



## **Life Sciences**

Accounting and Financial Reporting Update —  
Interpretive Guidance on Revenue Recognition  
Under ASC 606

March 2017

# Revenue Recognition

## Background

In May 2014, the FASB<sup>1</sup> and IASB issued their final standard on revenue from contracts with customers. The standard, issued as [ASU 2014-09](#)<sup>2</sup> by the FASB and as [IFRS 15](#) by the IASB, outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance.

Upon issuing the new revenue standard, the FASB and IASB formed a joint revenue transition resource group (TRG). The purpose of the TRG is not to issue guidance but instead to seek and provide feedback on potential issues related to implementation of the new revenue standard. By analyzing and discussing potential implementation issues, the TRG has helped the boards determine whether to take additional action, such as providing clarification or issuing other guidance.

Largely as a result of feedback provided by the TRG after the issuance of the initial ASU, the FASB issued the following ASUs to amend and clarify the guidance in the new revenue standard:

- *ASU 2015-14, Deferral of the Effective Date.*
- *ASU 2016-08, Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net).*
- *ASU 2016-10, Identifying Performance Obligations and Licensing.*
- *ASU 2016-11, Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting.*
- *ASU 2016-12, Narrow-Scope Improvements and Practical Expedients.*
- *ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue From Contracts With Customers.*
- *ASU 2017-05, Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets.*

For public business entities (as well as certain not-for-profit entities and employee benefit plans) and all other entities, the new revenue standard is effective for annual reporting periods beginning after December 15, 2017, and December 15, 2018, respectively, with certain early adoption provisions available.

ASU 2014-09 states that the core principle of the new revenue recognition guidance is that an “entity shall recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.” The ASU indicates that an entity should perform the following five steps in recognizing revenue:

- “Identify the contract(s) with a customer” (step 1).
- “Identify the performance obligations in the contract” (step 2).

<sup>1</sup> For a list of abbreviations used in this publication, see [Appendix B](#).

<sup>2</sup> For the full titles of standards and other literature referred to in this publication, see [Appendix A](#).

- “Determine the transaction price” (step 3).
- “Allocate the transaction price to the performance obligations in the contract” (step 4).
- “Recognize revenue when (or as) the entity satisfies a performance obligation” (step 5).

As a result of the ASU, as amended, entities will need to comprehensively reassess their current revenue accounting policies and determine whether changes are necessary. In addition, the ASU requires significantly expanded disclosures about revenue recognition, including both quantitative and qualitative information about (1) the amount, timing, and uncertainty of revenue (and related cash flows) from contracts with customers; (2) the judgment, and changes in judgment, exercised in applying the new revenue standard; and (3) the assets recognized from costs to obtain or fulfill a contract with a customer.

The sections below discuss some of the key accounting considerations for life sciences entities. For more detailed information about the new revenue standard, see Deloitte’s [A Roadmap to Applying the New Revenue Recognition Standard](#) and its [TRG Snapshot](#) series. See also Deloitte’s February 22, 2017, [Heads Up](#) for a discussion of certain of the disclosure requirements that may be particularly challenging for life sciences entities to implement.

## Scope

The new revenue standard applies to all contracts with customers as defined in the standard except those that are within the scope of other topics in the *FASB Accounting Standards Codification*. For example, the ASU does not apply to contracts within the scope of ASC 840 and ASC 842 (leases). In addition, certain of the new revenue standard’s provisions also apply to transfers of nonfinancial assets, including in-substance nonfinancial assets that are not an output of an entity’s ordinary activities (e.g., intangible assets such as intellectual property rights). Such provisions include guidance on recognition (including determining the existence of a contract and control principles) and measurement.

Some of the more common questions that life sciences entities have faced when considering the scope of the new revenue standard are discussed below.

## Applicability of the New Revenue Standard to the Parties of a Collaborative Arrangement

### Question

Does the new revenue standard apply to the parties of a collaborative arrangement?

### Answer

It depends. The new revenue standard applies to all contracts with customers. ASC 606-10-15-3 defines a customer 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.” However, that provision also notes that a “counterparty to the contract would not be a customer if, for example, the counterparty has contracted with the entity to participate in an activity or process in which the parties to the contract share in the risks and benefits that result from the activity or process (such as developing an asset in a collaboration arrangement) rather than to obtain the output of the entity’s ordinary activities.”

The Basis for Conclusions of ASU 2014-09 also explains that the relationship between a customer and a vendor varies from industry to industry and that companies will therefore have to consider their own facts and circumstances to determine who is a customer in an arrangement. For many contracts, this will not be very difficult to determine; however, paragraph BC54 of ASU 2014-09 provides examples of arrangements in which the facts and circumstances would have to be assessed, including “[c]ollaborative research and development efforts between biotechnology and pharmaceutical entities or similar arrangements in the aerospace and defense, technology, and healthcare industries, or in higher education.”

The example below illustrates how an entity would determine whether an arrangement is a collaborative arrangement and, if so, whether it should be accounted for under ASC 606.

### **Example**

Biotech B and Pharma P enter into an agreement to research, develop, and commercialize drug X. Biotech B will perform the R&D, and Pharma P will commercialize the drug. Both parties agree to participate equally in all activities that result from the research, development, and commercialization. The reporting entity concludes that a collaborative arrangement exists because both parties are active participants and have agreed to share in the risks and rewards.

Despite this conclusion, however, there still could be an entity-customer relationship as a result of other contracts between the two companies. If such a relationship exists, those parts of the contract that are related to the entity-customer relationship should be accounted for under ASC 606.



### **Thinking It Through**

ASC 606 does not change the guidance in ASC 808 on the income statement presentation, classification, and disclosures applicable to collaborative arrangements within the scope of the new revenue standard. It is important to understand that a contract could be within the scope of both the new revenue standard and the guidance on collaborative agreements, as indicated in paragraph BC55 of ASU 2014-09:

The Boards noted that a contract with a collaborator or a partner (for example, a joint arrangement as defined in IFRS 11, *Joint Arrangements*, or a collaborative arrangement within the scope of Topic 808, Collaborative Arrangements) also could be within the scope of Topic 606 if that collaborator or partner meets the definition of a customer for some or all of the terms of the arrangement.

This is important because companies may have to assess the scope of both ASC 606 and ASC 808 for these types of arrangements. In addition, the ASU's Basis for Conclusions does not preclude companies from analogizing to the guidance in ASC 606 when accounting for collaborative arrangement transactions within the scope of ASC 808.

## **Considerations Relevant to Applying Revenue Literature by Analogy**

Collaborative arrangements involving life sciences entities frequently involve activities such as R&D, regulatory activities, manufacturing, distribution, sales and marketing activities, and general and administrative tasks. Often, a governance structure (e.g., a joint steering committee) is also established to facilitate decision making during the terms of the endeavor. Upon entering into a collaborative arrangement, the partners frequently exchange up-front license fees and agree to subsequent payments based on the achievement of milestones during drug development, as well as future royalties and profit/loss-sharing provisions.

In determining the accounting for these arrangements, many entities currently apply revenue recognition guidance by analogy. These entities often conclude that the collaborative activities do not represent separate deliverables (i.e., they conclude that there is one “unit of accounting,” which represents the right to actively participate in the collaborative arrangement over its term and to share in the profits or losses from the underlying drug endeavor). Notwithstanding this conclusion, in practice the up-front proceeds that the parties exchange upon entering into the collaborative arrangement are frequently accounted for separately from the consideration subsequently exchanged as the parties fulfill their responsibilities and share costs. This accounting is often referred to as a “multiple attribution for a single unit of accounting” method of recognizing arrangement consideration in earnings.

### **Question**

What considerations are relevant to entities that apply revenue literature by analogy when adopting the new revenue standard?

### **Answer**

ASC 606-10-25-32 states that an “entity shall apply a single method of measuring progress for each performance obligation satisfied over time, and the entity shall apply that method consistently to similar performance obligations and in similar circumstances.” This “single attribution” method differs from the multiple attribution method currently used in practice by many life sciences entities in accounting for their collaborative arrangements. The FASB recently commenced a project aimed at making targeted improvements to clarify when transactions between partners in a collaborative arrangement are within the scope of the new revenue standard. However, it is currently unclear to what extent, if any, the FASB project will address the single attribution requirement of the new revenue standard with respect to collaboration arrangements. In the interim, entities are encouraged to discuss these accounting arrangements with their accounting advisers.

### **Free Placement of Medical Device Consumables in Exchange for the Customer’s Commitment to a Minimum Purchase**

The new revenue standard does not apply to contracts with customers (or portions thereof) that fall within the scope of other applicable guidance, such as ASC 840 and ASC 842 (leases). Some entities may need to obtain an understanding of the new leases standard as well as their lease contracts to determine the full scope of customer arrangements that fall within the scope of ASC 606. For example, to facilitate the sale and use of medical device consumables, medical device companies may place equipment for free at the customer’s location for a multiyear term. In exchange for the placed equipment, the customer is typically required to commit to a minimum purchase of consumable products during that term.

### **Question**

What considerations are relevant to the determination of how to apply the new revenue standard to this type of arrangement?

## Answer

To determine how the arrangement should be accounted for under the new revenue standard, the reporting entity should first consider whether the placement of equipment meets the definition of a lease under ASC 840 (current U.S. GAAP) and ASC 842 (future U.S. GAAP). If the arrangement includes elements that meet the definition of a lease, the lease-related elements of the arrangement would need to be accounted for under the lease accounting literature. If the arrangement does not meet the definition of a lease and no other literature is directly applicable, the new revenue standard would be applied to the entire arrangement. For additional considerations related to the new leases standard, refer to Deloitte's March 1, 2016, [Heads Up](#).

## Sale or Outlicensing of Intellectual Property Rights in Exchange for Future Milestone Payments, Royalties, or Both

Life sciences entities frequently sell or outlicense intellectual property rights (e.g., in-process R&D (IPR&D) or developed product rights) in exchange for future milestone payments, royalties, or both (i.e., variable consideration).

## Question

What considerations are relevant to the determination of the accounting model to apply to these types of arrangements?

