalers for the difference between the gross sales price at which a pharmaceutical company sells its products to the wholesalers (called wholesaler acquisition cost or WAC) and the prices of the products charged at the time of resale by the wholesaler to the end distributor (e.g., to the pharmacy or hospital). These chargebacks often represent the largest reduction when determining the transaction price for pharmaceutical companies.

4.2 Accounting for contract modifications

It is common for contracts in the life sciences industry to be modified, particularly those contracts that span multiple years. ASC 606 provides a comprehensive model related to accounting for contract

modifications. When a contract modification has been approved, the model results in accounting for the contract modification as a separate contract when it includes both additional promised goods or services that are distinct (see Section 5.2) and additional consideration that reflects the standalone selling prices (see Section 7.2) of the additional promised goods or services adjusted for the contract's specific facts and circumstances. When a contract modification does not meet both of these requirements to be accounted for as a separate contract, it is accounted for as either:

- *The termination of one contract and execution of a new contract (i.e., prospectively)* when the modified contract includes only promised goods or services that are distinct from the goods or services that were transferred on or before the modification date and any additional consideration does not reflect the standalone selling prices of the additional promised goods or services adjusted for the contract's specific facts and circumstances.
- *Part of the original contract (which could result in recognition of a cumulative catch-up adjustment)* when the modified contract includes only promised goods or services that are not distinct.

5. Step 2: Identifying the performance obligations in the contract

After contract identification (Step 1), a life sciences entity needs to identify the performance obligations in the contract (Step 2). Identifying the performance obligations in the contract establishes the units of account to which the transaction price should be allocated and for which revenue is recognized.

Contracts in the life sciences industry often include multiple promised goods or services. For example, a contract may include a license of intellectual property (IP), contract research services, contract manufacturing services or participation on a joint steering committee; or a contract may include complex medical equipment and the consumable cartridges needed to operate the equipment. After an entity identifies each of the promised goods or services in the contract, the next step to account for a contract with multiple promised goods or services is to determine whether the promises to provide goods or service should be treated as performance obligations and accounted for separately. Each of these steps is discussed further in this section along with the additional considerations involved in identifying the units of account in contracts that include options for additional goods or services (e.g., contract renewal options).

5.1 Identifying promises to transfer goods or services

The first step in identifying the performance obligations in the contract is to identify all promises to provide goods or services. Entities in the life sciences industry should scrutinize their customer contracts and identify all the promises to transfer goods or services to the customer. Consideration also needs to be given to whether there are promises to transfer goods or services that arise from the entity's customary business practices rather than an explicit contract provision.

Not all activities performed by the entity in connection with the contract transfer a good or service to the customer. For example, setup activities do not transfer a good or service to the customer. Instead, those activities are necessary for the entity to fulfill the contract and do not themselves represent a good or service transferred to the customer. As a result, they cannot represent a performance obligation.

5.2 Separating promises to transfer goods or services into performance obligations

If there is more than one promise to transfer goods or services in a contract, consideration must be given to whether the promises to transfer goods or services should each be considered performance obligations and accounted for separately. The determining factor in this analysis is whether each promised good or service is distinct. A promised good or service is considered distinct if it it is capable of being distinct and is distinct within the context of the contract. A promised good or service that is considered distinct is

accounted for separately as a performance obligation unless the series exception applies. For additional information about the series exception, refer to Section 6.3 of our revenue recognition guide.

Consider the following example related to whether complex medical equipment and consumable cartridges needed to operate the equipment are distinct:

- *Capable of being distinct.* If a customer can benefit from the medical equipment on its own or by combining it with other resources readily available to the customer (e.g., consumable cartridges sold by the entity on a standalone basis or by a third party), then the equipment is capable of being distinct. If a customer can benefit from the consumable cartridges on their own or by combining them with resources readily available to the customer (e.g., the medical equipment provided by the life sciences entity), then the consumable cartridges are capable of being distinct.
- *Distinct within the context of the contract.* If the medical equipment and consumable cartridges are separately identifiable from each other, then each is distinct within the context of the contract. For this purpose, the life sciences entity must ascertain which of the following best describes its promise within the context of the contract:
  - *The promise in the contract is to transfer the promised good or service (medical equipment and consumable cartridges) individually.* If this best describes the life sciences entity's promise within the context of the specific contract, then the promised goods or services (medical equipment and consumable cartridges) are each distinct within the context of the contract.
  - *The promise in the contract is to transfer a combined item or items to which the promised good or services is an input (medical equipment solution to which the medical equipment and consumable cartridges are inputs).* If this best describes the life sciences entity's promise within the context of the specific contract, the promised goods or services (medical equipment and consumable cartridges) are not distinct within the context of the contract.

Indicators are provided to assist in determining whether a promised good or service is distinct within the context of the contract. When the promised goods or services involved are medical equipment and consumable cartridges, those indicators are focused on whether the consumable cartridges significantly modify or customize the medical equipment and whether the medical equipment is highly interdependent or highly interrelated with the consumable cartridges. Life sciences entities will need to exercise significant judgment when evaluating this criterion.

Case E of Example 11 starting at ASC 606-10-55-150G illustrates how to identify the units of account in a situation in which a piece of off-the-shelf equipment and specialized consumables are sold to the customer.

Additional discussion related to determining whether a license of IP is distinct from any other promised goods or services included in the contract under ASC 606 and determining whether the various services performed in conjunction with contract manufacturing services are distinct from each other under ASC 606 is provided in Chapter 9 and Chapter 10, respectively.

5.3 Customer options for additional goods or services

It is not uncommon in the life sciences industry for a contract to include an option to purchase additional goods or services in the future. A common example of such an option is a contract renewal option.

