Changes to revenue recognition in the life sciences industry

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A. Introduction and background

In May 2014, the Financial Accounting Standards Board (FASB) and International Accounting Standards Board (IASB) issued substantially converged final standards on revenue recognition. These final standards are the culmination of a joint project between the Boards that spanned many years. FASB Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606)*, provides a robust framework for addressing revenue recognition issues and replaces almost all pre-existing revenue recognition guidance in current U.S. generally accepted accounting principles (GAAP) (i.e., legacy GAAP), including industry-specific guidance and SEC Staff Accounting Bulletin Topic 13 (which is also part of legacy GAAP for public entities).

Implementation of the robust framework provided by ASU 2014-09 should result in improved comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets. For public business entities (PBEs) and certain not-for-profit entities, implementation was required no later than annual reporting periods beginning after December 15, 2017, and the interim periods therein. However, if an entity is a PBE solely because its financial statements or financial information is included in a filing with the SEC pursuant to certain SEC rules and regulations (e.g., an acquired private company when its financial statements must be included in the acquirer's filing with the SEC), it may choose to adopt the new guidance in accordance with either (a) the effective date otherwise applicable to PBEs or (b) the effective date applicable to private companies, which is annual reporting periods beginning after December 15, 2018, and interim periods thereafter.

The FASB has changed the new guidance originally included in ASU 2014-09 several times since its issuance. The new guidance primarily is included within the following sections of the FASB's Accounting Standards Codification (ASC):

- Topic 606, "Revenue from Contracts with Customers"
- Subtopic 340-40, "Other Assets and Deferred Costs – Contracts with Customers"

For a detailed discussion of the new guidance (as amended), refer to A guide to revenue recognition. Additional information is available in our Revenue Recognition Resource Center.

To help address issues identified by entities as they implement the new guidance, the FASB and IASB established the Joint Transition Resource Group (TRG). In addition, the American Institute of Certified Public Accountants (AICPA) organized several industry-specific task forces. The culmination of the AICPA task forces' activities was the issuance in 2019 of a final comprehensive nonauthoritative revenue recognition audit and accounting guide (the Revenue Recognition AAG). Although there was no task force designated for the life sciences industry, the Revenue Recognition AAG provides helpful discussion and illustrative examples on how to apply the new guidance that may be helpful to all industries. Additional information about the Revenue Recognition AAG can be found on its website.

ASC 606 supersedes virtually all of the guidance previously applied by entities in the life sciences industry. Implementing the new guidance when accounting for customer contracts in the life sciences industry could significantly affect the timing and amount of revenue recognized in an accounting period. This white paper highlights aspects of the new guidance that are particularly relevant to life sciences companies.

B. Scope

In general, the new guidance 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." 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 the new guidance.

It is not uncommon for entities in the life sciences industry to enter into collaboration agreements. Limited guidance on the accounting for such agreements existed in legacy GAAP in ASC 808, "Collaborative Arrangements," to which ASU 2014-09 made relatively minor conforming amendments. One of the challenges in accounting for collaboration agreements is determining whether they give rise to revenue. Whether this is the case under the new guidance 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.

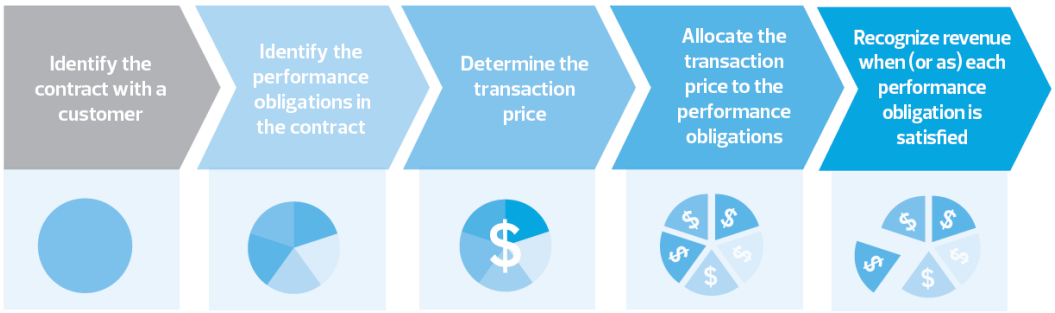
The need to determine whether the counterparty in a collaboration agreement is a customer or a collaborator was raised in ASC 606-10-15-3, which provides an example of a situation in which the counterparty to a contract would not be considered a customer. The example is the development of an asset in a collaboration agreement in which the counterparty is sharing in the risks and benefits of the activity or process underlying the transaction instead of just obtaining the entity's output from its ordinary activities or processes. While this example provides some guidance on what life sciences entities should consider in determining whether the counterparty in a collaboration agreement is a customer, many believed that additional guidance was necessary. As a result, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*, which removes the example in ASC 606-10-15-3 and makes the following changes:

- Clarifies 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.
- Adds unit-of-account guidance in ASC 808 to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606.
- Precludes 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.

Legacy GAAP included limited guidance on the accounting for collaborative agreements in ASC 808. However, paragraph BC56 of ASU 2014-09 indicates that it may be appropriate to account for a collaborative agreement by analogizing to ASC 606 provided there is not more relevant guidance in the ASC with respect to how to account for a particular collaborative agreement. In addition, ASC 808-10-45-3 indicates that presentation of arrangements that are outside the scope of authoritative accounting literature should be determined by analogizing to other guidance in the ASC when possible or by consistently applying a reasonable, rational accounting policy election when no appropriate analogy is available. However, the circumstances under which an entity should present transactions that arise from a collaborative arrangement as revenue is limited by the ASU as discussed earlier.