## Answer

Transactions involving the transfer of intellectual property rights require significant judgment. Accounting for these transactions depends on whether the transfer involves the sale of intellectual property rights, the license of intellectual property rights, or the sale of intellectual property rights together with other inputs and processes that meet the definition of a business. Consider the following:

- *Sale of intellectual property rights* — The new revenue standard's provisions apply to transfers of nonfinancial assets, including in-substance nonfinancial assets that are not an output of an entity's ordinary activities (e.g., intangible assets such as intellectual property rights). The following example in ASC 610-20-55-17 through 55-19 illustrates how an entity would account for the sale of a nonfinancial asset in exchange for variable consideration:

### ASC 610-20

#### Example 3 — Sale of a Nonfinancial Asset for Variable Consideration

**55-17** An entity sells (that is, does not out license) the rights to in-process research and development that it recently acquired in a business combination and measured at fair value of \$50 million in accordance with Topic 805 on business combinations. The entity concludes that the transferred in-process research and development is not a business. The buyer of the in-process research and development agrees to pay a nonrefundable amount of \$5 million at inception plus 2 percent of sales of any products derived from the in-process research and development over the next 20 years. The entity concludes that the sale of in-process research and development is not a good or service that is an output of the entity's ordinary activities.

## ASC 610-20 (continued)

**55-18** Topic 350 on goodwill and other intangibles requires the entity to apply the guidance in this Subtopic to determine the amount and timing of income to be recognized. Therefore, the entity applies the derecognition guidance in this Subtopic as follows:

- a. The entity concludes that it does not have a controlling financial interest in the buyer.
- b. The entity concludes that the contract meets the criteria in paragraph 606-10-25-1.
- c. The entity also concludes that on the basis of the guidance in paragraph 606-10-25-30, it has transferred control of the in-process research and development asset to the buyer. This is because the buyer can use the in-process research and development's records, patents, and supporting documentation to develop potential products and the entity has relinquished all substantive rights to the in-process research and development asset.
- d. In estimating the consideration received, the entity applies the guidance in Topic 606 on determining the transaction price, including estimating and constraining variable consideration. The entity estimates that the amount of consideration that it will receive from the sales-based royalty is \$100 million over the 20-year royalty period. However, the entity cannot assert that it is probable that recognizing all of the estimated variable consideration in other income would not result in a significant reversal of that consideration. The entity reaches this conclusion on the basis of its assessment of factors in paragraph 606-10-32-12. In particular, the entity is aware that the variable consideration is highly susceptible to the actions and judgments of third parties, because it is based on the buyer completing the in-process research and development asset, obtaining regulatory approval for the output of the in-process research and development asset, and marketing and selling the output. For the same reasons, the entity also concludes that it could not include any amount, even a minimum amount, in the estimate of the consideration. Consequently, the entity concludes that the estimate of the consideration to be used in the calculation of the gain or loss upon the derecognition of the in-process research and development asset is limited to the \$5 million fixed upfront payment.

**55-19** At inception of the contract, the entity recognizes a net loss of \$45 million (\$5 million of consideration, less the in-process research and development asset of \$50 million). The entity reassesses the transaction price at each reporting period to determine whether it is probable that a significant reversal would not occur from recognizing the estimate as other income and, if so, recognizes that amount as other income in accordance with paragraphs 606-10-32-14 and 606-10-32-42 through 32-45.

- *License of intellectual property rights* — In contrast to the accounting for a sale of intellectual property, for a licensing transaction in which consideration is tied to the subsequent sale or usage of intellectual property, the new revenue standard provides an exception to the recognition principle that is part of step 5 (i.e., recognize revenue when or as control of the goods or services is transferred to the customer). Under this sales- or usage-based royalty exception, an entity would not estimate the variable consideration from sales- or usage-based royalties. Instead, the entity would wait until the subsequent sale or usage occurs to determine the amount of revenue to recognize.
- *Sale of intellectual property rights together with other inputs and processes that meet the definition of a business* — ASC 610-20 does not amend or supersede guidance that addresses how to determine the gain or loss on the derecognition of a subsidiary or a group of assets that meets the definition of a business. Gains or losses associated with such a transaction will continue to be determined in accordance with ASC 810-10-40. Entities should establish an accounting policy for the initial and subsequent measurement of this type of arrangement.

## Identify the Contract (Step 1)

For contracts within the scope of ASC 606, the first step of the new revenue standard is to determine whether a contract exists, for accounting purposes, between an entity and its customer. ASC 606-10-25-1 lists the criteria that must be met for a contract to exist:

### ASC 606-10

#### 25-1 [Omitted text]

- a. **The parties to the contract have approved the contract (in writing, orally, or in accordance with other customary business practices) and are committed to perform their respective obligations.**
- b. **The entity can identify each party's rights regarding the goods or services to be transferred.**
- c. **The entity can identify the payment terms for the goods or services to be transferred.**
- d. **The contract has commercial substance (that is, the risk, timing, or amount of the entity's future cash flows is expected to change as a result of the contract).**
- e. **It is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer (see paragraphs 606-10-55-3A through 55-3C). In evaluating whether collectibility of an amount of consideration is probable, an entity shall consider only the customer's ability and intention to pay that amount of consideration when it is due. The amount of consideration to which the entity will be entitled may be less than the price stated in the contract if the consideration is variable because the entity may offer the customer a price concession (see paragraph 606-10-32-7).**

A contract does not have to be written to meet the criteria for revenue recognition. However, it does need to create enforceable rights and obligations.

Some of the more common questions that life sciences entities have faced as they consider step 1 of the new revenue standard are discussed below.

## Identifying the Parties That Are Relevant to the Determination of Whether a Contract Exists

### Question

Given the number of entities involved in the distribution channel/pricing chain within the life sciences industry, questions have arisen about which parties are relevant to the determination of whether a contract exists. For example, for a pharmaceutical company, does a contract for purposes of step 1 include only the contract between the pharmaceutical company and the wholesaler, or does it also include "downstream" contracts with others in the pricing chain to whom discounts or rebates may be provided?

### Answer

An important step in the new revenue standard is determining when an agreement with a customer represents a contract for accounting purposes. The criteria in ASC 606-10-25-1 that need to be in place to establish that a contract exists are intended to demonstrate that there is a valid and genuine transaction between an entity *and its customer* and that the parties to the contract have enforceable rights and obligations that will have true economic consequences. For a traditional pharmaceutical

company, the wholesaler to which the company's products are shipped would generally represent the customer. In these circumstances, other parties that may be involved in the distribution/pricing chain do not represent the company's customers and therefore are irrelevant to the determination of whether a contract exists for accounting purposes. However, life sciences entities should keep in mind that any pricing adjustments (e.g., rebates, chargebacks) that are payable as result of these arrangements may represent variable consideration that is required to be estimated and potentially constrained under step 3 of the model.

## Whether the Transaction Price Must Be Fixed or Determinable

### *Question*

Does the criterion in ASC 606-10-25-1 that the "entity can identify the **payment terms** for the goods or services to be transferred" (emphasis added) require that the transaction price be fixed or determinable as currently required by ASC 605?

### *Answer*

No. A contract must include payment terms for each of the promised goods and services in an arrangement for an entity to determine the transaction price. The payment terms do not need to be fixed, but the contract must contain enough information to allow an entity to reasonably estimate the consideration to which it will be entitled for transferring the goods and services to the customer.

### *Example*

Pharmaceutical Company X has received approval from a foreign government to sell drug A to government hospitals in advance of obtaining full market authorization in the jurisdiction. During this "early access period" in which X's application for full marketing authorization is being evaluated by the foreign government, X will be paid a preliminary price by the government hospitals. During this same period, X will be negotiating with the foreign government the final price to be paid to X. Upon obtaining full marketing authorization and completing pricing negotiations, X will be required to rebate to the foreign government the difference between the preliminary price and the final price.

Under current U.S. GAAP, the lack of a fixed or determinable selling final price would generally preclude the recognition of revenue until the final price is determined. Under the new revenue standard, however, payment terms may have been established between X and the government hospitals because X can determine, for example, when payment is due and that the consideration is variable, and can reasonably estimate the amount of consideration to which it will ultimately be entitled on the basis of the ongoing negotiations with the foreign government.

## Price Concessions

### *Question*

How do price concessions (variable consideration) affect the timing of revenue recognition under ASC 606-10-25-1, which requires that "[i]t is **probable** that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer" (emphasis added)?

## Answer

As part of determining whether a valid and genuine contract exists, an entity is required to evaluate whether it is probable that the entity will collect substantially all of the consideration to which it is entitled under the contract. However, the consideration to which an entity is ultimately entitled may be less than the price stated in the contract because the customer is offered a price concession. Price concessions are a form of variable consideration and need to be analyzed when the transaction price is being determined (as part of step 3 of the new revenue model). However, as part of step 1, an entity would evaluate whether it is probable that the entity will collect the consideration to which it will be entitled for providing goods or services to a customer after considering any price concessions. This evaluation requires aspects of step 3 to be performed in conjunction with step 1. Differentiating between credit risk (i.e., the risk of collecting less consideration than the amount the entity legitimately expected to collect from the customer) and price concessions (i.e., entering into a contract with a customer with the expectation of accepting less than the contractual amount of consideration in exchange for goods or services) may be difficult. Entities will need to use significant judgment in determining whether they have provided an implicit price concession or have accepted a customer's credit risk. This is particularly true of entities in highly regulated industries, such as health care and consumer energy, which may be required by law to provide certain goods and services to their customers regardless of the customers' ability to pay. Because of the nature of these arrangements, entities will need to evaluate all of the relevant facts and circumstances of their arrangements to determine whether they have provided implicit price concessions or whether the anticipated receipt of less than the total contractual consideration represents credit risk.

Example 2 in the new revenue standard, which is reproduced below, illustrates how a life sciences entity would evaluate implicit price concessions when assessing whether the collectibility criterion is met:

### ASC 606-10

#### Example 2 — Consideration Is Not the Stated Price — Implicit Price Concession

**55-99** An entity sells 1,000 units of a prescription drug to a customer for promised consideration of \$1 million. This is the entity's first sale to a customer in a new region, which is experiencing significant economic difficulty. Thus, the entity expects that it will not be able to collect from the customer the full amount of the promised consideration. Despite the possibility of not collecting the full amount, the entity expects the region's economy to recover over the next two to three years and determines that a relationship with the customer could help it to forge relationships with other potential customers in the region.

**55-100** When assessing whether the criterion in paragraph 606-10-25-1(e) is met, the entity also considers paragraphs 606-10-32-2 and 606-10-32-7(b). Based on the assessment of the facts and circumstances, the entity determines that it expects to provide a price concession and accept a lower amount of consideration from the customer. Accordingly, the entity concludes that the transaction price is not \$1 million and, therefore, the promised consideration is variable. The entity estimates the variable consideration and determines that it expects to be entitled to \$400,000.