As discussed in more detail later in this section, if an option provides a material right to the customer that the customer would not have received without entering into the contract with the life sciences entity, the option itself is a performance obligation. In other words the goods or services that would be provided to the customer if the option were exercised are not identified as promised goods or services or performance obligations and the transaction price does not include the amounts to which the life sciences entity would expect to be entitled in exchange for transferring control of any promised goods or services the customer elects to purchase upon exercising the option. For example, an option to renew a license of

a cell therapy technology at potentially favorable rates once the initial license term expires or an option to purchase multiple renewal periods at once for a discount should be evaluated under ASC 606 to determine whether it represents a material right to the customer that it would not have received without entering into the license with the life sciences entity. If a license renewal option represents such a material right, it is a performance obligation to which a portion of the transaction price is allocated. It is not uncommon for medical device entities to sell a product that consists of a hardware component and a software component. While the hardware is purchased at the onset and requires no additional future consideration, the software requires an annual subscription renewal. These renewal options must be evaluated to determine whether they represent a material right to the customer that it would not have received without entering into the contract with the entity. If the renewal option represents a material right, it is a performance obligation, and a portion of the transaction price is allocated to it. If it is not a material right, allocation of a portion of the transaction price is not required. See Section 5.3.2 for discussion of quantitative and qualitative considerations when evaluating potential material rights.

Making the determination as to whether an option for additional goods or services represents a performance obligation under ASC 606 requires significant judgment. In addition, if such an option should be treated as a performance obligation, estimating its standalone selling price for allocation purposes (see Section 5.3.3.1) could be challenging. However, there is a practical alternative provided in ASC 606 that allows an entity in certain circumstances to allocate a portion of the transaction price to the optional goods or services based on the consideration to which the entity expects to be entitled for the goods or services that are expected to be provided.

5.3.1 Determining whether a contract includes a customer option for additional goods or services or variable consideration

In many cases, determining whether a contract includes a customer option for additional goods or services will be relatively straightforward. However, in other cases, such as those in which the contract has variable attributes, it may not initially be clear whether those variable attributes give rise to an option for additional goods or services or variable consideration.

Understanding the life sciences entity's and the customer's rights and obligations is critical to determining whether the variable attributes in a contract should be accounted for as an option or variable consideration. The following table captures the rights and obligations of the life sciences entity and the customer that point to the variable attributes in a contract being either an option or variable consideration for accounting purposes.

Points to variable attributes in a contract being…	
An option	**Variable consideration**
The life sciences entity is not obligated to transfer additional promised goods or services unless and until the customer exercises its right to purchase those additional goods or services.	The life sciences entity is obligated to provide the promised goods or services without the customer exercising an incremental right. The action taken by the customer is resolving the uncertainty of how much it will pay.
The customer becomes obligated to transfer additional consideration to the life sciences entity only after it both exercises its right to purchase additional promised goods or services and takes control of those goods or services.	The customer becomes obligated to transfer additional consideration to the life sciences entity after (or as) it obtains control of the promised goods or services transferred by the life sciences entity.
Actions taken by the customer obligate the life sciences entity to provide additional promised goods or services.	Actions taken by the customer serve to resolve the uncertainty related to the amount of consideration it is obligated to pay.

While in some situations there will be minimal differences between accounting for the variable attributes in a contract as an option instead of variable consideration (or vice versa), it remains important in those situations to reach the appropriate conclusion, given the disclosure requirements in ASC 606. For example, if the contract includes an option that is accounted for as a performance obligation, the life sciences entity would be required to include the option in its disclosure requirements about its performance obligations. Conversely, if the contract includes variable consideration, the life sciences entity's disclosures about the transaction price allocated to the remaining performance obligations would be affected (unless the entity is eligible for and elects an available practical expedient - see Section 6.6.3.1 of our revenue recognition guide for details on the practical expedient).

5.3.2 Determining whether customer options for additional goods or services are performance obligations

The question that arises when a life sciences entity includes an option for additional goods or services in a contract is whether that option is a performance obligation that should be accounted for separately. The answer to this question hinges on whether the option provides a material right to the customer that it would not have received without entering into the contract with the life sciences entity. In general, if an option included in a contract gives the customer the right to a discount that is incremental to the range of discounts typically given by the life sciences entity on the same goods or services to the same class of customer in the same geographical area or market, the option provides a material right to the customer that it would not have received without entering into the contract. Conversely, if an option included in a contract gives the customer the right to purchase products or services at their standalone selling prices in the future, the option does not provide a material right to the customer that it would not have received without entering into the contract. This type of option is essentially a marketing offer that is not accounted for until the customer exercises the option.

When evaluating whether an option provides a material right, the life sciences entity should take into consideration all current, past and future transactions with the customer that are relevant to the evaluation.

A question that arises when evaluating whether an option provides a material right is whether the life sciences entity should consider only quantitative factors or both quantitative and qualitative factors. The FASB staff and Transition Resource Group (TRG) discussed this question. A summary of their discussion was provided in Question 13 of FASB's Revenue Recognition Implementation Q&As. The FASB staff and TRG concluded that both quantitative and qualitative information should be considered by an entity when evaluating whether an option provides a material right.

See Section 6.6.2 of our revenue recognition guide for examples of how this guidance is applied.

5.3.3 Accounting for an option that is a performance obligation

When an option is a performance obligation, a life sciences entity must determine the standalone selling price for the option for purposes of allocating a portion of the transaction price to the option (see Section 5.3.3.1). In addition, the transaction price does not include any additional consideration that would result from the customer exercising the option because the option is a material right that the customer is implicitly obligated to pay for as part of the contract in which it is included. The transaction price allocated to the option is recognized as revenue when or as the option is exercised (see Section 5.3.3.2) or, if it is not exercised, when the option expires unused. This accounting model essentially reflects the customer partially paying in advance for goods and services it will purchase when it exercises the option.

5.3.3.1 Estimating the standalone selling price of an option that is a performance obligation

While unlikely to be the case, if there is a directly observable standalone selling price for the option, it should be used for allocation purposes. For the more likely scenario in which a directly observable standalone selling price for the option is not available, the life sciences entity must estimate the

standalone selling price (which is discussed in detail in Section 8.2 of our revenue recognition guide). In doing so, the life sciences entity should ensure that the estimate reflects both of the following:

- *If the customer could get a discount without exercising the option, that discount should be taken into consideration in the standalone selling price of the option.* For example, consider a situation in which a customer has an option to purchase product from the life sciences entity in the future at a 30% discount. If the customer could get a 10% discount on future purchases of the product without the option because, for example, the life sciences entity is offering a 10% discount on future purchases of any product to all customers, that should be taken into consideration in estimating the standalone selling price of the option. In this situation, the discount that should be evaluated to determine whether it provides the customer with a material right is the incremental 20% discount on future purchases that the life sciences entity is offering to only this customer. This is important to keep in mind because the effects of the customer only getting an incremental discount of 20% (compared to 30%) decreases the value of the option, all other things being equal.
- *How likely it is that the customer will exercise the option.* For example, consider a situation in which a customer has an option to purchase up to $1,000 of medical devices from the life sciences entity in the future at a 30% discount. If the customer is only expected to use the discount to purchase $800 of medical devices, the standalone selling price of the option should reflect the expected purchases of $800 and not the maximum possible purchases of $1,000.