C. New five-step revenue recognition model

The new guidance includes the following five-step revenue recognition model:



An overview of each step is provided in this section of the white paper. For a comprehensive discussion of the five-step revenue recognition model and other aspects of the new guidance, refer to A guide to revenue recognition.

C.1. Step 1 - Identify 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 ASC 606, the following five criteria (the contract existence criteria) must be met:

- Commercial substance exists.
- 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.
- 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) (the collectibility criterion).

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 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 is only recognized when the amounts paid by the customer (or by another party on the customer's behalf) are nonrefundable and at least one of the following applies:

- 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 (a) transferred control of the goods or services to which the nonrefundable consideration relates and (b) stopped transferring additional goods or services to the customer and is under no obligation to transfer any additional goods or services to the customer.

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.

If all of the contract existence criteria have been met (one of which requires the entity 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), the remaining four steps would be applied to the contract for purposes of recognizing revenue. If accounts receivable or a contract asset is recognized

as a result of applying the new guidance to the contract, the recognition of any related credit losses is reflected as bad debt expense (and not a reduction of revenue).

Spotlight on change

While both legacy GAAP and the new guidance include a collectibility threshold that affects the timing of revenue recognition, the new guidance includes more considerations when evaluating collectibility. In addition, while the new guidance could result in the deferral of nonrefundable cash received due to a customer's inability to pay the remaining amount to which the entity will be entitled in exchange for the goods or services that will be transferred to the customer, this would typically not have been the case under legacy GAAP. In other words, application of legacy GAAP typically would not result in the deferral of nonrefundable cash received if the criteria for revenue recognition were otherwise met. As a result, there is a greater likelihood of revenue deferral due to collectibility issues in these situations under the new guidance compared to legacy GAAP.

All entities in the life sciences industry will need to change the processes they have in place to evaluate collectibility to ensure compliance with the new guidance, particularly as it relates to (a) determining whether amounts not expected to be collected from a customer result from a price concession or the customer's inability to pay and (b) accounting for nonrefundable cash received when the collectibility criterion has not been met. In doing so, an entity will need to understand and document the terms of its contracts, its customary business practices and the knowledge it has of its customers.

C.2. Step 2 - Identify the performance obligations in the contract

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. The first step in identifying the performance obligations in the contract is to identify all of the promises to provide goods or services in the contract.

Contracts in the life sciences industry often include multiple promised goods or services. For example, a contract may include a license of IP, contract research services and contract manufacturing services, 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).

C.2.1. Identifying promises to transfer 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 out of the entity's customary business practices instead of out of 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.

Spotlight on change

While legacy GAAP includes various multiple-element arrangement models (which was the terminology used in legacy GAAP), there was very little discussion in those models with respect to what constitutes

an element. Conversely, detailed guidance on identifying the promised goods or services in a contract is provided in the new guidance, which indicates that entities should not only consider the promised goods or services explicitly stated in the contract, but also what the customer expects to receive or the entity expects to provide based on its customary business practices and communications (i.e., implicit promised goods or services). For example, if a life sciences entity sells complex medical equipment and customarily provides training on how to use that equipment, the training services should be identified as a promised service regardless of whether providing the training is explicitly stated in the contract. Additional discussion of identifying the promised goods or services in a contract that includes contract manufacturing and (or) contract research services is provided in Section E.

Applying the new guidance for identifying promised goods or services in a contract could result in the identification of more promised goods or services or different promised goods or services when compared to the elements identified under legacy GAAP. The identification of more promised goods or services under the new guidance, in turn, could result in the identification of more or different units of account when compared to the units of account identified under legacy GAAP. The identification of more or different units of account could change the timing and (or) pattern of revenue recognition for a contract.

C.2.2. 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 treated separately for accounting purposes. The determining factor in this analysis is whether each promised good or service is distinct. To be distinct, a promised good or service must meet two criteria focused on whether it is: (a) capable of being distinct and (b) distinct in the context of the contract. For example, consider the following discussion related to whether complex medical equipment and consumable cartridges needed to operate the equipment are distinct under the new guidance:

- ***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 within the context of the specific contract is to transfer the 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 medical equipment and consumable cartridges are each distinct within the context of the contract.
  - *The promise within the context of the specific contract is to transfer a 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, then the medical equipment and consumable cartridges are not distinct within the context of the contract.

Indicators are provided in the new guidance 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 is provided in Sections D and E of this white paper related to: (a) determining whether a license of IP is distinct from any other promised goods or services included in the contract under the new guidance and (b) determining whether the various services performed in conjunction with contract manufacturing services are distinct from each other under the new guidance.

Spotlight on change

The basis for determining whether a promised good or service is distinct under the new guidance is different from the basis for determining whether an element has standalone value to the customer under the general multiple-element arrangement model in legacy GAAP. While both models include a criterion that requires consideration of whether the element or promised good or service is sold separately by the entity or another party, the analysis of whether a promised good or service is distinct under the new guidance also requires consideration of whether the promised good or service is distinct within the context of the contract. This difference could result in an entity identifying fewer units of account under the new guidance, which could lead to changes in the timing and amount of revenue recognized.

C.2.3. Additional considerations when accounting for options for additional goods or services (e.g., renewal options)

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.

An option for additional goods or services is treated as a performance obligation (and some of the transaction price is allocated to it) if it provides a material right to the customer that it would not have received without entering into the contract with the entity. For example, an option to renew a license of a cell therapy technology at potentially favorable rates once the initial license term expires or to offer an option to purchase multiple renewal periods at once for a discount should be evaluated under the new guidance 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.