**55-101** The entity considers the customer's ability and intention to pay the consideration and concludes that even though the region is experiencing economic difficulty it is probable that it will collect \$400,000 from the customer. Consequently, the entity concludes that the criterion in paragraph 606-10-25-1(e) is met based on an estimate of variable consideration of \$400,000. In addition, based on an evaluation of the contract terms and other facts and circumstances, the entity concludes that the other criteria in paragraph 606-10-25-1 are also met. Consequently, the entity accounts for the contract with the customer in accordance with the guidance in this Topic.

## Identify the Performance Obligations (Step 2)

Step 2 is one of the most critical steps in the new revenue framework since it establishes the unit of account for revenue recognition. This step requires an entity to identify what it has promised to the customer. The entity then determines whether a promise or multiple promises represent one or more performance obligations to the customer. To accomplish this, the entity should determine whether the promises in the contract are distinct. ASC 606-10-25-19 notes that “a good or service that is promised to a customer is distinct if both of the following criteria are met”:

- a. The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct).
- b. The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract).

Further, ASC 606-10-25-22 states that “[i]f a promised good or service is not distinct, an entity shall combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. In some cases, that would result in the entity accounting for all the goods or services promised in a contract as a single performance obligation.”

The new revenue standard's guidance on determining whether a customer can benefit from a good or service on its own or together with other readily available resources is generally consistent with the current guidance in ASC 605-25 on determining whether a good or service has stand-alone value. However, the requirement that a good or service be “separately identifiable from other promises in the contract” is a new concept under which entities must further evaluate a good or service for separability.

To help an entity assess whether its promises to transfer goods or services to the customer are separately identifiable, ASC 606-10-25-21 identifies the following factors “that indicate that two or more promises to transfer goods or services to a customer are *not* separately identifiable” (emphasis added):

- a. The entity provides a significant service of integrating [the] goods or services with other goods or services promised in the contract into a bundle of goods or services that represent the combined output or outputs for which the customer has contracted. . . .
- b. One or more of the goods or services significantly modifies or customizes, or are significantly modified or customized by, one or more of the other goods or services promised in the contract.
- c. The goods or services are highly interdependent or highly interrelated. In other words, each of the goods or services is significantly affected by one or more of the other goods or services in the contract. For example, in some cases, two or more goods or services are significantly affected by each other because the entity would not be able to fulfill its promise by transferring each of the goods or services independently.

Some of the more common questions that life sciences entities have faced when considering step 2 of the new revenue standard are discussed below.

### License of Intellectual Property Bundled With Other Services

Arrangements involving the license of intellectual property and other services (e.g., contract R&D services or contract manufacturing services) are common in the life sciences industry. For example, biotechnology companies frequently enter into license and development arrangements with pharmaceutical companies, and contract manufacturers frequently enter into license and supply arrangements with pharmaceutical companies.

## Question

With respect to identifying performance obligations, how does the analysis of such arrangements under ASC 606 compare with that under current U.S. GAAP?

## Answer

Life sciences entities that grant a license bundled with other services (e.g., contract R&D services or contract manufacturing services) may need to use significant judgment when determining whether the goods or services in a contract (1) are capable of being distinct (have stand-alone value) and (2) are not highly interdependent or highly interrelated and do not significantly modify or customize one another (are separately identifiable). While the analysis of whether the goods or services are capable of being distinct is generally consistent with the analysis of “standalone value” under current U.S. GAAP, the “separately identifiable” concept is new and may require entities to account for a bundle of goods or services, which may represent a separate unit of accounting under current U.S. GAAP, as a single performance obligation (unit of accounting).

## Considering Whether It Is Feasible for Another Vendor to Perform the Same Services

### Question

In evaluating whether a license of intellectual property and contract R&D services (or contract manufacturing services) are separate performance obligations, how should an entity consider whether it is feasible for another vendor to provide the same services?

### Answer

ASC 606-10-55-367 through 55-372A of the new revenue standard, which are reproduced below, include two fact patterns that illustrate how the determination of whether it is feasible for another life sciences entity to provide the same services affects the analysis of whether the “capable of being distinct” criterion is met.

#### ASC 606-10

##### Example 56 — Identifying a Distinct License

**55-367** An entity, a pharmaceutical company, licenses to a customer its patent rights to an approved drug compound for 10 years and also promises to manufacture the drug for the customer for 5 years, while the customer develops its own manufacturing capability. The drug is a mature product; therefore, there is no expectation that the entity will undertake activities to change the drug (for example, to alter its chemical composition). There are no other promised goods or services in the contract.

##### Case A — License Is Not Distinct

**55-368** In this case, no other entity can manufacture this drug while the customer learns the manufacturing process and builds its own manufacturing capability because of the highly specialized nature of the manufacturing process. As a result, the license cannot be purchased separately from the manufacturing service.

**55-369** The entity assesses the goods and services promised to the customer to determine which goods and services are distinct in accordance with paragraph 606-10-25-19. The entity determines that the customer cannot benefit from the license without the manufacturing service; therefore, the criterion in paragraph 606-10-25-19(a) is not met. Consequently, the license and the manufacturing service are not distinct, and the entity accounts for the license and the manufacturing service as a single performance obligation.

[Omitted paragraph]

## ASC 606-10 (continued)

### **Case B — License Is Distinct**

**55-371** In this case, the manufacturing process used to produce the drug is not unique or specialized, and several other entities also can manufacture the drug for the customer.

**55-372** The entity assesses the goods and services promised to the customer to determine which goods and services are distinct, and it concludes that the criteria in paragraph 606-10-25-19 are met for each of the license and the manufacturing service. The entity concludes that the criterion in paragraph 606-10-25-19(a) is met because the customer can benefit from the license together with readily available resources other than the entity's manufacturing service (that is, because there are other entities that can provide the manufacturing service) and can benefit from the manufacturing service together with the license transferred to the customer at the start of the contract.

**55-372A** The entity also concludes that its promises to grant the license and to provide the manufacturing service are separately identifiable (that is, the criterion in paragraph 606-10-25-19(b) is met). The entity concludes that the license and the manufacturing service are not inputs to a combined item in this contract on the basis of the principle and the factors in paragraph 606-10-25-21. In reaching this conclusion, the entity considers that the customer could separately purchase the license without significantly affecting its ability to benefit from the license. Neither the license nor the manufacturing service is significantly modified or customized by the other, and the entity is not providing a significant service of integrating those items into a combined output. The entity further considers that the license and the manufacturing service are not highly interdependent or highly interrelated because the entity would be able to fulfill its promise to transfer the license independent of fulfilling its promise to subsequently manufacture the drug for the customer. Similarly, the entity would be able to manufacture the drug for the customer even if the customer had previously obtained the license and initially utilized a different manufacturer. Thus, although the manufacturing service necessarily depends on the license in this contract (that is, the entity would not contract for the manufacturing service without the customer having obtained the license), the license and the manufacturing service do not significantly affect each other. Consequently, the entity concludes that its promises to grant the license and to provide the manufacturing service are distinct and that there are two performance obligations:

- a. License of patent rights
- b. Manufacturing service.

## **Contractual Requirement That the Entity's Customer Must Use the Entity's Services**

### **Question**

In the evaluation of whether a license of intellectual property and contract R&D services (or contract manufacturing services) are separate performance obligations, how should an entity consider a contractual requirement that the entity's customer must use the entity's services?

### **Answer**

A contractual requirement that the entity's customer must use the entity's R&D services (or manufacturing services) does not change the evaluation of whether the promised goods and services are distinct. In accordance with ASC 606-10-55-150F, "[t]his is because the contractual requirement to use the entity's . . . services does not change the characteristics of the goods or services themselves, nor does it change the entity's promises to the customer." Specifically, ASC 606-10-55-64 notes the following:

Contractual provisions that explicitly or implicitly require an entity to transfer control of additional goods or services to a customer (for example, by requiring the entity to transfer control of additional rights to use or rights to access intellectual property that the customer does not already control) should be distinguished from contractual provisions that explicitly or implicitly define the attributes of a single promised license (for example,

restrictions of time, geographical region, or use). Attributes of a promised license define the scope of a customer's right to use or right to access the entity's intellectual property and, therefore, do not define whether the entity satisfies its performance obligation at a point in time or over time and do not create an obligation for the entity to transfer any additional rights to use or access its intellectual property.

Consequently, if the license and the services are otherwise capable of being distinct and separately identifiable, the license and the services would be accounted for as two performance obligations.

## Evaluating Whether a Promised Good or Service Is Immaterial in the Context of the Contract

In April 2016, the FASB issued [ASU 2016-10](#), which states that an entity "is not required to assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer." This guidance should not apply to a customer option to acquire additional goods and services that provides a customer with a material right in accordance with ASC 606-10-55-41 through 55-45.

### Question

How should an entity evaluate whether a promised good or service is immaterial in the context of the contract?

### Answer

ASU 2016-10 added ASC 606-10-25-16A and 25-16B, which provide the following guidance on immaterial promised goods or services:

#### ASC 606-10

**25-16A** An entity is not required to assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer. If the revenue related to a performance obligation that includes goods or services that are immaterial in the context of the contract is recognized before those immaterial goods or services are transferred to the customer, then the related costs to transfer those goods or services shall be accrued.

**25-16B** An entity shall not apply the guidance in paragraph 606-10-25-16A to a customer option to acquire additional goods or services that provides the customer with a material right, in accordance with paragraphs 606-10-55-41 through 55-45.

In light of the ASU's wording, stakeholders have asked about the framework an entity should use to identify a potential good or service that is immaterial in the context of the contract. The following have been considered, both of which we think are relevant to the assessment of whether a good or service is immaterial in the context of the contract:

- An entity may conclude that a potential good or service is immaterial in the context of the contract if the estimated stand-alone selling price of the potential good or service is immaterial (quantitatively) compared with the total consideration in the contract (i.e., the amount that would be allocated to such good or service is immaterial in the context of the contract).
- An entity may conclude that a potential good or service is immaterial in the context of the contract if it determines that the customer does not consider the potential good or service material to the contract (i.e., the entity would evaluate qualitative factors, including the customer's perspective, in determining whether a potential good or service is immaterial in the context of the contract).