Given the difficulties that may arise in estimating the standalone selling price of an option for additional goods or services, a life sciences entity may instead allocate a portion of the transaction price to the optional goods or services based on the goods or services expected to be provided in connection with the option and the related expected consideration. However, this practical alternative may only be elected if the optional goods or services are:

- Similar to the original goods or services in the contract
- Provided in accordance with the terms of the original contract

An example of a material right that can use the practical alternative above is detailed in Example 51 from ASC 606-10-55-343 to 55-352, where an entity offers a renewal option to its maintenance contract. The price offered for renewal is significantly lower than the price that would be charged if the customer did not sign up for the maintenance services initially or allowed the services to lapse or expire. The renewal option is for the continuation of the maintenance services and those services are defined in the terms of the original contract.

While the type of option for additional goods or services that most likely would qualify for this practical alternative is a contract renewal option, other types of options also may qualify.

5.3.3.2 Accounting for the customer's exercise of an option that provides a material right

The FASB staff and TRG discussed how an entity should account for the customer's exercise of an option that provides a material right. For this purpose, the FASB staff and TRG concluded that two models are supportable under ASC 606. One of the models is based on continuing to account for the performance obligations previously identified in the contract as they otherwise would have been accounted for absent exercise of the option and separately accounting for the performance obligations created by the customer's exercise of the option. The other model is based on the change in scope or price resulting from exercise of the option being evaluated as a contract modification. A life sciences entity must elect an accounting policy related to which model it will use to account for the customer's exercise of an option that provides a material right, disclose that accounting policy and consistently apply it in similar facts and circumstances. It is worth noting that the TRG and FASB staff considered and rejected a view that the customer's exercise of an option that provides a material right should (or may) be accounted for as variable consideration. They did not believe this view was supportable under ASC 606.

Additional information about (and an example illustrating) each of the supportable models is provided in Section 6.6.3.2 of our revenue recognition guide.

6. Step 3: Determining the transaction price

6.1 General requirements for determining the transaction price

Transaction price is defined in ASC 606-10-32-2 as "the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes)." A life sciences entity may elect an accounting policy under which it excludes from the transaction price taxes it collects from its customers that were assessed by a government authority on (or contemporaneous with) the life sciences entity's revenue-generating transactions with its customers. Examples of taxes to which this accounting policy would apply if elected are sales taxes, use taxes, value-added taxes, excise taxes and other similar taxes. Examples of taxes to which this accounting policy would not apply if elected are gross receipts taxes and taxes imposed during the inventory procurement process.

If a life sciences entity elects this accounting policy, it must apply the policy to all sales and similar taxes. In addition, if the life sciences entity elects the accounting policy, the accounting policy disclosure requirements in ASC 235 apply.

If a life sciences entity does not elect the accounting policy, it must determine whether it is a principal or an agent with respect to each sale or similar tax assessed on its revenue-generating transactions. If it is a principal, the sales or similar tax is included in the transaction price. If it is an agent, the sales or similar tax is not included in the transaction price. Making the determination as to whether the entity is a principal or an agent with respect to each sale or similar tax in every tax jurisdiction in which its revenue-generating transactions are subject to such taxes could be a very onerous exercise. It is for this reason that the FASB provided the alternative accounting policy that an entity may elect. For further details on the principal versus agent considerations, refer to Chapter 11 of our revenue recognition guide.

6.2 Accounting for variable consideration

It is fairly common for there to be at least one element of variable consideration in a contract between a life sciences entity and a customer. Variable consideration can take many forms. In the life sciences industry, common examples include milestone payments, pay for performance, other performance-based bonuses, chargebacks, price protection adjustments, discounts, price concessions, rebates and return rights. The variability in the amount of consideration to which the life sciences entity is entitled may be caused by explicit terms in the contract or by an implicit price concession that the life sciences entity intends to offer the customer or the customer has a valid expectation of receiving based on the life sciences entity's customary business practices, published policies or specific statements (an illustration of such involving the sale of prescription drugs to a customer is included in Example 2 starting at ASC 606-10-55-99). The variability in the consideration could affect whether a life sciences entity is entitled to the consideration (e.g., obtaining regulatory approval to which a milestone payment is tied) or the specific amount of consideration the customer will ultimately have to pay (e.g., a performance bonus that depends on how early the life sciences entity is able to complete a research project).

There are certain scenarios in which an entity may not be required to estimate variable consideration:

- An entity provides a series of distinct good or services for which the variable payments relate specifically to the entity's efforts to transfer each distinct good or service within the series (see Section 8.3.2.1 5 of our revenue recognition guide).
- An entity is entitled to sales- or usage-based royalties and the only, or predominant, items to which the royalty relates is the license of IP (see Section 6.2.2).

- An entity elects to apply the practical expedient that allows revenue to be recognized for the amount the entity has a right to invoice, when certain conditions are met (see Section 9.3.1.1 of our revenue recognition guide).

Outside of these exceptions, an estimate of the amount of variable consideration to which a life sciences entity expects to be entitled should be included in the transaction price to the extent it is probable that its inclusion will not result in a significant reversal of cumulative revenue recognized when the uncertainty giving rise to the variability is resolved. This approach to determining the amount of variable consideration that a life sciences entity should include in the transaction price suggests the following two steps should be performed:

1. Estimate the amount of variable consideration to which a life sciences entity expects to be entitled using either the expected value method or the most likely amount method (the specific method used depends on which will better predict the amount of variable consideration in a particular set of facts and circumstances).
2. Constrain the estimated amount of variable consideration such that it is probable that the inclusion of the estimate in the transaction price will not result in a significant reversal of cumulative revenue recognized for the contract when the uncertainty giving rise to the variability is resolved.