Making the determination as to whether an option for additional goods or services represents a performance obligation under the new guidance requires significant judgment. In addition, if such an option should be treated as a performance obligation, estimating its standalone selling price for allocation purposes could be quite difficult. However, there is a practical alternative provided in the new guidance that allows an entity in certain circumstances (often involving contract renewal options) 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.

Spotlight on change

While there was limited industry-specific guidance in legacy GAAP about how to account for options for additional goods or services, the new guidance addresses how to account for such options on a holistic basis. Given the introduction of a holistic approach in the new guidance to account for options to purchase additional goods or services, entities that include such options in their contracts will need to

change the processes they have in place to track and evaluate these options to ensure compliance with the new guidance. The revised processes will need to incorporate a careful evaluation of options to purchase additional goods or services to determine whether such options should be accounted for as performance obligations under the new guidance.

C.3. Step 3 - Determine the transaction price

Step 3 of the five-step revenue recognition model in ASC 606 requires an entity to determine the transaction price, which often incudes variable consideration. In the life sciences industry, variable consideration can take many forms – milestone payments, pay for performance, other performance-based bonuses, chargebacks, price protection adjustments, discounts, price concessions, rebates and return rights, just to name a few.

C.3.1. 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. The variability in the amount of consideration payable by the customer may be stated in the contract, or it may be caused by an implicit price concession that the life sciences entity intends to offer the customer or that 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) and (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).

Entities must estimate the amount of variable consideration to which the entity expects to be entitled and include it within the transaction price if it is probable that a significant reversal of cumulative revenue recognized will not occur when the underlying uncertainty is resolved. The only exceptions to this are for:

- Sales or usage-based royalty when the only, or predominant, item to which the royalty relates is the license of IP (see Section C.3.3)
- Variable consideration allocated entirely to a distinct good or service that forms part of a series subject to certain criteria

When accounting for other forms of variable consideration an entity must assess: (a) whether it expects to be entitled to the variable consideration, and if so, how much it expects to be entitled to and (b) whether it is probable that a significant reversal of cumulative revenue recognized based on these expectations will not occur when the underlying uncertainties are resolved.

Spotlight on change

Under legacy GAAP applied by entities in the life sciences industry, one of the criteria that had to be met before revenue was recognized required there to be a fixed or determinable fee. If some or all of the fee was not considered fixed or determinable at the onset of the contract, the amount of the arrangement consideration that was not fixed or determinable was deferred. In addition, legacy GAAP provided more detailed guidance on the following topics, which are considered variable consideration under the new guidance:

- ***Milestone payments*.** ASC 605-28, "Revenue Recognition – Milestone Method," provided guidance on the milestone method of accounting for milestone payments, which was one method an entity could elect as its accounting policy for such payments. Under the milestone method, if certain criteria were met, substantive milestone payments were recognized in the period in which

the milestone was achieved. The milestone method was the only accounting policy an entity could elect under legacy GAAP that would result in recognizing the milestone payment in its entirety in the period in which the milestone was achieved.

- ***Right of return*.** Under legacy GAAP, certain criteria had to be met to recognize revenue from a product sale subject to a right of return at the time of sale. If the criteria were not met, revenue from the product sale was not recognized until all of the criteria were subsequently met or the return right lapses. While the new guidance addresses in one way or another many of the criteria in legacy GAAP, treating a right of return as variable consideration under the new guidance is fundamentally different from the approach used to account for a right of return in legacy GAAP, which was focused on determining whether the risks and rewards of owning the product had transferred to the customer and whether the returns could be reasonably estimated.

In many circumstances, the change in how variable consideration is evaluated under the new guidance will result in revenue being recognized sooner than it would be recognized under legacy GAAP. In other words, the potential exists for some or all of a milestone payment payable only upon meeting certain conditions in the future to be recognized under the new guidance before those conditions are actually met. Because this potential exists under the new guidance, all life sciences entities need to change the processes they have in place to identify, track and account for variable consideration.

Estimating the expected amount of variable consideration

To estimate the amount of variable consideration to which the entity expects to be entitled, the entity must use one of two methods: (a) the expected value method or (b) the most likely amount method. The method an entity should use depends on which method better predicts the amount of variable consideration in the particular set of facts and circumstances.

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 7 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, calculated using the expected value method.

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 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.

Applying the variable consideration constraint

After the transaction price is estimated using either the expected value method or most likely amount method, the amount included in the transaction price is constrained to the amount for which it is probable that there will not be a significant reversal in cumulative revenue recognized upon resolution of the underlying contingency. The following are examples of questions the entity should consider when applying the variable consideration constraint:

- Is the variability caused by factors outside the entity's influence?
- Is the amount of time expected to pass until resolution of the uncertainty lengthy?
- Is the entity's experience with similar contracts limited or does it offer limited predictive value?
- Does the entity offer price concessions or change payment terms after contract inception in similar situations?
- Is there a large number and (or) broad range of possible outcomes?

Answering yes to any of these questions increases the likelihood and (or) magnitude of a potential revenue reversal.

In addition, when applying the variable consideration constraint, the entity will need to take into consideration the probabilities it used in applying either the expected value method or most likely amount method. For example, consider the situation introduced earlier in which the 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. If the life sciences entity uses the most likely amount method and believes it is 60 percent probable that regulatory approval will be obtained, the estimate of the variable consideration to which the life sciences entity expects to be entitled is $1 million. However, in this situation, the amount of variable consideration included in the transaction price is constrained to zero because it is not probable (i.e., a 60 percent likelihood is not probable) that there will not be a significant reversal (assuming $1 million is significant relative to the entire contract amount) in cumulative revenue recognized upon resolution of the underlying contingency.