In addition, we think that when an entity performs an assessment to identify immaterial promised goods or services, it should also consider the guidance in ASU 2016-10 on customer options (i.e., potential material rights) as well as the SEC staff's view of "material" as discussed in SAB Topic 1.M.



### Thinking It Through

As noted above, the guidance in ASC 606-10-25-16A may not be applied to a customer option to acquire additional goods or services that provides the customer with a material right. For example, life sciences companies may have a practice of providing customers with the ability to purchase 12 weeks of treatment at list price with an option to purchase an additional 12 weeks of treatment at a significantly discounted price if it is determined that the patient is benefiting from the treatment and additional treatment will be helpful. Options that are deemed to represent material rights — and, therefore, a performance obligation — would result in a deferral of revenue associated with that performance obligation.

## Shipping and Handling Activities

Shipping and handling activities are often provided by life sciences entities as part of a revenue arrangement.

### Question

What considerations are relevant to the evaluation of shipping terms and the determination how to account for shipping and handling activities performed by a vendor?

### Answer

It is important to understand the shipping terms of an arrangement to determine when control of the good transfers to the customer. This is because the shipping terms often trigger some of the key control indicators (e.g., transfer of title and present right to payment). Therefore, a careful evaluation of shipping terms in a manner similar to their evaluation under current U.S. GAAP is critical to the assessment of transfer of control. Common shipping terms include FOB shipping point (title transfers to the customer at the entity's shipping dock) and FOB destination (title transfers to the customer at the customer's location).

Current practice, under a risks-and-rewards model, requires a careful evaluation of the entity's involvement during the period of shipment in FOB shipping point fact patterns. That is, when the entity replaces lost or damaged products during shipping even though the shipping terms are FOB shipping point, it is often inappropriate under current guidance to recognize revenue upon shipment because the risks and rewards of ownership did not pass to the customer at the shipping point. Such practice should be reevaluated under the new control-based model. While the fact that the customer has the significant risks and rewards of ownership is an indicator of control, that indicator may be overcome by the other indicators of control. As a result, it may be appropriate to recognize revenue upon shipment when the terms are FOB shipping point, even in instances in which the entity retains the risks associated with loss or damage of the products during shipment.

When FOB shipping point fact patterns are reassessed and control is determined to transfer upon shipment, the seller should consider whether the risk of loss or damage that it assumed during shipping gives rise to another performance obligation (a distinct service-type obligation) that needs to be accounted for separately in accordance with the new revenue standard. For example, such risk may represent another performance obligation if goods are frequently lost or damaged during shipping.

Further, entities should consider the practical expedient under U.S. GAAP (ASC 606-10-25-18B, added by ASU 2016-10) that allows entities the option to treat shipping and handling activities that occur after control of the good transfers to the customer as fulfillment activities. Entities that elect to use this practical expedient would not need to account for the shipping and handling as a separate performance obligation. Instead, when the practical expedient is elected and revenue for the related good is recognized before the shipping and handling activities occur, the entity should accrue the costs of the shipping and handling activities at the time control of the related good is transferred to the customer (i.e., at the time of sale).

ASU 2016-10 also explains that shipping and handling activities performed before control of a product is transferred do not constitute a promised service to the customer in the contract (i.e., they represent fulfillment costs).

### Determine the Transaction Price (Step 3)

In step 3 of the new revenue standard, an entity determines the “transaction price,” which, as stated in ASC 606-10-32-2, represents **“the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both.”** Because the transaction price is an expected amount, estimates are inherently required. When determining the transaction price, an entity is required under ASC 606-10-32-3 to “consider the effects of all of the following”:

- “Variable consideration.”
- “Constraining estimates of variable consideration.”
- “The existence of a significant financing component in the contract.”
- “Noncash consideration.”
- “Consideration payable to a customer.”

The effects of these elements are particularly relevant to life sciences entities, as explained in the Q&As below.

## Variable Consideration

### *Examples of Variable Consideration*

#### *Question*

What are examples of variable consideration in the life sciences industry?

#### *Answer*

ASC 606-10-32-6 explains that variable consideration may arise “because of discounts, rebates, refunds, credits, price concessions, incentives, performance bonuses, penalties, or other similar items” and that the promised consideration can vary “if an entity’s entitlement to the consideration is contingent on the occurrence or nonoccurrence of a future event” (e.g., when “a product [is] sold with a right of return or a fixed amount is promised as a performance bonus on achievement of a specified milestone.” In the life sciences industry, common forms of variable consideration include returns, chargebacks, rebates, cash and volume-based discounts, promotions, shelf stock adjustments, and other adjustments to revenue, as well as royalties, development-based milestones, and sales-based milestones.

## ***Methods of Estimating Variable Consideration***

### ***Question***

Which methods should a life sciences entity use to estimate variable consideration?

### ***Answer***

Regardless of the form of variability or its complexity, once variable consideration is identified, an entity is required under ASC 606-10-32-8 to estimate the amount of variable consideration to determine the transaction price in a contract with a customer by using either the “expected value” method or the “most likely amount” method, “depending on which method the entity expects to better predict the amount of consideration to which it will be entitled.” As ASC 606-10-32-8 explains, the expected value is “the sum of probability-weighted amounts in a range of possible consideration amounts. An expected value may be an appropriate estimate of the amount of variable consideration if an entity has a large number of contracts with similar characteristics.” ASC 606-10-32-8 further states that the most likely amount is “the single most likely amount in a range of possible consideration amounts (that is, the single most likely outcome of the contract).”

In the life sciences industry, it may be appropriate for an entity to estimate development and sales-based milestones by using the most likely amount method since the achievement of a milestone has only two possible outcomes (an entity either achieves the milestone or it does not). Other forms of variable consideration may be estimated under the expected value method. For example, estimates of returns under the expected value method may take into account factors such as the following:

- The period in which returns can occur.
- Experiences with products (or the inability to apply such experiences to current products).
- Availability of information about product levels and the age of the product in the distribution channel.
- Predictability of market conditions and competition (e.g., competitive entry of a similar or generic product).
- The current stage in the product life cycle (i.e., initial product launch vs. end/maturity of product life).
- Historical, current, and projected demand.

In addition to the factors listed above, the following factors may be relevant to the development of estimates of variable consideration in the form of chargebacks and rebates under the expected value method:

- The existence of product-specific historical information about chargebacks and rebates.
- The availability and specificity of customer-specific pricing information (including contractual arrangements with retailers, insurance providers, or governmental agencies).
- Information about the specific retailer and consumer product sales mix (to understand which customer pricing arrangement is applicable).
- The availability and specificity of customer inventory levels.

In applying the expected value method to these types of estimates, life sciences entities are not necessarily expected to develop complex modeling techniques to identify all possible outcomes of variable consideration. Although we think that it is appropriate for an entity to be pragmatic in deriving an estimate by using one of the required methods, we do not think that it is appropriate to use a method described as management's best estimate as either the most likely amount or the expected value of variable consideration. Consequently, entities are encouraged to evaluate their current estimation approaches for variable consideration and document the basis for any conclusion that these approaches align with the estimation methods of ASC 606.

### ***Price Protection Arrangements***

Life sciences entities sometimes enter into price protection arrangements, under which wholesalers are reimbursed for any difference between the current sales price and the lowest price offered during a subsequently specified period (e.g., one year).

#### ***Question***

How should an entity consider the guidance on variable consideration when accounting for price protection arrangements?

#### ***Answer***

Under current U.S. GAAP, the amount of revenue recognized is generally limited to the amount that is not contingent on a future event (i.e., the sales price is "fixed or determinable" and no longer variable). A price protection arrangement may lead a life sciences entity to conclude that the selling price is not fixed or determinable on the date of sale because of the possibility of future price concessions. Consequently, revenue in such an arrangement might not be recognized until reliable estimates can be established or the product is sold through to the end user (i.e., on a sell-through basis).

Under the new revenue standard, an entity must include some or all of an estimate of variable (or contingent) consideration in the transaction price (which is the amount to be allocated to each unit of account and recognized as revenue) when the entity concludes that it is probable that changes in its estimate of such consideration will not result in significant reversals of revenue in subsequent periods. In price protection arrangements, the transaction price would therefore include an estimate of expected price protection determined under either the expected value method or the most likely outcome method (i.e., whichever method the entity expects to better predict the amount of consideration to which it will be entitled), with revenue recognized when control transfers to the distributor.

### ***New Product Launches With a Right of Return***

#### ***Question***

How should an entity consider the guidance on variable consideration when accounting for new product launches that include a right of return?

#### ***Answer***

Under current U.S. GAAP, life sciences entities must be able to make a reasonable estimate regarding future returns to recognize revenue upon shipment of the product. ASC 605-15-25-3 indicates that the ability to make such an estimate depends on many factors and identifies a number of factors that may impair this ability.

Under the new revenue standard, a sale with a right of return is not a separate variable consideration model or — as some have thought about it under current guidance — a “failed” sale model. Rather, the uncertainty associated with whether a product may be returned is treated, for measurement purposes, consistently with the uncertainty associated with other variable consideration. That is, under ASC 606-10-55-25:

An entity should . . . determine the amount of consideration to which the entity expects to be entitled (that is, excluding the products expected to be returned). For any amounts received (or receivable) for which an entity does not expect to be entitled, the entity should not recognize revenue when it transfers products to customers but should recognize those amounts received (or receivable) as a refund liability. Subsequently, at the end of each reporting period, the entity should update its assessment of amounts for which it expects to be entitled in exchange for the transferred products and make a corresponding change to the transaction price and, therefore, in the amount of revenue recognized.

### ***Variable Consideration in Pay-for-Performance Arrangements***

Pay-for-performance arrangements are becoming increasingly more common in the life sciences industry. In these arrangements, a drug manufacturer could be required to reimburse all or a portion of the amounts originally received upon sale of the drug if, after a defined treatment period, a patient does not exhibit certain predetermined objective criteria.

#### ***Question***

How should an entity consider the guidance on variable consideration when accounting for pay-for-performance arrangements?

#### ***Answer***

Under current U.S. GAAP, life sciences entities must be able to reasonably estimate future adjustments to the amounts billed for the product. If the vendor does not have a company-specific historical basis to estimate refunds, revenue should be deferred until the close of the predetermined contingency period.

Under the new revenue standard, pay-for-performance arrangements represent another form of variable consideration. In a manner similar to the accounting in the examples above, a life sciences entity with these types of arrangements must include some or all of an estimate of variable consideration in the transaction price when the entity concludes that it is probable that changes in its estimate of such consideration will not result in significant reversals of cumulative revenue in subsequent periods.