While these appear to be two discrete steps, as discussed in Question 7Q.3.3.1 of our revenue recognition guide, a life sciences entity's use of the expected value method to estimate the variable consideration to which it expects to be entitled may reduce, depending on the facts and circumstances, the probability of a revenue reversal such that the life sciences entity does not have to separately constrain its estimate of variable consideration.

The expected value method involves identifying a number of potential outcomes for the variable consideration and the likelihood of each one of those outcomes occurring. Using this information, a probability-weighted amount is determined for each potential outcome and the sum of those probability-weighted amounts is the estimate of variable consideration using the expected value method. This method likely is best suited for situations in which there are many different potential outcomes related to the variable consideration. For example, consider a situation in which a life sciences entity will receive a milestone payment if it obtains regulatory approval. In addition, the amount of the milestone payment depends on how quickly the life sciences entity obtains regulatory approval:

If the life sciences entity obtains regulatory approval within…	The milestone payment is…
The first six months of the contract	$1,000,000
Months seven through 12 of the contract	$750,000
The second year of the contract	$500,000
After the second year of the contract	$250,000

Because there are five different potential outcomes related to this variable consideration (the four milestone payment amounts depending on when regulatory approval is obtained and receiving no milestone payment if regulatory approval is not obtained), the life sciences entity might conclude that the expected value method better predicts the expected amount of variable consideration to which the entity expects to be entitled in its facts and circumstances. Under the expected value method, the life sciences entity assigns a probability (i.e., likelihood of occurrence) to the potential outcomes and calculates a probability-weighted amount for each potential outcome. The sum of those probability-weighted amounts is the estimate of variable consideration to which the life sciences entity expects to be entitled.

The most likely amount method involves identifying the range of potential outcomes for the variable consideration and identifying the amount within that range that is most likely to occur. This method likely is best suited for situations in which there are a limited number of outcomes (i.e., two or three). For example, consider a situation in which a life sciences entity will receive a milestone payment of $1 million if it obtains regulatory approval and no milestone payment if it does not obtain regulatory approval. Because there are only two outcomes (the life sciences entity will receive either $1 million or nothing), the most likely amount method likely is best suited for estimating the expected amount of variable consideration to which the life sciences entity expects to be entitled. Using this method requires the life sciences entity to estimate the probability of regulatory approval being obtained. In practice, due to the high degree of uncertainty of obtaining regulatory approval, the estimate of variable consideration is often $0 until regulatory approval is actually received.

In applying either the expected value method or the most likely amount method, the entity should consider all reasonably available information and a reasonable number of potential outcomes. Reasonably available information may include historical, current or forecasted information. Consideration also should be given to the information used during contract negotiations.

One method should be used consistently when accounting for a contract's variable payment stream. However, to the extent a contract includes two different variable payment streams based on the resolution of different uncertainties, the facts and circumstances may support using different methods to estimate the variable consideration expected upon the resolution of each uncertainty.

The estimate of variable consideration must be reassessed each reporting period until the underlying uncertainty is resolved. Any changes in the estimate of variable consideration are treated the same as any other changes in the transaction price. The method used to initially estimate the variable consideration included in the transaction price also should be used when the estimate is reassessed each reporting period.

When a contract has variable attributes, it may not initially be clear whether those variable attributes give rise to an option for additional goods or services or variable consideration. Additional discussion and examples are provided in Section 5.3.1.

6.2.1 Right of return or refund

A customer's right to return a product and receive a refund of fees for services is not considered a performance obligation. Instead, it is treated as variable consideration. As a result, when the life sciences entity recognizes revenue, it does so for the amount of the transaction price to which it expects to be entitled, limited to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur (i.e., the transaction price reflects expected returns and refunds). In assessing the probability of a significant reversal in the cumulative revenue recognized, a life sciences entity should take many factors into consideration, including its history with the same or similar return rights, relevant industry information and economic trends.

A life sciences entity recognizes a refund liability for the amount received or receivable to which it ultimately does not expect to be entitled as a result of the return or refund right (i.e., the amount it is expected to refund). In addition, a life sciences entity also separately recognizes an asset representing the right to returned inventory and an adjustment to cost of sales for estimated returns. The asset for the right to returned inventory is measured by using the former carrying amount of the product reduced for the costs expected to be incurred to recover the product, which include any decrease in value of the returned product. If the product to be returned is expected to be expired or close to its expiration date, the value of the asset for the right to returned inventory is likely to be negligible. The refund liability and asset for the right to returned inventory should be separately recognized (i.e., they should not be netted against each other). In addition, the refund liability to the customer typically is not considered a contract liability and should not be included with the contract liability for presentation purposes.

At the end of each reporting period, a life sciences entity should review its estimated and actual returns and refunds and determine whether any adjustments are needed to refund liability, revenue, asset for the right to returned inventory, and cost of goods sold related to products sold subject to a right of return or refund.

This guidance does not apply to product exchanges, which have no accounting effect provided the products are of the same type, quality, condition and price, or product returns due to defects, which are accounted for as warranties.

6.2.2 Sales- or usage-based royalty exception

The overall variable consideration guidance in ASC 606 should not be applied to a sales- or usage-based royalty when the only, or predominant, item to which the royalty relates is the license of IP. For example, this exception would apply to a situation in which a biotechnology company (Biotech) licenses use of a patented drug compound to a pharmaceutical company (Pharma) and Pharma must pay Biotech a royalty based on Pharma's sales of any prescription drugs that incorporate the licensed drug compound. In this and other situations in which the exception applies, the sales or usage-based royalty should not be included in the transaction price until the later of the resolution of the related uncertainty (i.e., sales or usage occur) or the satisfaction of the related performance obligation in whole or in part. In the example involving Biotech and Pharma, the related performance obligation consists of a license to use a patented drug compound. Because the patented drug compound is functional IP, it would be considered a right to use IP, for which revenue is recognized at the point in time control of the licensed patented drug compound transfers to Pharma (see Chapter 9). As a result, the later of the resolution of the related uncertainty and the satisfaction of the related performance obligation would be the resolution of the related uncertainty.