C.3.2. Accounting for a right of return

When an entity accounts for the sale of a product subject to a right of return, it recognizes the following:

- *Revenue for the amount to which it expects to be entitled (estimated using either the expected value method or most likely amount method), limited to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur.* In assessing the probability of a significant reversal in the cumulative revenue recognized, the entity should take many factors into consideration, including its history with the same or similar return rights.
- *A refund liability for the amount to which it ultimately does not expect to be entitled as a result of the return right (i.e., the amount it is expected to refund).* The refund liability should be presented separate from any contract liabilities recognized.
- *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 includes any decrease in the value of the returned product.

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

C.3.3. Exception for sales and (or) usage-based royalties

An exception to the overall model for variable consideration in the new guidance relates to a sales and (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 and (or) usage-based royalty should not be included in the transaction price until the later of: (a) the resolution of the related uncertainty (i.e., sales and [or] usage occur) or (b) 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 Section D). 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 the following: (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 and (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 and (or) usage-based royalties that are not subject to this exception (e.g., a usage-based royalty on a piece of medical equipment) should be accounted for using the overall variable consideration guidance.

C.4. Step 4 - Allocate the transaction price to the performance obligations

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 and (or) variable consideration that can be shown to be related to one or more (but less than all) performance obligations. In addition, a contract with one performance obligation also may be affected by the guidance on allocating variable consideration when that one performance obligation is made up of a series of distinct goods or services that are treated as a single performance obligation under the series exception.

C.4.1. Estimating standalone selling price

The standalone selling price of a performance obligation is the amount the 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 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 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.
- 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.
- Residual approach - This approach determines a standalone selling price for the underlying goods or services based on the difference (i.e., residual) between: (a) the total transaction price and (b) the total observable standalone selling prices for the other goods or services in the contract.

A residual approach may only be used to estimate a standalone selling price when there is an observable standalone selling price for the other performance obligation(s) in the contract and one of the following criteria is met:

- The prices at which the entity has sold the goods or services underlying a performance obligation on a standalone basis at or near the same time represent 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 entity has not yet established a price for those goods or services (i.e., the selling price is uncertain).

In making an estimate of standalone selling prices, the entity should maximize observable inputs and consider all reasonably available and relevant information, which includes information specific to the 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.

Spotlight on change

Both the general multiple-element arrangement model in legacy GAAP and the new guidance include approaches that must be followed to allocate arrangement consideration (which is the terminology typically used in legacy GAAP) or the transaction price (which is the terminology used in the new guidance) to the elements or performance obligations that should be accounted for separately (i.e., the units of account). While there are some similarities between the allocation approach in the general multiple-element arrangement model in legacy GAAP and the new guidance, there are also some noteworthy differences, including the use of a residual approach in the allocation process under the new guidance and the limitation of revenue to the amount not contingent upon delivery of any undelivered elements under legacy GAAP.

Using a residual approach in the allocation process

Under the general multiple-element arrangement model in legacy GAAP, a relative selling price method always was used for allocation purposes (i.e., use of a residual allocation method was not permitted). A residual approach may only be used under the new guidance to estimate a standalone selling price for a performance obligation (i.e., unit of account) in the following circumstances: (a) the prices at which the entity has sold the goods or services underlying a performance obligation on a standalone basis at or near the same time represent a broad range of prices within which a representative standalone selling price cannot be identified (i.e., the selling price is highly variable) or (b) the goods or services underlying a performance obligation have not previously been sold on a standalone basis and the entity has not yet established a price for those goods or services (i.e., the selling price is uncertain). The latter circumstance may exist, for example, when a life sciences entity licenses IP to a customer and the entity has not previously licensed the IP on a standalone basis nor established a price for the license of the IP.

While a residual approach may be used in the circumstances noted to estimate the standalone selling price of a performance obligation under the new guidance, the transaction price is still allocated to all of the performance obligations in the contract using the relative standalone selling price method (except in certain situations involving discounts and [or] variable consideration that can be shown to be related to one or more [but less than all] performance obligations).

Limiting revenue to the amount not contingent upon delivery of any undelivered elements

Under the general multiple-element arrangement model in legacy GAAP, any arrangement consideration allocated to a delivered element that was contingent upon delivery of the undelivered elements in the arrangement was deferred until delivery of those undelivered elements occurred.

Under the new guidance, when some or all of the transaction price is contingent upon the delivery of undelivered promised goods or services, the effects of that contingency are addressed by applying the variable consideration guidance. While the new guidance includes a constraint on the variable consideration included in the transaction price (i.e., it must be probable that a significant reversal of cumulative revenue recognized will not occur upon resolution of the contingency), this constraint is not expected to limit the transaction price to the amount that is not contingent upon delivery of the undelivered promised goods or services in many cases because resolution of the contingency is typically within the entity's control (i.e., the entity typically controls whether it delivers the undelivered promised goods or services).

The change in how amounts contingent upon the delivery of undelivered promised goods or services are treated from an accounting perspective is expected to result in recognizing those contingent amounts as revenue sooner in many cases under the new guidance. Consider a situation in which a life sciences entity licenses IP and provides contract manufacturing services to the customer, and payment for the license of IP is contingent upon delivery of the contract manufacturing services. Under the general multiple-element arrangement model in legacy GAAP, no revenue is recognized for the license of IP until the contract manufacturing services are provided. However, under the new guidance, if the license of IP and contract manufacturing services are considered separate performance obligations and the license of IP is considered a right to use IP (see Sections D and E), the transaction price allocated to the license of IP (which would reflect the possibility [if any] of the contract manufacturing services not being provided) would be recognized by the life sciences entity when control of the licensed IP transfers to the customer.