### **Constraining Estimates of Variable Consideration**

Since revenue is one of the most important metrics to users of financial statements, the FASB and IASB and their constituents agreed that estimates of variable consideration are only useful to the extent that an entity is confident that the revenue recognized as a result of those estimates will not be subsequently reversed. Accordingly, as noted in paragraph BC203 of ASU 2014-09, the boards acknowledged that some estimates of variable consideration should not be included in the transaction price if the inherent uncertainty could prevent a faithful depiction of the consideration to which the entity expects to be entitled in exchange for delivering goods or services. Thus, the focus of the boards’ deliberations on a mechanism to improve the usefulness of estimates in revenue as a predictor of future performance was to limit subsequent downward adjustments in revenue (i.e., reversals of revenue recognized). The result of those deliberations is what is commonly referred to as the “constraint.”

ASC 606-10-32-11 and 32-12 describe the constraint and provide guidance on how it should be applied:

#### **ASC 606-10**

**32-11** An entity shall include in the transaction price some or all of an amount of variable consideration estimated in accordance with paragraph 606-10-32-8 only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

**32-12** In assessing whether it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur once the uncertainty related to the variable consideration is subsequently resolved, an entity shall consider both the likelihood and the magnitude of the revenue reversal. Factors that could increase the likelihood or the magnitude of a revenue reversal include, but are not limited to, any of the following:

- a. The amount of consideration is highly susceptible to factors outside the entity's influence. Those factors may include volatility in a market, the judgment or actions of third parties, weather conditions, and a high risk of obsolescence of the promised good or service.
- b. The uncertainty about the amount of consideration is not expected to be resolved for a long period of time.
- c. The entity's experience (or other evidence) with similar types of contracts is limited, or that experience (or other evidence) has limited predictive value.
- d. The entity has a practice of either offering a broad range of price concessions or changing the payment terms and conditions of similar contracts in similar circumstances.
- e. The contract has a large number and broad range of possible consideration amounts.

Importantly, the constraint does not apply to sales- or usage-based royalties derived from the licensing of intellectual property; rather, consideration from such royalties is only recognized as revenue at the later of when the performance obligation is satisfied or when the uncertainty is resolved (e.g., when subsequent sales or usage occurs). See the [Licensing](#) section below for additional discussion.

### ***Factors for Determining Whether to Constrain Estimates of Variable Consideration***

#### ***Question***

What factors may be relevant to a life sciences entity's determination of whether to constrain its estimates of variable consideration?

#### ***Answer***

Inherent in ASC 606-10-32-12 are three key aspects of the assessment necessary to determine whether an estimate of variable consideration in a contract with a customer should be constrained in an entity's transaction price:

- The likelihood of a reversal in the cumulative amount of revenue recognized (i.e., a qualitative aspect).
- The magnitude (or significance) of the potential reversal in the cumulative amount of revenue recognized (i.e., a quantitative aspect).
- The threshold that triggers a constrained estimate (i.e., the use of "probable").

The determination of whether to constrain estimates of variable consideration may require significant judgment depending on the nature of the revenue stream being estimated. For example, it may be unnecessary to constrain revenue on the sale of established pharmaceutical products to wholesalers since variable consideration (e.g., rebates, discounts) may not be highly susceptible to factors outside the entity's influence (e.g., volatility in a market, the judgment or actions of third parties, a high risk of obsolescence), the uncertainty about the amount of consideration may be resolved in a shorter period, the entity may have significant experience with similar types of contracts or with contracts that have predictive value, and the range of price concessions is narrow.

In contrast, it may be necessary to constrain a significant portion of revenue on the sale of IPR&D, a nonfinancial asset, in exchange for future development milestones and royalties and sales-based milestones since the likelihood of reversal in the cumulative amount of revenue recognized could be high and the magnitude of the potential reversal could be significant. The uncertainty associated with revenue related to such a transaction arises from a number of factors:

- Before regulatory approval, uncertainty may arise from potential delays with clinical trials, success of competitor trials, or an inability to obtain regulatory approvals.
- After regulatory approval, uncertainty may arise from product safety concerns, manufacturing issues, potential product recalls, the introduction of competitor products, or possible sales and distribution channel issues.
- Both before and after regulatory approval, the amount of consideration to be received may be highly susceptible to factors outside the entity's influence because success is predicated on the efforts of the party to which the IPR&D was sold.

Although the guidance on constraining estimates of variable consideration is intended to avoid significant downward adjustments in revenue after it has been recognized, we generally do not think that it would be appropriate to constrain 100 percent of an estimate of variable consideration. That is, we do not think that the factors in ASC 606-10-32-12 could be so significant that an estimate of variable consideration should be entirely constrained from the transaction price. This concept is different from a \$0 estimate of variable consideration. A 100 percent constraint on an estimate of variable consideration that is not \$0, however, would generally go against the measurement principle of ASC 606, which is to include in the transaction price the amount to which an entity expects to be entitled for its performance so that the entity can provide financial statement users a better prediction of future revenues.

While the above is a general interpretation, there are exceptions in the new revenue standard that may allow for a 100 percent constraint on an estimate of variable consideration. Example 25 in ASC 606-10-55 discusses an exception in which market-based factors are a significant driver of variability in the transaction price. Also, in paragraph BC415 of ASU 2014-09, the boards discuss their rationale for providing an exception for sales- or usage-based royalties in a license of intellectual property.

## Significant Financing Components

In certain contracts with customers, one party may provide a service of financing (either explicitly or implicitly) to the other. Such contracts effectively contain two transactions: one for the delivery of the good or service and another for the benefit of financing (i.e., what is in substance a loan payable or loan receivable). The FASB and IASB decided that an entity should account for both transactions included in a contract with a customer when the benefit of the financing provided is significant. ASC 606-10-32-15 states the following:

### ASC 606-10

**32-15** In determining the transaction price, an entity shall adjust the promised amount of consideration for the effects of the time value of money if the timing of payments agreed to by the parties to the contract (either explicitly or implicitly) provides the customer or the entity with a significant benefit of financing the transfer of goods or services to the customer. In those circumstances, the contract contains a significant financing component. A significant financing component may exist regardless of whether the promise of financing is explicitly stated in the contract or implied by the payment terms agreed to by the parties to the contract.

In determining the transaction price, an entity adjusts the promised amount of consideration to determine the cash selling price of the good or service to be delivered and reflect the time value of money if the contract has a significant financing component. The direction of the financing component (i.e., whether financing provided to the entity through an advance payment or to the customer through payments in arrears) is irrelevant to the assessment, and as a result of the adjustment to the transaction price, the entity could recognize interest expense or interest income.

However, ASC 606-10-32-18 provides a practical expedient under which an entity does not need to adjust the promised amount of consideration for the effects of a significant financing component “if the entity expects, at contract inception, that the period between when the entity transfers a promised good or service to a customer and when the customer pays for that good or service will be one year or less.”

## ***Factors for Determining Whether a Significant Financing Component Exists***

### ***Question***

What factors may be relevant for life sciences entities to consider in determining whether there is a significant financing component in a contract with a customer?

## Answer

Entities must use judgment in determining whether a significant financing component exists. However, ASC 606-10-32-17 notes that a contract with a customer would not have a significant financing component if certain factors exist. The table below describes the factors of greatest relevance to life sciences entities and examples of arrangements in which these factors may apply.

Factor (ASC 606-10-32-17)	Example
"A substantial amount of the consideration promised by the customer is variable, and the amount or timing of that consideration varies on the basis of the occurrence or nonoccurrence of a future event that is not substantially within the control of the customer or the entity."	Royalty arrangements, in which variability is provided to confirm the value of goods delivered.
"The difference between the promised consideration and the cash selling price of the good or service (as described in [ASC] 606-10-32-16) arises for reasons other than the provision of finance to either the customer or the entity, and the difference between those amounts is proportional to the reason for the difference. For example, the payment terms might provide the entity or the customer with protection from the other party failing to adequately complete some or all of its obligations under the contract."	Customer withholds consideration until the achievement of a certain milestone and to protect against nonperformance.  Customer required to pay up front to secure supply of a good.

## Allocate the Transaction Price to the Performance Obligations (Step 4)

In step 4 of the new revenue standard, an entity allocates the transaction price to each of the identified performance obligations. For a contract containing more than one performance obligation, the allocation is generally performed on the basis of the relative stand-alone selling price of each distinct good or service. However, as discussed in Deloitte's [A Roadmap to Applying the New Revenue Recognition Standard](#), there are exceptions that allow an entity to allocate a disproportionate amount of the transaction price to a specific performance obligation. For example, an entity may allocate a discount to a single performance obligation rather than proportionately to all performance obligations if certain factors indicate that the discount is related to a specific performance obligation.

In many respects, the allocation model under the new revenue standard may be similar to the model under current U.S. GAAP, except for the new revenue standard's elimination of the selling price hierarchy required under current U.S. GAAP. For certain life sciences companies, however, the model may result in differences as a result of the elimination of the "contingent cap" concept. Specifically, under current U.S. GAAP, the allocation of arrangement consideration to delivered items is limited to the amount of revenue that is not contingent on the delivery of future items. The new revenue standard does not include this same contingent cap. As a result, the timing of revenue recognition under the new revenue standard may be accelerated as compared with its timing under current U.S. GAAP.

### Example

A medical device company sells infusion pumps and intravenous solutions (consumables). In accordance with the company's contracts with customers, title to the pumps is transferred to the customer for free when the pumps are sold in conjunction with a minimum commitment for the purchase of consumables. Assume that the pumps and solutions are considered separate performance obligations.

Under current U.S. GAAP, because the consideration to be received for one of the deliverables in the arrangement (i.e., equipment) is contingent on the sale of other deliverables in the arrangement (i.e., consumables), the medical device company should only recognize revenue for the delivered element up to the amount of consideration that is not contingent on the future sales. In this case, because the pump is provided to the customer for free and all of the consideration from the arrangement is contingent on the sale of disposables, the company would not recognize revenue when the pump is delivered to the customer. Under the new revenue standard, however, the company would estimate the amount of consideration to which it expects to be entitled and allocate the consideration on a relative stand-alone selling price basis to each separate performance obligation.