A question that arises in the example with Biotech and Pharma involves the lag that likely exists between when Pharma sells the prescription drugs and when Biotech receives the sales data from Pharma to calculate the sales-based royalty. The question in this and similar situations is whether Biotech should estimate the sales-based royalty due from Pharma when Pharma does not provide the sales data before Biotech must issue its financial statements. For example, assume: (a) Pharma provides sales data to Biotech on a quarterly basis, but two months in arrears, (b) Biotech must file its Form 10-Q with the SEC 40 days after its quarter end and (c) Biotech has a calendar year end and is in the process of preparing its June 30, 20X1, interim financial statements for inclusion in its second quarter Form 10-Q. In this situation, because the related performance obligation already has been satisfied, as discussed earlier in this section, Biotech should estimate and recognize in its June 30, 20X1, interim financial statements the sales-based royalties due from Pharma for its second quarter sales of the prescription drugs because the uncertainty related to the royalty has been resolved.

It is important to note the following about the sales- or usage-based royalty exception:

- It does not apply to outright sales of IP.
- It should not be applied to part of a royalty stream (i.e., it is applied on an all-or-nothing basis).
- It should not be applied by analogy to account for other types of variable consideration or other types of promised goods or services.

Sales- or usage-based royalties that are not subject to this exception (e.g., a usage-based royalty on a piece of medical equipment that was sold) should be accounted for using the overall variable consideration guidance.

7. Step 4: Allocating the transaction price to the performance obligations

7.1 Overall allocation model

Step 4 of the five-step revenue recognition model in ASC 606 requires a life sciences entity to allocate the transaction price (determined in Step 3) to each performance obligation in the contract (identified in Step 2).

The overall objective of the guidance on allocating the transaction price is to allocate an amount to each performance obligation (or distinct good or service in a single performance obligation resulting from the series exception [refer to Section 6.3 of our revenue recognition guide]) that represents the consideration to which the life sciences entity expects to be entitled as a result of transferring control of the underlying goods or services to the customer.

If a contract has more than one performance obligation, the transaction price generally should be allocated to each performance obligation based on the standalone selling prices of each performance obligation in relation to the total of those standalone selling prices (i.e., on a relative standalone selling price basis). Exceptions are provided for certain situations involving discounts or variable consideration that can be shown (by meeting certain criteria) to be related to one or more (but less than all) performance obligations. Those exceptions are discussed in Section 8.3.1 of our revenue recognition guide.

7.2 Standalone selling prices

The standalone selling price of a performance obligation is the amount the life sciences entity charges (or would charge) when the distinct goods or services that make up the performance obligation (i.e., the underlying distinct goods or services) are sold on their own to a customer. Standalone selling prices are determined at contract inception and are not subsequently adjusted for changes in facts and circumstances.

The best evidence of the standalone selling price of the underlying goods or services is the observable price charged by the life sciences entity for those goods or services when they are sold separately in similar circumstances to similar customers. Absent evidence of a directly observable standalone selling price, the life sciences entity is required to estimate a standalone selling price. While there are any number of approaches to estimating a standalone selling price that are consistent with the overall objective of allocating the transaction price, ASC 606 discusses the following three approaches:

- Adjusted market assessment approach – This approach identifies the price at which customers would be willing to buy the underlying goods or services on a standalone basis, which might include looking at prices charged by competitors for similar goods or services and making the appropriate entity specific adjustments. Due to the unique nature of products offered by life sciences entities, this approach is less commonly used in practice.
- Expected cost plus a margin approach – This approach builds up a standalone selling price for the underlying goods or services using the costs the entity expects to incur to provide the goods or services and adding an appropriate margin to those costs. In practice, the cost plus margin approach is most commonly used. Refer to Section 8.2 of our revenue recognition guide for additional discussion.

- Residual approach – This approach determines a standalone selling price for the underlying goods or services based on the difference (i.e., residual) between the total transaction price and the total observable standalone selling prices for the other goods or services in the contract.
  - A residual approach may only be used when there is an observable standalone selling price for the other performance obligations in the contract and one of the following criteria is met:
    - The prices at which the life sciences entity has sold the goods or services on a standalone basis at or near the same time represents a broad range of prices within which a representative standalone selling price cannot be identified (i.e., the selling price is highly variable).
    - The goods or services underlying a performance obligation have not previously been sold on a standalone basis, and the life sciences entity has not yet established a price for those goods or services (i.e., the selling price is uncertain).

In making this estimate, the entity should maximize observable inputs and consider all reasonably available and relevant information, including information specific to the life sciences entity, the market, the customer and the customer class. In addition, an entity should be consistent in how it applies an estimation method and the situations in which it applies an estimation method.

7.3 Allocating variable consideration

Variable consideration included in the transaction price should be allocated on a proportionate basis to each of the performance obligations in a contract, except when the following two criteria are met:

- The terms of the variable payment are specifically related to the life sciences entity's efforts to satisfy, or achieve a specific outcome from satisfying, a specific performance obligation or transfer, or achieve a specific outcome from transferring, a distinct good or service in a single performance obligation resulting from application of the series exception.
- Allocating the variable payment to the specific performance obligation, or distinct good or service in a single performance obligation resulting from the series exception, depicts the amount of consideration to which the life sciences entity expects to be entitled in exchange for transferring that good or service to the customer when considering all of the performance obligations and payment terms in the contract.

When these criteria are met, the variable payment included in the transaction price that meets these criteria, and any change in the estimate of that payment, should be allocated in their entirety to the specific performance obligation or distinct good or service to which the variable payment relates.

The remaining transaction price is allocated as it otherwise would be under ASC 606 (i.e., on a relative standalone selling price basis unless the discount exception applies [which is discussed in Section 8.3.1 of our revenue recognition guide]). Example 8-5 in our revenue recognition guide provides a detailed numerical example illustrating how to allocate the transaction price when the contract includes variable consideration.