C.5. Step 5 - Recognize 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, an entity must perform at contract inception an evaluation focused on whether a performance obligation is satisfied at a point in time or over time. Specific guidance, which is discussed in Section D, 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, at least one of the following criteria must be met to conclude that the performance obligation is satisfied over time:

- The customer simultaneously receives and consumes benefits as the entity performs.
- Control of the promised goods or services transfers to the customer as the entity performs.
- The asset created by the entity's performance does not have an alternative use to the entity, and the entity's right to payment for its performance to date is enforceable.

If none of these criteria are met, revenue is recognized at a point in time. In addition to determining whether a performance obligation is satisfied (and revenue is recognized) at a point in time or over time, the new guidance also addresses: (a) the point in time control of a good or service transfers to the customer and (b) 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 Section E.2.

Spotlight on change

Under legacy GAAP, revenue was recognized when it was earned and realized or realizable. While there was guidance in legacy GAAP addressing when revenue was earned and realized or realizable in certain industries (e.g., software, construction), such guidance typically did not apply to life sciences entities. In addition, while there was guidance in legacy GAAP that was applicable to life sciences entities, it addressed how revenue recognition was affected when specific issues were present (e.g., rights of return, sales subject to guaranteed minimum resale value). As a result, the overall guidance for determining whether revenue had been earned and was realized or realizable that typically was applied by life sciences entities was that provided in SEC Staff Accounting Bulletin (SAB) Topic 13, which was codified in ASC 605-10-S99 and was followed when there was no other directly applicable guidance in legacy GAAP. Under SAB Topic 13, there were four criteria that had to be met to recognize

revenue, one of which was that delivery has occurred or services have been rendered. While some guidance existed with respect to the application of this criterion, it mostly was focused on when delivery of a product has occurred. In other words, there was very little guidance related to accounting for service contracts in legacy GAAP.

Under legacy GAAP, one of the criteria that had to be met before revenue was recognized required there to be a fixed or determinable fee. As a result, revenue from sales involving a distributor often was recognized by a manufacturer of products, such as pharmaceutical drugs or medical devices, on a sell-through basis, which resulted in revenue being deferred until the product was sold to the end user (rather than being recognized when the products were delivered to the distributor). This was because arrangements with a distributor may include provisions for extended payment terms or significant product return rights, which draw into question whether the fee is fixed or determinable and whether the risks and rewards of ownership have transferred to the distributor — two key attributes of the general revenue recognition model in legacy GAAP.

Under the new guidance, revenue is recognized when the customer obtains control of the product. A customer obtains control when it has the ability to direct the use of, and receive substantially all the related remaining benefits from, the product. The new guidance provides a number of indicators that should be considered in assessing whether control has transferred, including the customer's obligation to pay, customer acceptance and transfer of legal title, physical possession, and the significant risks and rewards of ownership. Under the new guidance, the estimated transaction price is recognized as revenue at the point in time control transfers to the distributor (i.e., the customer), which may be sooner than it would have been recognized if it were accounted for on a sell-through basis under legacy GAAP.

While it is possible that the timing of revenue recognition (i.e., whether revenue is recognized over time or at a point in time) will not change under the new guidance, a life sciences entity will not know whether there is a change until it applies the new guidance to its contracts. For example, as discussed in Section E, life sciences entities that provide contract manufacturing services and recognize revenue upon delivery of the manufactured product under legacy GAAP should consider whether revenue should be recognized over time as the product is manufactured under the new guidance either because: (a) control of the manufactured product transfers to the customer as the life sciences entity performs or (b) the manufactured product does not have an alternative use to the life sciences entity and the life sciences entity's right to payment for its performance to date is enforceable.

D. Accounting for licenses of 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, copyrights, etc. 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 the following two aspects of the new guidance should be applied to contracts that include a license of IP: (a) identifying the performance obligations (i.e., units of account) and (b) 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).

Spotlight on change

While legacy GAAP provides industry-specific guidance on how to recognize revenue for certain licenses of IP (e.g., software, motion pictures), the types of licenses entered into by life sciences entities were not typically within the scope of that guidance. If there was no specific guidance in the ASC that applied to the license entered into by a life sciences entity, the general revenue recognition

guidance in legacy GAAP (which is included in ASC 605, "Revenue Recognition") was applied, including the guidance on multiple-element arrangements.

One of the most important aspects of the new guidance is that it explicitly addresses and illustrates how the relevant concepts should be applied to all licenses of IP. As a result, the diversity in practice that exists with respect to how the general revenue recognition guidance in ASC 605 is applied to licenses not within the scope of the industry-specific legacy GAAP on licenses should no longer exist after the effective date of the new guidance.

D.1. Identifying the performance obligations in a contract that includes a license of IP

Evaluating restrictions of time, geographical region or use

To the extent a customer contract includes a license of IP, the entity should consider whether the contract includes any restrictions in: (a) the timeframe or geographical region in which the licensed IP may be used by the customer and (or) (b) the manner in which the licensed IP may be used by the customer. If any such restrictions exist, the entity must determine which of the following the restriction(s) represents:

- *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. 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 facts and circumstances.

Determining whether a license of IP is distinct

As discussed in Section C.2, entities are required under the new guidance to determine whether promised goods or services are distinct from each other for purposes of identifying the units of account (i.e., the performance obligations). This determination is based on whether two criteria are met, which are focused on whether the promised goods or services are capable of being distinct from each other and separately identifiable from each other in the context of the contract. Consider the following discussion related to whether the license of a drug compound and contract manufacturing services are distinct under the new guidance:

- ***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 within the context of the specific 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 within the context of the specific 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 criteria.