## Determine When to Recognize Revenue (Step 5)

In a manner consistent with the core principle of the new revenue standard — “an entity shall recognize **revenue to depict the transfer of promised goods or services to customers** in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services” (emphasis added) — step 5 focuses on recognition (i.e., **when** it is appropriate to recognize revenue).

The new standard requires an entity first to determine, at contract inception, whether control of a good or service is transferred over time; if so, the entity would recognize the related revenue over time in a manner consistent with the transfer of the good or service over time to the customer. This method is similar to the percentage-of-completion and proportional-performance methods in current practice. If the entity cannot conclude that control is transferred over time, control is considered to be transferred at a point in time. As a result, the entity must determine at what specific point in time to recognize the related revenue. While generally speaking, goods are transferred at a point in time and services are transferred over time, this is not the case in all circumstances. Some of the more common questions that life sciences entities have faced when considering step 5 are described below.

## Determining Whether to Recognize Revenue Over Time or at a Point in Time

### *Question*

Contract manufacturing is common in the life sciences industry. Should entities that are delivering goods (e.g., contract manufacturers and other customer manufacturing arrangements) recognize revenue over time or at a particular point in time?

### *Answer*

It depends. Entities should carefully analyze the contractual arrangement in accordance with the three criteria in ASC 606-10-25-27 to determine whether the promise in the contract to construct and transfer goods to the customer is a performance obligation that will be satisfied over time or at a point in time.

If an entity's obligation to produce a customized product meets one of the criteria in ASC 606-10-25-27 for revenue recognition over time (e.g., the entity's performance does not create an asset with an alternative use, and the entity has an enforceable right to payment for performance completed to date), revenue related to that product would be recognized as the product is produced, not when the product is delivered to the customer.

For example, an entity that has a contract with an original equipment manufacturer (OEM) to produce a customized part for the OEM's product would meet the criteria for revenue recognition over time if the customized part has no alternative use other than as a part for the OEM's product and, as stated in ASC 606-10-25-29, the entity has an enforceable right to payment for performance completed to date "at all times throughout the duration of the contract." ASC 606-10-25-28 and 25-29 as well as ASC 606-10-55-8 through 55-15 provide detailed guidance on whether an asset has an alternative use to the entity and whether an entity has an enforceable right to payment for performance completed to date. An entity would need to carefully analyze the contractual arrangements and the specific facts and circumstances to determine whether those criteria are met.

If the entity concludes that revenue should be recognized over time, it would then be required to select a method of recognizing revenue over time that most faithfully depicts the entity's performance to date for producing the product. Therefore, contract revenue should be recognized as revenue when the entity performs (i.e., the products are produced) rather than when the products are delivered to the customer.

### **Selecting a Measure of Progress Toward Complete Satisfaction of a Performance Obligation**

When a performance obligation is satisfied over time, an entity must select a measure of progress (e.g., time elapsed, labor hours, costs incurred) to depict its progress toward complete satisfaction of that obligation.

In accordance with ASC 606-10-25-33, appropriate methods of measuring progress include:

- *Output methods* — ASC 606-10-55-17 states that output methods "recognize revenue on the basis of direct measurements of the value to the customer of the goods or services transferred to date relative to the remaining goods or services promised under the contract." These methods "include surveys of performance completed to date, appraisals of results achieved, milestones reached, time elapsed, and units produced or units delivered."
- *Input methods* — ASC 606-10-55-20 states that input methods "recognize revenue on the basis of the entity's efforts or inputs to the satisfaction of a performance obligation (for example, resources consumed, labor hours expended, costs incurred, time elapsed, or machine hours used) relative to the total expected inputs to the satisfaction of that performance obligation."

In discussing the selection of a measure of progress, paragraph BC164 of ASU 2014-09 states:

The [FASB and IASB] decided that, conceptually, an output measure is the most faithful depiction of an entity's performance because it directly measures the value of the goods or services transferred to the customer. However, the Boards observed that it would be appropriate for an entity to use an input method if that method would be less costly and would provide a reasonable proxy for measuring progress.

Many contract research organizations (CROs) recognize revenue over time by using either input or output methods under current U.S. GAAP.

### **Question**

Does the statement in paragraph BC164 of ASU 2014-09 mean that it is preferable for an entity to use an output method when measuring progress toward complete satisfaction of a performance obligation?

## **Answer**

No. As stated in paragraph BC159 of ASU 2014-09, an entity does not have a free choice in selecting an appropriate method of measuring progress toward complete satisfaction of a performance obligation but should exercise judgment in identifying a method that fulfills the stated objective in ASC 606-10-25-31 of depicting an entity's performance in transferring control of goods or services promised to a customer (i.e., the satisfaction of the performance obligation).

Neither an input method nor an output method is preferred since each has benefits and disadvantages that will make it more or less appropriate to the facts and circumstances of each contract. While an output method is, as stated in paragraph BC164 of ASU 2014-09, conceptually preferable in a general sense, an appropriate measure of output will not always be directly observable; and sometimes, an apparent measure of output will not in fact provide an appropriate measure of an entity's performance. Information needed to apply an input method is more likely to be available to an entity without undue cost, but care should be taken to ensure that any measure of an entity's inputs used is reflective of the transfer of control of goods or services to the customer.

Considerations that may be relevant to the selection of a measure of progress include the following:

- An output method would not provide a faithful depiction of the entity's performance if the output selected fails to measure some of the goods or services transferred to the customer. For example, a units-of-delivery or a units-of-production method may sometimes understate an entity's performance by excluding work in progress that is controlled by the customer. (See paragraph BC167 of ASU 2014-09.)
- An input method may better reflect progress toward complete satisfaction of a performance obligation over time when (1) the performance obligation consists of a series of distinct goods or services that meets the criteria in ASC 606-10-25-14(b) to be treated as a single performance obligation and (2) the effort required to create and deliver the first units is greater than the effort to create the subsequent units because of the effect of a "learning curve" of efficiencies realized over time. (See paragraph BC314 of ASU 2014-09.)
- An entity applying an input method must exclude from its measure of progress the costs incurred that (1) do not contribute to the entity's progress in satisfying a performance obligation (e.g., the costs of unexpected amounts of wasted materials) and (2) are not proportionate to the entity's progress in satisfying the performance obligation (e.g., the cost of obtaining goods from a vendor that accounts for most of the product's cost). (See ASC 606-10-55-21.) For example, in the life sciences industry, CROs often incur "pass-through costs" related to payments made to investigators (physicians) who participate in the clinical studies being conducted. A CRO should carefully consider whether such costs are proportionate to the CRO's progress in satisfying its performance obligation(s) before including those costs in its measure of progress.

## **Multiple Measures of Progress Toward Complete Satisfaction of a Performance Obligation**

CROs often provide multiple services for their customers (pharmaceutical and biotechnology entities). For example, CROs may help design studies, recruit investigators (physicians), recruit patients, help manage clinical trials, monitor safety, and write reports on study results.

Assume that a CRO concludes that its contract with a biotechnology customer contains a single performance obligation (i.e., in the context of the contract, the various services to be performed are not separable) and that the CRO concludes that the performance obligation is satisfied over time. Consequently, the CRO is required to identify an appropriate measure to depict progress toward complete satisfaction of its performance obligation (see ASC 606-10-25-31 through 25-37).

### **Question**

When a single performance obligation satisfied over time consists of multiple promised goods or services, or both, can multiple measures of progress be used to depict an entity's progress toward complete satisfaction of that performance obligation?

### **Answer**

No. ASC 606-10-25-32 states that an entity should apply a single measure of progress for each performance obligation. This applies even when that single performance obligation is made up of a number of goods or services.

Selecting a measure of progress may be challenging when a single performance obligation contains multiple goods or services or has multiple payment streams. Regardless of the number of goods, services, or payment streams in a performance obligation, an entity is required to identify a single measure of progress that appropriately depicts its progress toward complete satisfaction of the performance obligation.

### **Licensing**

Under the new revenue standard, the framework used to account for licensing of intellectual property is essentially the same as the framework used to account for a sale of goods or services. That is, the five-step model is generally applied to licensing transactions as well. However, licensing of intellectual property can take many forms, and the economics and substance of such transactions can often be difficult to identify. Determining how to account for licensing transactions will often depend on the specific facts and circumstances and will require the exercise of professional judgment. To help preparers exercise such judgment, the new revenue standard provides supplemental guidance on recognizing revenue from contracts related to the licensing of intellectual property to customers. The scope of the guidance includes all licenses that provide a customer with rights to intellectual property, except for certain software hosting arrangements.

In the evaluation of how to account for a licensing transaction under the new revenue standard, it is important for an entity to consider each of the five steps in the model (although, as discussed below, certain exceptions are provided for licensing transactions). Specifically, an entity will need to do each of the following:

- *Step 1: Identify the contract with the customer* — This step includes evaluating the enforceable rights and obligations (including implicit rights) of each party to the contract and determining whether amounts under the contract are collectible.
- *Step 2: Identify the performance obligation under the contract* — This includes determining whether the entity's obligation to transfer a license to a customer results in (1) a single promise that will be satisfied (i.e., a single performance obligation) or (2) multiple performance obligations. This step could also involve determining whether the license of intellectual property is the predominant element in the arrangement.

- *Step 3: Determine the transaction price* — This includes identifying and, potentially, measuring and constraining variable consideration.
- *Step 4: Allocate the transaction price* — This includes considering whether the residual method could be used for determining the stand-alone selling price of one (or a bundle) of the performance obligations.
- *Step 5: Determining when control of the license is transferred to the customer* — This includes determining whether the license is transferred at a point in time (for a right to use intellectual property) or over time (for a right to access intellectual property).

Some of the key judgments an entity will need to make are likely to be in connection with step 2 (identify the performance obligations) and step 5 (recognize revenue) of the model. As part of step 2, an entity will need to evaluate license restrictions (and changes in any such restrictions) when determining whether the restrictions merely define the licenses (which may be the case when the restrictions are related to time or geography) or, in effect, give rise to multiple performance obligations (which may be the case when the restrictions change over the license period and require the entity to transfer additional rights to the customer).

As part of step 5, when an entity is determining whether it has granted a customer a right to use or a right to access its intellectual property, it will need to (1) assess the nature of the promised license to determine whether the license has significant stand-alone functionality and (2) evaluate whether such functionality can be retained without ongoing activities of the entity. For licenses with significant stand-alone functionality, ongoing activities of the entity providing the license do not significantly affect the license's functionality (i.e., its utility). However, certain licenses do not have significant stand-alone functionality and require ongoing activities from the entity to support or maintain the license's utility to the customer. The nature of an entity's license of intellectual property will determine the pattern of transfer of control to the customer, which is either at a point in time (if the customer is granted a right to use the intellectual property) or over time (if the customer is granted a right to access the intellectual property).