8. Step 5: Recognizing revenue when (or as) each performance obligation is satisfied

Revenue is recognized when (or as) a performance obligation is satisfied, which is when control of the underlying good or service (i.e., an asset) is transferred to the customer. The amount of revenue recognized upon satisfaction of a performance obligation is the transaction price allocated to it.

To properly assess when revenue should be recognized, a life sciences entity must perform at contract inception an evaluation focused on whether a performance obligation is satisfied over time or at a point in

time. Specific guidance, discussed in Chapter 9, is provided with respect to making this determination when the performance obligation consists solely of a license of IP.

When accounting for a performance obligation that does not include a license of IP or that includes a license of IP combined with other goods or services, one of the following criteria must be met to conclude that the performance obligation is satisfied over time:

- *Customer simultaneously receives and consumes benefits as the life sciences entity performs.* A performance obligation is satisfied over time if the customer consumes the benefits of the life sciences entity's performance at the same time as the customer receives those benefits and the entity performs and creates those benefits.
- *Customer controls the asset as the entity creates or enhances the asset.* A performance obligation is satisfied over time if the customer controls the asset (which could be tangible or intangible) as it is created or enhanced by the life sciences entity's performance.
- *No alternative use and an enforceable right to payment for performance to date.* A performance obligation is satisfied over time if the asset created by the life sciences entity's performance does not have an alternative use to the entity upon its completion and the life sciences entity's right to payment for its performance to date is enforceable.

If a performance obligation does not meet any of these criteria, then it is considered satisfied at a point in time and revenue is recognized at the point in time the customer obtains control over the underlying good or service. In addition to determining whether a performance obligation is satisfied (and revenue is recognized) at a point in time or over time, ASC 606 also addresses the point in time control of a good or service transfers to the customer and the manner or pattern in which control of a good or service transfers to a customer over time. Evaluating these criteria and identifying a single method by which to measure the progress toward complete satisfaction of a performance obligation that includes contract manufacturing or contract research services is discussed in Chapter 10. Additionally, life sciences entities may offer the customer a trial period for a product. ASC 606-10-55-88 states, "if an entity delivers products to a customer for trial or evaluation purposes and the customer is not committed to pay any consideration until the trial period lapses, control of the product is not transferred to the customer until either the customer accepts the product or the trial period lapses." As a result, any trial periods should be considered when determining if the customer has obtained control over the product.

9. Licenses and rights to use IP

Licensing involves an entity (i.e., licensor) providing a customer (i.e., licensee) with a right to use its IP, which may come in many different shapes and sizes. Examples of IP that may be the subject of a license include drug compounds, patents, trademarks or copyrights. It is important to note that the entity still owns the IP subject to the license (i.e., ownership of the IP does not transfer to the customer).

The discussion in the remainder of this section focuses on how identifying the performance obligations (i.e., units of account) and determining when a performance obligation that includes a license of IP is satisfied (i.e., when does control of the IP transfer to the customer) should be applied to contracts that include a license of IP.

9.1 Identifying the performance obligations in a contract that includes a license of IP

9.1.1 Evaluating restrictions of time, geographical region or use

To the extent a contract includes a license of IP, the life sciences entity should consider whether the contract includes any restrictions in the period of time or geographical region in which the licensed IP may be used by the customer or the way in which the licensed IP may be used by the customer. If any such restrictions exist, the life sciences entity must determine which of the following the restrictions represent:

- *Attributes of the license that define its scope*. If the restrictions represent attributes of the license that define its scope, they do not give rise to additional promised goods or services and do not affect whether the license of IP is a performance obligation that is satisfied over time or at a point in time.
- *Additional rights that will be transferred to the customer in the future*. If the restrictions represent additional rights that will be transferred to the customer in the future, those additional rights are promised goods or services that must be reflected in the identification of the performance obligations.

Making the determination as to whether a restriction of time, geographical region or use represents an attribute of the license that defines its scope or additional rights that will be transferred to the customer in the future will require exercising a significant amount of judgment and careful consideration of all the facts and circumstances. Case A of Example 61A starting at ASC 606-10-55-399A and Example 61B starting at ASC 606-10-55-399K illustrate how this determination should be made in certain circumstances.

9.1.2 Determining whether a license of IP is distinct

When a contract includes a license of IP and other promised goods or services, the entity must consider whether the license of IP is distinct from the other implicit or explicit promised goods or services. Consider the following discussion related to whether the license of a drug compound and contract manufacturing services are distinct under ASC 606:

- *Capable of being distinct.* If a customer can benefit from the drug compound license on its own or by combining it with other resources readily available to the customer (e.g., contract manufacturing provided by a third party), then the license is capable of being distinct. If a customer can benefit from the contract manufacturing services on their own or by combining them with resources readily available to the customer (e.g., the drug compound license provided by the life sciences entity), then the contract manufacturing services are capable of being distinct.
- *Distinct within the context of the contract.* If the drug compound license and contract manufacturing services are separately identifiable from each other, then each is distinct within the context of the contract. For this purpose, the life sciences entity must ascertain which of the following best describes its promise within the context of the specific contract:
  - *The promise in the contract is to transfer the drug compound license and contract manufacturing services individually.* If this best describes the life sciences entity's promise within the context of the specific contract, then the drug compound license and contract manufacturing services are distinct within the context of the contract.
  - *The promise in the contract is to transfer manufactured pharmaceutical drugs to which the drug compound license and contract manufacturing services are inputs.* If this best describes the life sciences entity's promise within the context of the specific contract, then the drug compound license and contract manufacturing services are not distinct within the context of the contract.

Indicators are provided to assist in determining whether a promised good or service is distinct within the context of the contract. When the promised goods or services involved are a drug compound license and contract manufacturing services, those indicators are focused on whether the contract manufacturing services significantly integrate, modify or customize the drug compound (and vice versa) and whether the drug compound license and contract manufacturing services are highly interdependent or highly interrelated with each other. Entities will need to exercise significant judgment when evaluating this criterion.

Example 56 starting at ASC 606-10-55-367 illustrates application of this guidance by a pharmaceutical company when it licenses a drug compound for ten years and provides contract manufacturing services for five years. Two fact patterns are provided — one in which the drug compound license and contract manufacturing services are distinct and one in which they are not. In addition, discussion is provided in Chapter 10 with respect to whether contract manufacturing services include multiple promised services

and, if so, whether those promised services should be accounted for as one or more performance obligations.