Example 56 starting at ASC 606-10-55-367 illustrates application of the new 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 later in Section E 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 the next section of this white paper.

Spotlight on change

While entities are required to determine whether the license of IP should be accounted for separate from other elements in a contract under legacy GAAP, the basis for making that determination is different under the new guidance. As a result, different units of account could be identified under the new guidance, which, in turn, could affect the timing and amount of revenue recognized.

D.2. Determining when a performance obligation that includes a license of IP is satisfied

License of IP is distinct

When the license of IP is distinct (i.e., its own performance obligation) under the new guidance, 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) a right to use the IP, in which case the allocated transaction price would be recognized at a point time, or (b) a right to access the IP, in which case the allocated transaction price would 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, the IP must derive a substantial portion of its utility (i.e., its ability to provide benefit or value to the licensee) from its significant standalone functionality. IP with significant standalone functionality includes IP that provides benefits to the licensee through its ability to process a transaction, perform a function or task or

be 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 (for which revenue is recognized at a point in time) would be considered a right to access the IP (for which revenue is recognized over time). The FASB indicated in paragraph BC59 of ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, 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 property 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, just to name a few. 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 (i.e., whether the transaction price allocated to the license of IP should be recognized over time or at a point in time), 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 indicators for transfer of control are considered 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, an appropriate method must be identified by which to measure progress toward the 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 licensee.
- The period over which the licensee 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 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.

License of IP is not distinct

When the license of IP is not distinct under the new guidance, it is combined with other promised goods or services in the contract until a performance obligation exists. The entity then applies the overall approach to recognizing revenue under the new guidance, which requires consideration of whether the performance obligation is satisfied at a point in time or over time (see Section C.5) and, if it is the latter, the method that should be used to measure progress towards the complete satisfaction of the performance obligation.

E. Accounting for contract manufacturing and contract research services

Life sciences entities may enter into service agreements to provide contract manufacturing and (or) contract research services. Accounting for these agreements when they also include a license of IP is discussed in Section D. The discussion in the remainder of this section is focused on agreements to provide only contract manufacturing and (or) 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 following aspects of the new guidance: (a) identifying the performance obligations (i.e., units of account) and (b) determining when a performance obligation is satisfied.

E.1. Identifying the performance obligations

As discussed in Section C.2, entities are required to identify the promised goods or services in the contract and then determine whether those promised goods or services are distinct from each other for purposes of identifying the units of account (i.e., the performance obligations). Whether promised goods or services are distinct is based on whether two criteria are met, which are focused on whether the promised goods or services are capable of being distinct from each other and distinct in the context of the contract.

Spotlight on change

Applying the new guidance on identifying promised goods or services could result in the identification of different promised goods or services compared to the elements identified under legacy GAAP and (or) the identification of different units of account. For example, consider Case B of Example 10 starting at ASC 606-10-55-140A, which illustrates a situation in which the customer contract requires the delivery of multiple units of a highly complex, specialized device that is built to the customer's unique design specifications and involves procuring materials, identifying and managing subcontractors and manufacturing, assembling and testing the devices. Based on the facts and circumstances presented in that example, the FASB concluded that the contract involves providing services to produce "the full complement of devices for which the customer has contracted in accordance with the customer's specifications." In addition, the FASB concluded that the different services being provided are not distinct. As a result, the customer contract includes only one performance obligation. Accounting for this arrangement under legacy GAAP could result in the identification of multiple elements—one for each device to be produced—that should be accounted for separately. Given the stark difference in how this type of arrangement could be accounted for under legacy GAAP vs. the new guidance, life sciences entities should carefully consider this example and the new guidance on identifying the performance obligations when accounting for contract manufacturing services.

E.2. Determining when a performance obligation is satisfied

As discussed in Section C.5, a determination must be made regarding whether a performance obligation (i.e., unit of account) 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 as discussed in the preceding section of this white paper) would require the entity to answer the following questions:

- *Does the customer simultaneously receive and consume the benefits of the contract manufacturing and (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 and (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 either: (a) contract manufacturing services are provided to the customer and control of the manufactured product transfers to the customer as the product is manufactured, or (b) 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 life sciences 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. The new guidance 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, the new guidance 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 and reliably measure the progress toward complete satisfaction of a performance obligation, 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 used only until the entity is able to reasonably and reliably measure the outcome of a performance obligation.

Spotlight on change

In considering the new guidance compared to legacy GAAP, how life sciences entities recognize revenue for contract manufacturing services could change significantly. For example, life sciences entities that recognize revenue upon delivery of the manufactured product under legacy GAAP must consider whether revenue should be recognized over time as the product is manufactured under the new guidance. If applying the new guidance results in a change from recognizing revenue at a point in time to recognizing revenue over time, the amount of revenue recognized in a particular accounting period could be significantly affected.

F. Contract costs

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 include: (a) costs to fulfill a contract and (b) costs to obtain a contract.

F.1. 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 this other accounting guidance include: (a) ASC 330, "Inventory," (b) ASC 350-40, "Intangibles—Goodwill and Other – Internal-Use Software," (c) ASC 360, "Property, Plant, and Equipment," and (d) the guidance for preproduction costs related to long-term supply contracts in ASC 340-10, "Other Assets and Deferred Costs – Overall." ASC 340-40 is applied to costs to fulfill a contract when there is no other applicable guidance in the ASC. For example, certain setup costs that do not fall within the scope of other guidance in the ASC would be accounted for in accordance with ASC 340-40.