For licensing transactions in which consideration is tied to the subsequent sale or usage of intellectual property, the new revenue standard provides an exception to the recognition principle that is part of step 5 (i.e., recognize revenue when or as control of the goods or services is transferred to the customer). Under this sales- or usage-based royalty exception, an entity would not estimate the variable consideration from sales- or usage-based royalties. Instead, ASC 606-10-55-65 requires an entity to recognize revenue associated with a sales- or usage-based royalty promised in exchange for a license of intellectual property when (or as) the later of the following events occurs:

- a. The subsequent sale or usage occurs.
- b. The performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

Some of the more common questions that life sciences entities have faced when considering the licensing guidance of the new revenue standard are discussed below.

## **Determining Whether the Sales- or Usage-Based Royalty Exception Applies to an In-Substance Sale of Intellectual Property**

### ***Question***

An entity may license intellectual property to a customer under an arrangement that gives the customer exclusive use of the intellectual property for a period that is substantially the same as the intellectual property's useful life. Is this type of arrangement within the scope of (1) the licensing implementation guidance in ASC 606-10-55-54 through 55-65B or (2) the general recognition and measurement model in the new revenue standard, which could result in a different pattern of revenue recognition? Specifically, does the sales- or usage-based royalty exception apply to an in-substance sale of intellectual property?

### ***Answer***

The FASB considered, but rejected, expanding the scope of the royalty recognition constraint because of complexities in legal differences between a sale of intellectual property and a license of intellectual property. We generally believe that the legal form of the transaction will determine which revenue accounting guidance (i.e., the guidance on estimating royalties or the guidance on applying the royalty recognition constraint) is applicable.

## **Distinguishing Between an Attribute of a License and an Additional Promise**

A contract with a customer may contain provisions that limit the customer's use of a license of intellectual property to a specific period, a specific geographical region, or a specific use. For example, an entity may license drug distribution rights to a customer that can be (1) used for three years, (2) made available only to consumers in North America, and (3) used only for a specific drug indication. Often, such restrictions will be attributes of the license. That is, the restrictions will define the rights the customer has under the license. However, some restrictions, or changes in restrictions over time, will require an entity to transfer additional rights to a customer. Specifically, the amendments in ASU 2016-10 clarify that (1) certain contractual provisions indicate that an entity has promised to transfer additional rights (i.e., an additional license) to a customer and (2) promises to transfer additional rights should be accounted for as separate performance obligations.

### ***Question***

How should a life sciences entity determine whether contractual provisions represent an attribute of a license or an additional promise?

### ***Answer***

The determination of whether contractual provisions related to a license of intellectual property represent an additional promise may require significant judgment. Contractual provisions (restrictions) that define the scope of a license of intellectual property that has already been transferred to a customer would generally not be accounted for as a separate performance obligation. For example, a restriction that limits the use of a license to a five-year period would be an attribute of the single license. However, contractual provisions that define additional rights that will be transferred at a future date would generally be accounted for as a separate performance obligation, as illustrated in the example below.

### **Example**

An entity transfers to a customer a two-year license of intellectual property that can be used only in Jurisdiction A during year 1 but can be used in both Jurisdiction A and Jurisdiction B during year 2. In this example, the customer does not obtain control of the license in Jurisdiction B until year 2. That is, in year 2, the entity must transfer additional rights that entitle the customer to use the license in Jurisdiction B. Although the entity transfers the license to use the intellectual property in Jurisdiction A at the beginning of year 1, the entity must still fulfill a second promise to deliver the license to use the intellectual property in Jurisdiction B in year 2. Although the license of intellectual property obtained by the customer in year 1 may be the same license of intellectual property that will be used in year 2 (i.e., the customer currently controls the right to use or access the intellectual property), the customer is precluded from using and benefiting from that license in Jurisdiction B until year 2. The obligation to transfer additional rights to the customer at the beginning of year 2 should be identified as an additional performance obligation under the contract with the customer.

### **Functional Versus Symbolic Intellectual Property**

In determining whether to recognize revenue from a license of intellectual property over time or at a point in time, an entity needs to determine the nature of the licensing arrangement. The nature of the arrangement is determined on the basis of the entity's promise to the customer and whether that promise (1) provides access to the intellectual property throughout the license term (i.e., "right to access") or (2) provides a right to use the intellectual property as it exists at the point in time when control of the license is transferred to the customer (i.e., "right to use"). Revenue from a license that grants a right to access an entity's intellectual property is recognized over time since the customer simultaneously receives and consumes the benefits of the entity's intellectual property throughout the license periods (i.e., meets the requirement in ASC 606-10-25-27(a)). Revenue from a license that grants a right to use an entity's intellectual property is recognized at the point in time when control of the license is transferred to the customer.

To assist in the evaluation of whether the license provides the customer with a right to access or right to use the entity's intellectual property, the new revenue standard distinguishes between two types of intellectual property: (1) functional and (2) symbolic.

### **Question**

In the life sciences industry, are most licenses of intellectual property of a functional or symbolic nature? What impact does the nature of a license have on the timing of revenue recognition?

### **Answer**

Examples of licenses of functional intellectual property could include software, drug compounds and formulas, and completed media content. In accordance with ASC 606-10-55-62, the nature of a license to functional intellectual property that is distinct will provide a customer with the right to use an entity's intellectual property (i.e., point-in-time revenue recognition) unless (1) the entity's ongoing activities that will not transfer promised goods to the customer (i.e., those not deemed to be additional promised goods to the customer) will significantly change the utility of the license and (2) the customer is contractually or practically required to use the updated intellectual property once available. If these criteria are met, the nature of the license is a right to access the entity's intellectual property (i.e., a license for which revenue is recognized over time). As discussed in paragraph BC58 of ASU 2016-10, the FASB expected that at the time of issuance of ASU 2016-10, the criteria in ASC 606-10-55-62 "will be met only infrequently, if at all." Consequently, revenue from a license of drug compounds and

formulas that represents a distinct performance obligation would generally represent a right to use an entity's intellectual property and would be recognized at the point in time when control of the license is transferred to the customer.

## **Considerations for Determining Whether a License Is Predominant**

Under the sales- or usage-based royalty exception to the new revenue standard's general rule requiring an entity to include variable consideration in the transaction price, if an entity is entitled to consideration in the form of a sales- or usage-based royalty, revenue is not recognized until (1) the underlying sales or usage has occurred and (2) the related performance obligation has been satisfied (or partially satisfied). That is, an entity is not required to estimate the amount of a sales- or usage-based royalty at contract inception; rather, revenue would be recognized as the subsequent sales or usage occurs (assuming that the associated performance obligation has been satisfied or partially satisfied).

As explained in ASC 606-10-55-65A, the sales- or usage-based royalty exception applies "when the royalty relates only to a license of intellectual property or when a license of intellectual property is the **predominant** item to which the royalty relates (for example, the license of intellectual property may be the predominant item to which the royalty relates when the entity has a reasonable expectation that the customer would ascribe significantly more value to the license than to the other goods or services to which the royalty relates)" (emphasis added).

In the life sciences industry, licenses are often included with R&D services, manufacturing services, or both, with consideration in the form of a sales-based royalty. When the license and the services do not qualify as separate performance obligations, an entity will need to use significant judgment to assess whether the intellectual property license is "the predominant item to which the royalty relates."

### **Question**

What factors should a life sciences entity consider in determining whether a license is predominant and therefore subject to the sales- or usage-based royalty exception?

### **Answer**

The new revenue standard does not define "predominant." However, the standard notes that the license may be predominant "when the entity has a reasonable expectation that the customer would ascribe significantly more value to the license than to the other goods or services to which the royalty relates." Consequently, life sciences entities should consider the customer's perspective of value and the relative importance and value of the promised goods or services. Since different interpretations may arise in practice and the consequences of these differences could be significant to the timing of revenue recognition, entities are encouraged to contemporaneously document the basis for their conclusion on whether the license, rather than the other services, is predominant.

## **Applicability of the Sales- or Usage-Based Royalty Exception to Sales-Based Milestones, Development-Based Milestones, or Guaranteed Minimum Royalties**

### ***Question***

Is the sales- or usage-based royalty exception applicable to sales-based milestones, development-based milestones, or guaranteed minimum royalties?

### ***Answer***

The sales- or usage-based royalty exception would apply to sales-based milestones as the payment becomes due on the basis of the customer's subsequent sales. However, the exception cannot be applied to development-based milestone payments because these payments are not contingent on the customer's sales. In addition, the exception cannot be applied to guaranteed minimum royalties because those payments are essentially fixed consideration. However, the exception would apply to any variable consideration that exceeds the fixed (guaranteed minimum) portion.

## **Application of the Sales- or Usage-Based Royalty Exception to a Variable Royalty Arrangement With Declining Royalties**

An entity may enter into a contract with a customer in which the parties agree to a variable royalty arrangement with declining royalties. Consider the example below.

### ***Example***

An entity enters into a contract to provide a customer with a noncancelable license to the entity's intellectual property. The entity determines that the license is a right-to-use license (i.e., a license for which revenue is recognized at a point in time) for a three-year period. The customer's estimated sales are expected to be approximately equal for each of the three years under license. For the use of the intellectual property, the agreement requires the customer to pay the entity a royalty of 10 percent of the customer's sales in year 1, 8 percent of the customer's sales in year 2, and 6 percent of the customer's sales in year 3.

### ***Question***

In the example above, should the entity account for the royalty payments by using the general model, which requires estimates of variable consideration?

### ***Answer***

No. The entity should account for the royalty payments in a manner consistent with the legal form of the arrangement and in accordance with the exception to the variable consideration guidance for licenses of intellectual property that include a sales- or usage-based royalty. Consequently, the entity would include the royalties in the transaction price on the basis of the applicable contractual rate and the customer's sales in each year and then, in accordance with ASC 606-10-55-65, recognize revenue at the later of when (1) the "subsequent sale or usage occurs" or (2) the "performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied)."