When the drug compound license and contract manufacturing services are not distinct, they are treated as a single performance obligation. Additional information about accounting for a single performance obligation that includes a license and other promised goods or services is provided in Section 9.2.

9.2 Determining when a performance obligation that includes a license of IP is satisfied

9.2.1 License of IP is distinct

When the license of IP is distinct (i.e., its own performance obligation), the entity must determine whether the transaction price allocated to the license should be recognized over time or at a point in time. The key question in making this determination is whether the license of the IP represents a right to use the IP, in which case the allocated transaction price should be recognized at a point time, or a right to access the IP over time (the shorter of the license period or the IP's remaining economic life), in which case the allocated transaction price should be recognized over time.

Determining whether the license of IP represents a right to use the IP or a right to access the IP is based on whether the IP has significant standalone functionality. To have significant standalone functionality, a substantial portion of the IP's utility must come from its ability to provide benefit or value to the customer in and of itself (i.e., the entity does not need to undertake any additional activities over the license period for the IP to provide benefit and value to the customer). IP with significant standalone functionality includes IP that provides benefits or value to the customer because it is capable of processing a transaction, executing a function or task or being played or aired. When the IP has significant standalone functionality, the license of the IP is considered a right to use the IP unless both of the following criteria are met:

- Substantive changes to the functionality of the IP are expected to result during the license period from activities of the entity that do not transfer a promised good or service to the customer.
- The customer must use (either contractually or practically) the substantively changed IP.

If both of these criteria are met, what would otherwise be considered a right to use the IP would be considered a right to access the IP. The FASB indicated in paragraph BC58 of ASU 2016-10, that it would expect both of these criteria to be met "only infrequently."

When the IP does not have significant standalone functionality, it is considered symbolic IP. The utility derived from symbolic IP is its association with the licensor's past or ongoing activities, including its ordinary business activities. A license of symbolic IP is considered a right to access the IP.

The types of IP licensed by a life sciences entity to its customers can vary depending on the nature of the entity. In other words, the type of IP licensed by a biotechnology company may differ from that licensed by a pharmaceutical company or a medical device manufacturer. Examples of IP in the life sciences industry that have significant standalone functionality include pharmaceutical drug compounds or formulas, medical device technologies, biologics and cell therapy technologies. Conversely, an example of IP that is symbolic (i.e., without significant standalone functionality) is a trademark for a brand of medicine. Given the significant accounting implications of reaching an appropriate conclusion about whether the licensed IP has significant standalone functionality, life sciences entities should exercise care in evaluating the nature of the IP it is licensing to its customers.

When a license is considered a right to use the IP, the life sciences entity should consider the indicators for transfer of control for purposes of determining whether control was transferred at the point in time the license was granted or at another point in time. When a license is considered a right to access the IP, the entity has to identify an appropriate method by which to measure its progress toward complete

satisfaction of the right to access the IP. Regardless of whether a license is considered a right to use the IP or a right to access the IP, revenue related to a license of IP should not be recognized before both of the following occur:

- A copy of the IP has been provided or otherwise made available to the customer.
- The period over which the customer is able to use and benefit from its rights to the IP has started (i.e., the license period has begun).

The need to meet the second of these criteria before revenue is recognized results in revenue related to a license renewal being recognized no earlier than the beginning of the renewal period.

9.2.2 License of IP is not distinct

When the license of IP is not distinct, it is combined with other licenses of IP and other promised goods or services in the contract until a performance obligation exists. The life sciences entity then applies the overall approach to recognizing revenue, which requires consideration of whether the performance obligation is satisfied at a point in time or over time (see Chapter 8) and, if it is the latter, the method that should be used to measure progress towards the complete satisfaction of the performance obligation.

10. Accounting for contract manufacturing or contract research services

Life sciences entities may enter into service agreements to provide contract manufacturing or contract research services, or both. Accounting for these agreements when they also include a license of IP is discussed in Chapter 9. The discussion in the remainder of this section is focused on agreements to provide only contract manufacturing and contract research services. While all of the topics discussed in this white paper could have applicability, this section addresses incremental considerations that may arise when applying the aspects of ASC 606 to determining when a performance obligation is satisfied.

10.1 Determining when a performance obligation is satisfied

As discussed in Chapter 8, a determination must be made regarding whether a performance obligation is satisfied at a point in time (in which case revenue is recognized at the point in time control of the underlying goods or services is transferred to the customer) or over time (in which case revenue is recognized over time as control of the underlying goods or services is transferred to the customer). At least one of three criteria must be met to conclude that the performance obligation is satisfied over time. Considering those criteria in the context of contract manufacturing or contract research services that should be accounted for as a single performance obligation (e.g., the single performance obligation identified in Case B of Example 10 starting at ASC 606-10-55-140A) would require the entity to answer the following questions:

- *Does the customer simultaneously receive and consume the benefits of the contract manufacturing or contract research services as the life sciences entity performs?* If so, the performance obligation is satisfied over time. This may be the case, for example, when contract research services are provided to the customer on an hourly basis and any results of the research are used by the customer as the research is performed.
- *Does control of the contract manufacturing or contract research services transfer to the customer as the life sciences entity performs?* If so, the performance obligation is satisfied over time. This may be the case, for example, when contract manufacturing services are provided to the customer and control of the manufactured product transfers to the customer as the product is manufactured, or when contract research services are provided to the customer on an hourly basis and any results of the research are the property of the customer as the research is performed.

- *Does the asset created by the life sciences entity's performance have no alternative use to the entity and is the entity's right to payment for its performance to date enforceable?* If so, the performance obligation is satisfied over time. This may be the case, for example, when contract manufacturing services are provided to the customer and the results of providing those services (e.g., the work in progress and finished goods inventory) have no alternative use to the life sciences entity and the life sciences entity has an enforceable right to payment (including a representative profit margin) for all contract manufacturing services performed to date.

If none of these criteria are met, revenue is recognized at a point in time.