If there is no specific guidance in the ASC that applies to costs incurred to fulfill a contract, the new guidance should be applied, which requires capitalization of those costs if all of the following criteria are met:

- The costs incurred by the entity are directly related to a specific contract or anticipated contract (e.g., direct labor related to setup activities).
- The costs generate or enhance resources that the entity will use in satisfying its future performance obligations under the contract (e.g., the activities giving rise to the costs are not a performance obligation in and of themselves).
- The entity expects to recover the costs (e.g., based on net cash flows from the contract and expected contract renewals).

If these criteria are met, the fulfillment costs must be capitalized. In other words, the option does not exist to expense fulfillment costs for which these criteria are met.

F.2. Costs to obtain a 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 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 entity expects to recover those costs (e.g., based on net cash flows from the contract and expected renewals). However, if the amortization period would otherwise be one year or less, an entity may elect a practical expedient under which the incremental costs of obtaining a contract are expensed.

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 entity enters into a contract with the customer. Otherwise, such costs are expensed as incurred.

Spotlight on change

Capitalization of customer acquisition and setup costs for which there was no specific guidance in legacy GAAP generally depended on whether those costs met the definition of an asset and whether the entity made an accounting policy election to capitalize such costs. Under the new guidance, an entity may be required to capitalize incremental customer acquisition costs and setup costs under certain circumstances.

The degree to which an entity is affected by the new guidance will depend on the accounting policies it elected under legacy GAAP to account for customer acquisition and setup costs. For example, if an entity's accounting policy under legacy GAAP was to expense setup costs as incurred, its accounting

for those costs under the new guidance will change significantly if the criteria for capitalization under the new guidance are met. In addition, if an entity elected an accounting policy under legacy GAAP to capitalize setup costs to the extent they met the definition of an asset and amortize those costs over the contract term, it may be required by the new guidance to amortize those costs (to the extent they meet the criteria for capitalization) over a period longer than the contract term.

F.3. Amortization of capitalized costs

The amortization method and period used to amortize capitalized costs related to obtaining or fulfilling a contract (including an anticipated contract, such as a contract renewal) should be systematic and consistent with how and when the related goods or services are transferred to the customer. Determining whether it is appropriate to include contract renewals (i.e., specified anticipated contract[s]) in the amortization period for capitalized costs depends on whether the costs relate to goods or services expected to be transferred under: (a) only the initial contract or (b) both the initial contract and one or more expected contract renewal(s). When the capitalized costs relate to goods or services expected to be transferred under both the initial contract and one or more expected contract renewal(s), the expected contract renewals are reflected in the amortization period.

If capitalized contract costs relate to more than one distinct good or service, TRG Memo No. 23 indicates that entities may choose to either (a) allocate the contract asset among those distinct goods and services or (b) amortize the capitalized costs using a single measure of progress.

G. Disclosure requirements

The new guidance includes many new qualitative and quantitative disclosure requirements. The objective of the disclosure requirements is to help financial statement users understand the nature, amount, timing and uncertainty of revenue and related cash flows. In general, entities are required to disclose a variety of information about the contracts they have with customers and significant judgments used in the application of the new guidance.

While the most disclosures are required of public entities, many disclosures also are required of nonpublic entities. In addition, more disclosures are required of public entities on an annual basis than an interim basis, with many of the disclosures required on an interim basis being quantitative in nature.

A life sciences entity should review its systems, processes, procedures and controls to determine whether it is capable of providing the information necessary to satisfy the new disclosure requirements discussed in the remainder of this section and, if not, what changes it must make to enable it to provide the necessary information.

G.1. Disaggregated revenue

Public companies are required to disclose a quantitative disaggregation of revenue based on how economic factors affect the nature, amount, timing and uncertainty of revenue recognition and cash flows.

Nonpublic companies that do not elect to provide the quantitative disclosures required for public entities should disaggregate revenue based on when control of the goods or services transfers to the customer (e.g., over time or at a point in time). In addition, such nonpublic entities should provide qualitative discussion about how economic factors (such as those that might otherwise serve as the basis for quantitative disaggregation) affect the nature, amount, timing and uncertainty of revenue recognition and cash flows.

When determining the appropriate disaggregation levels and categories to use in financial statement disclosures, public entities (and other entities that elect to provide the disclosures required of public companies) should consider how they present revenue for other purposes, such as to investors and members of management or governance committees. In considering the needs of financial statement

users, an entity will want to carefully evaluate all sources of revenue and the varying judgments used to recognize different types of revenue. Common categories of disaggregated revenue include: (a) type of good or service (e.g., by major product line), (b) geographic region, (c) contract and customer type (e.g., fixed-price and time-and-materials contracts), (d) contract duration, (e) timing of transfer of goods or services (e.g., at a point in time or over time) or (f) market type (revenue from international or U.S. governments), among others.

G.2. Contract balances

All entities should disclose, or present separately on the face of the balance sheet, the opening and closing balances of accounts receivable, contract assets and contract liabilities.

Public entities also are required to disclose the following, which are optional for nonpublic entities:

- *The amount of revenue recognized in the current reporting period that was included in the contract liability balance at the end of the previous reporting period.* For example, if an entity had a contract liability balance at the end of the previous reporting period due to it receiving upfront nonrefundable payments for which it had not yet fully performed, it should disclose the amount of that liability that was recognized as revenue in the current reporting period.
- *An explanation (which may be qualitative) of the timing of the entity's satisfaction of its performance obligations compared to the timing of when it typically receives payment for providing the underlying goods or services and how the contract asset and contract liability balances are affected by this timing.*
- *A qualitative and quantitative explanation of what caused significant changes in the contract assets or contract liabilities during the reporting period.* For example, if an entity acquires another entity during the reporting period, it should explain the acquisition's effects on contract assets and contract liabilities.