When revenue is recognized over time, the entity must identify a single method by which to measure the progress toward complete satisfaction of the performance obligation. ASC 606 discusses the factors that should be considered in identifying an appropriate method of measuring progress toward complete satisfaction of a performance obligation, including the circumstances under which it may or may not make sense to use a particular input or output method. In addition, ASC 606 provides a practical expedient that allows an entity to recognize revenue for the amount it has a right to invoice the customer if its right to consideration from that customer directly corresponds to the value of the entity's performance completed to date. For example, if a life sciences entity is providing contract research services to a customer and has the right to invoice the customer for the number of hours worked by each researcher at an hourly rate that corresponds to the hourly value of each researcher's performance, the life sciences entity could elect this practical expedient.

If an entity is unable to reasonably measure the progress toward complete satisfaction of a performance obligation using reliable information, it should recognize revenue to the extent of the costs incurred to satisfy the performance obligation, but only if it expects to recover those costs. This approach is expected to be used rarely and only until the entity is able to reasonably measure the outcome of a performance obligation.

11. Contract costs

11.1 Scope

ASC 340-40 addresses the circumstances under which certain costs that arise in conjunction with performing under contracts within the scope of ASC 606 should be capitalized. The two categories of costs addressed in ASC 340-40 are: (a) costs to fulfill a contract and (b) costs to obtain a contract.

11.2 Costs to fulfill a contract

If there is other guidance in the ASC that applies to the costs incurred to fulfill a contract within the scope of ASC 606, that other guidance should be applied. Examples of other guidance on how to account for costs that may be involved in the fulfillment of a contract are listed in the following table:

ASC	Type of fulfillment cost
330	Inventory
340-10-25-1 to 25-4	Preproduction costs related to long-term supply contracts
350-40	Costs of internal-use software
360	Costs related to property, plant and equipment
720-35-25-1A	Certain advertising expenditures incurred after revenue is recognized (e.g., cooperative advertising)

ASC	Type of fulfillment cost
946-720-25-3	Offering costs of advisors of both public and private funds
985-20	Costs of software to be sold, leased or marketed

Note 1: Prior to applying the guidance noted, it is important to understand the specific scope provisions of the guidance to ensure it is applicable to an entity and the specific cost being evaluated.

If the guidance in the table or other specific guidance is applicable to a fulfillment cost incurred by the entity, it must be applied. ASC 340-40 is only applicable to costs to fulfill a contract when there is no other applicable guidance.

If certain criteria are met (ASC 340-40-25-5), fulfillment costs within the scope of ASC 340-40 must be capitalized. A life sciences entity may not choose to expense such costs when the criteria are met. Refer to Section 13.1 of our revenue recognition guide for a more detailed discussion of the accounting for costs to fulfill a contract.

11.3 Costs to obtain a contract

It is not uncommon for certain entities in the life sciences industry to pay an employee a commission for signing a customer to a long-term contract. The incremental costs to obtain a specific contract within the scope of ASC 606 are those costs that would not have been incurred if the contract was not obtained, such as a sales commission. For a cost to be considered an incremental cost of obtaining a contract, the life sciences entity must be obligated to make a payment only as a result of entering into the contract. The incremental costs to obtain a contract should be capitalized if the life sciences entity expects to recover those costs (i.e., the net cash flows of the contract and expected renewals will cover the costs). However, a life sciences entity may elect a practical expedient that allows it to expense the incremental costs to obtain a contract if the amortization period for those costs would otherwise be one year or less.

Costs to obtain a contract within the scope of ASC 606 that are not incremental are those costs related to obtaining the contract that would have been incurred even if the contract was not obtained (e.g., travel costs incurred to present a proposal to the customer). These costs only should be capitalized if they are explicitly chargeable to the customer regardless of whether the life sciences entity enters into a contract with the customer. Otherwise, such costs are expensed as incurred. Refer to Section 13.2 of our revenue recognition guide for a more detailed discussion of the accounting for costs to obtain a contract.

11.4 Amortization and impairment of capitalized costs

ASC 340-40 provides guidance on amortizing costs capitalized in accordance with its provisions as well as testing those capitalized costs for impairment. This guidance is summarized and illustrated in Sections 13.3 and 13.4 in our revenue recognition guide. For life sciences entities, the impact of renewal commissions on the amortization period should be considered and assessed. Refer to Section 13.3.1 of our revenue recognition guide for discussion of the effect of contract renewals on the amortization period.

12. Disclosures

Many qualitative and quantitative disclosure requirements are included in ASC 606-10-50 and ASC 340-40-50. ASC 606-10-50-1 states the following as the overall disclosure objective of ASC 606 (which is also the overall disclosure objective of ASC 340-40): “The objective of the disclosure requirements in this Topic is for an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.”

The disclosures required to achieve this objective focus on providing a variety of revenue-related information. Some of the information that must be disclosed is high-level, such as the amount of revenue

recognized from customer contracts and the amount of any impairment (or credit) losses recognized on receivables or contract assets related to customer contracts. However, there is also a significant amount of detailed information that must be disclosed annually related to customer contracts, including information about:

- Disaggregated revenue
- Contract assets, contract liabilities and receivables
- Performance obligations
- Transaction price allocated to remaining performance obligations at the end of the reporting period (disclosures required for public entities and elective for nonpublic entities)
- Significant judgments about the timing of satisfying performance obligations
- Significant judgments about the transaction price and the amounts allocated to performance obligations
- Practical expedients (disclosures required for public entities and elective for nonpublic entities)
- Capitalized costs related to obtaining or fulfilling a customer contract (disclosures required for public entities and elective for nonpublic entities)

The nature and extent of the required disclosures in each of the preceding categories depends on whether the entity is a public entity (more required disclosures) or nonpublic entity (fewer required disclosures). In addition, while more disclosures are required for annual periods, some disclosures also are required for interim periods. However, when a life sciences entity applies ASC 606 and 340-40 in its interim financial statements for one or more interim periods before it applies ASC 606 and 340-40 in its annual financial statements, the entity must provide all the required annual disclosures in those interim financial statements.

Detailed discussion and illustrations of the disclosure requirements for both public and nonpublic entities are included in Chapter 15 of our guide to revenue recognition.

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