An entity's revision of estimates (e.g., variable consideration, percentage of completion), if any, should be evaluated for its effect on contract balances. If material, an entity should explain the effects on contract assets and contract liabilities of revising an estimate. This will provide relevant information about the timing of revenue recognition that was not a result of current-period performance.

G.3. Performance obligations

An entity is required to disclose the following about its performance obligations:

- When its performance obligations are typically satisfied
- Significant payment terms
- Nature of the promised goods or services provided to customers
- Obligations it has in its customer contracts related to rights of return or refund or other similar customer rights
- Warranties and related obligations
- Revenue recognized in the current reporting period related to performance obligations satisfied (or partially satisfied) in the prior reporting period

G.4. Transaction price allocated to remaining performance obligations

Remaining performance obligations are those performance obligations identified in a customer contract entered into before the end of a reporting period for which control of some or all of the underlying goods or services has not been transferred to the customer at the end of the reporting period. A remaining

performance obligation may be a partially satisfied performance obligation or a completely unsatisfied performance obligation.

With certain exceptions, the following information about remaining performance obligations at the end of a reporting period should be disclosed by public entities and may be disclosed by nonpublic entities:

- *The total amount of the transaction price allocated to those performance obligations*.
- *An explanation of when the entity expects to recognize the transaction price allocated to these performance obligations as revenue*. This disclosure requirement can be satisfied either quantitatively (using appropriate time bands for when the allocated transaction price is expected to be recognized as revenue) or qualitatively.

As described further in ASC 606-10-50-14 to 50-14B, there are two optional exemptions related to these remaining performance obligation disclosure requirements. An entity should disclose which of the optional exemptions it has elected to apply, as well as the following information about the related remaining performance obligations: (a) their nature, (b) their remaining duration and (c) a description of any variable consideration excluded from the disclosures as a result of electing one or both of the optional exemptions.

G.5. Significant judgments

An entity should disclose judgments (and changes to those judgments) it makes in applying the new guidance that significantly affect when and how much revenue is recognized related to its customer contracts. The disclosures should include those judgments (and changes in judgments) involved in determining the transaction price, allocating the transaction price to performance obligations and determining when performance obligations are satisfied.

The following information should be disclosed by all entities:

- *For performance obligations satisfied over time, the specific input or output method used to recognize revenue.*
- *In applying the variable consideration constraint, the judgments involved in identifying the methods, inputs and assumptions used.*

The following additional information should be disclosed by public entities and may be disclosed by nonpublic entities:

- *For performance obligations satisfied over time, an explanation of why the specific input or output method used to recognize revenue over time provides a faithful depiction of how the entity transfers control of goods or services to its customers.*
- *For performance obligations satisfied at a point time, the significant judgments made in determining when control of the goods or services transfers to the entity's customers*.
- *The judgments involved in identifying the methods, inputs and assumptions used to determine and allocate the transaction price and measure any obligations related to the customer contract* (e.g., returns, refunds), including (but not limited to) the following:
  - If there is variable consideration, the entity should explain how it estimates the variable consideration (e.g., the most likely amount method or the expected value method).
  - If there is a significant financing component, such as certain long-term payment plans, the entity should disclose how it was reflected in the transaction price. Public entities electing the practical expedient that results in not reflecting a significant financing component in the transaction price should disclose that fact.
  - If there is noncash consideration, the entity should disclose how it was measured.

- *For contracts that include more than one performance obligation, the judgments involved in identifying the methods, inputs and assumptions used to*: *(a) estimate the standalone selling price of each performance obligation and (b) allocate any discount or variable consideration included in the contract.*
- *For rights of return or refund (e.g., right of refund related to some or all of an advance payment), the judgments involved in identifying the methods, inputs and assumptions used to estimate the related obligation.*

G.6. Contract costs

The following information related to costs incurred to obtain or fulfill a customer contract should be disclosed by public entities and may be disclosed by nonpublic entities:

- A description of the judgments made in identifying the costs that should be capitalized
- A description of the method used in each reporting period to amortize the capitalized costs and the amount of related amortization recognized for the reporting period
- The ending balances of capitalized costs by main category of asset (e.g., incremental costs to obtain a contract, setup costs)
- Any impairment loss recognized in the reporting period related to the capitalized costs
- If an entity elects the practical expedient allowing it to expense the incremental costs to obtain a contract if the amortization period for those costs would otherwise be one year or less, that fact.

H. Conclusion

This white paper discusses those differences between the new guidance and legacy GAAP that are likely to have the most significant effects on how life sciences entities recognize revenue. For a comprehensive discussion about the new guidance, including its scope, core principle and key steps, implementation guidance, presentation and disclosure requirements, and effective date and transition provisions, refer to A guide to revenue recognition.

All life sciences entities whose financial statements are prepared in accordance with U.S. GAAP will be affected by the new guidance because their accounting policies for revenue recognition will need to change to reflect the five-step revenue recognition model. In addition, every entity will be significantly affected by the disclosure requirements in the new guidance because they substantially increase the volume of revenue-related information disclosed in the financial statements, particularly for public entities. The new guidance will require entities in the life sciences industry to evaluate whether any changes are needed to their current revenue and financial reporting processes, systems and procedures. This undoubtedly will require substantive involvement by more than just those involved in the accounting function. To discuss the impacts of the new guidance on your company and its financial statements, don't hesitate to contact your RSM representative, Matt Coffland (+1 919 645 6825) or Patricia Baldowski (+1 732 515 7285).

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