## Transition Methods

Entities have the option of using either a full retrospective or modified retrospective method to adopt the guidance in the new revenue standard:

- *Full retrospective application* — Retrospective application would take into account the requirements in ASC 250 (with certain practical expedients).
- *Modified retrospective application* — ASC 606-10-65-1(h) states that under the modified retrospective method, an entity recognizes “the cumulative effect of initially applying [ASU 2014-09] as an adjustment to the opening balance of retained earnings . . . of the annual reporting period that includes the date of initial application” (revenue in periods presented in the financial statements before that date is reported under guidance in effect before the change). When using this method, an entity applies the guidance in the ASU (as amended by ASU 2016-12) to either of the following:
  - Incomplete contracts (i.e., those contracts for which all (or substantially all) of the revenue has not been recognized in accordance with prior revenue guidance) as of the date of initial application.
  - All contracts as of, and new contracts after, the date of initial application.

Entities should carefully evaluate the respective advantages and disadvantages of each of the transition methods before selecting their method of adopting the ASU. The transparent trend information provided under the full retrospective method may be most effective for entities that expect to experience a significant change. Also, entities that have significant deferred revenue balances may prefer a full retrospective method to ensure that such revenue is not “lost” from operations by its recognition as a cumulative-effect adjustment to retained earnings. However, the full retrospective method will require a significant effort since the adjustments to prior reported results will change not only the revenue recognized but also the other “direct effects of a change” as defined in ASC 250.

### Question

In the evaluation of the transition approach to use, are there any considerations that may be unique to life sciences entities?

### Answer

As previously noted, collaborative arrangements are common in the life sciences industry, and many entities apply revenue literature directly or by analogy in the accounting for these arrangements. As life sciences entities with such collaborative arrangements evaluate which transition approach to use, they may need to consider the transition approach elected by their collaborative partners to ensure that the necessary information will be available to restate prior periods (if the full retrospective approach is used) or determine the cumulative-effect adjustment (if the modified retrospective approach is used).

In addition, life sciences entities should work with their collaboration partners to ensure that the parties are appropriately compensated for any changes in historical profit arising from differences in the amounts of revenue and costs from those previously reported. For any such changes in contractual cash flows that arise from these differences, entities are reminded that ASC 250-10-45-8 requires such “indirect effects” of changes in accounting principle to be reported in the period in which the accounting change is made (i.e., indirect effects are not included in the retrospective application).

## On the Horizon — Targeted Improvements to the Guidance in ASC 808 on Collaborative Arrangements

### Background

While ASC 808 defines collaborative arrangements and provides guidance on income statement presentation, classification, and disclosures related to such arrangements, it does not address recognition and measurement matters, such as (1) determining the appropriate unit of accounting or (2) when the recognition criteria are met.

Because of these omissions, stakeholders, including representatives from the life sciences industry, have informed the FASB that there are questions in practice about the accounting for transactions between participants in a collaborative arrangement. These stakeholders have observed that entities currently apply different approaches to account for collaborative arrangements, with some entities applying the revenue guidance to some or all elements of the arrangement and other entities establishing accounting policies for the recognition and measurement of transactions between participants, which may or may not be consistent with the revenue guidance.

As a result of the diversity in practice and the uncertainty about the accounting model that applies to these arrangements, the Board commenced a project in November 2016 that is aimed at making targeted improvements to clarify when transactions between partners in a collaborative arrangement are within the scope of the revenue guidance.

### Next Steps

The FASB staff will perform research on potential solutions to be presented to the Board during initial deliberations.

# Appendix A — Glossary of Standards and Other Literature

The standards and other literature below were cited or linked to in this publication.

## AICPA Literature

Accounting and Valuation Guide *Assets Acquired to Be Used in Research and Development Activities*

## FASB Accounting Standards Updates

ASU 2017-05, *Other Income — Gains and Losses From the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets*

ASU 2017-04, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*

ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*

ASU 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue From Contracts With Customers*

ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash — a consensus of the FASB Emerging Issues Task Force*

ASU 2016-17, *Consolidation (Topic 810): Interests Held Through Related Parties That Are Under Common Control*

ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*

ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments — a consensus of the Emerging Issues Task Force*

ASU 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*

ASU 2016-12, *Revenue From Contracts With Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*

ASU 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting*

ASU 2016-10, *Revenue From Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing*

ASU 2016-09, *Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*

ASU 2016-08, *Revenue From Contracts With Customers (Topic 606): Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net)*

ASU 2016-07, *Investments — Equity Method and Joint Ventures (Topic 323): Simplifying the Transition to the Equity Method of Accounting*

ASU 2016-03, *Intangibles — Goodwill and Other (Topic 350), Business Combinations (Topic 805), Consolidation (Topic 810), Derivatives and Hedging (Topic 815): Effective Date and Transition Guidance — a consensus of the Private Company Council*

ASU 2016-02, *Leases (Topic 842)*

ASU 2016-01, *Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*

ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*

ASU 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments*

ASU 2015-14, *Revenue From Contracts With Customers (Topic 606): Deferral of the Effective Date*

ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*

ASU 2015-02, *Consolidation (Topic 810): Amendments to the Consolidation Analysis*

ASU 2014-18, *Business Combinations (Topic 805): Accounting for Identifiable Intangible Assets in a Business Combination — a consensus of the Private Company Council*

ASU 2014-16, *Derivatives and Hedging (Topic 815): Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity — a consensus of the FASB Emerging Issues Task Force*

ASU 2014-15, *Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern*

ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*

ASU 2014-09, *Revenue From Contracts With Customers (Topic 606)*

ASU 2014-08, *Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity*

ASU 2014-07, *Consolidation (Topic 810): Applying Variable Interest Entities Guidance to Common Control Leasing Arrangements — a consensus of the Private Company Council*

ASU 2014-03, *Derivatives and Hedging (Topic 815): Accounting for Certain Receive-Variable, Pay-Fixed Interest Rate Swaps — Simplified Hedge Accounting Approach — a consensus of the Private Company Council*

ASU 2014-02, *Intangibles — Goodwill and Other (Topic 350): Accounting for Goodwill — a consensus of the Private Company Council*

ASU 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements — a consensus of the FASB Emerging Issues Task Force*

## **FASB ASC Topics and Subtopics**

*ASC 205, Presentation of Financial Statements*

*ASC 205-20, Presentation of Financial Statements: Discontinued Operations*

*ASC 230, Statement of Cash Flows*

*ASC 230-10, Statement of Cash Flows: Overall*

*ASC 235, Notes to Financial Statements*

*ASC 250, Accounting Changes and Error Corrections*

*ASC 250-10, Accounting Changes and Error Corrections: Overall*

*ASC 280-10, Segment Reporting: Overall*

*ASC 320, Investments — Debt and Equity Securities*

*ASC 321-10, Investments — Equity Securities: Overall*

*ASC 323-10, Investments — Equity Method and Joint Ventures: Overall*

*ASC 325-10, Investments — Other: Overall*

*ASC 325-40, Investments — Other: Beneficial Interests in Securitized Financial Assets*

*ASC 326-20, Financial Instruments — Credit Losses: Measured at Amortized Cost*

*ASC 326-30, Financial Instruments — Credit Losses: Available-for-Sale Debt Securities*

*ASC 330, Inventory*

*ASC 330-10, Inventory: Overall*

*ASC 350, Intangibles — Goodwill and Other*

*ASC 350-30, Intangibles — Goodwill and Other: General Intangibles Other Than Goodwill*

*ASC 360-10, Property, Plant, and Equipment: Overall*

*ASC 450, Contingencies*

*ASC 450-10, Contingencies: Overall*

*ASC 450-20, Contingencies: Loss Contingencies*

*ASC 450-30, Contingencies: Gain Contingencies*

*ASC 470-10, Debt: Overall*

*ASC 470-20, Debt: Debt With Conversion and Other Options*

*ASC 480-10, Distinguishing Liabilities From Equity: Overall*

*ASC 605, Revenue Recognition*

*ASC 605-10, Revenue Recognition: Overall*

*ASC 605-15, Revenue Recognition: Products*

*ASC 605-25, Revenue Recognition: Multiple-Element Arrangements*

*ASC 605-28, Revenue Recognition: Milestone Method*

*ASC 605-45, Revenue Recognition: Principal Agent Considerations*

*ASC 605-50, Revenue Recognition: Customer Payments and Incentives*

*ASC 606, Revenue From Contracts With Customers*

*ASC 606-10, Revenue From Contracts With Customers: Overall*

*ASC 610-20, Other Income: Gains and Losses From the Derecognition of Nonfinancial Assets*

*ASC 730, Research and Development*

*ASC 730-10, Research and Development: Overall*

*ASC 730-20, Research and Development: Research and Development Arrangements*

*ASC 740, Income Taxes*

*ASC 740-10, Income Taxes: Overall*

*ASC 740-270, Income Taxes: Interim Reporting*

*ASC 805, Business Combinations*

*ASC 805-10, Business Combinations: Overall*

*ASC 805-20, Business Combinations: Identifiable Assets and Liabilities, and Any Noncontrolling Interest*

*ASC 805-30, Business Combinations: Goodwill or Gain From Bargain Purchase, Including Consideration Transferred*

*ASC 805-50, Business Combinations: Related Issues*

*ASC 808, Collaborative Arrangements*

*ASC 808-10, Collaborative Arrangements: Overall*

*ASC 810, Consolidation*

*ASC 810-10, Consolidation: Overall*

*ASC 810-20, Consolidation: Control of Partnerships and Similar Entities*

*ASC 810-30, Consolidation: Research and Development Arrangements*

*ASC 815, Derivatives and Hedging*

ASC 820, *Fair Value Measurement*

ASC 825, *Financial Instruments*

ASC 840, *Leases*

ASC 842, *Leases*

ASC 915, *Development Stage Entities*

ASC 915-10, *Development Stage Entities: Overall*

ASC 985-605, *Software: Revenue Recognition*

## **FASB Proposed Accounting Standards Updates**

Proposed ASU 2017-200, *Debt (Topic 470): Simplifying the Classification of Debt in a Classified Balance Sheet (Current Versus Noncurrent)*

Proposed ASU 2017-210, *Inventory (Topic 330): Disclosure Framework — Changes to the Disclosure Requirements for Inventory*

Proposed ASU 2016-270, *Income Taxes (Topic 740) Disclosure Framework — Changes to the Disclosure Requirements for Income Taxes*

Proposed ASU 2015-340, *Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance*

Proposed ASU 2015-310, *Notes to Financial Statements (Topic 235): Assessing Whether Disclosures Are Material*

## **Other FASB Proposal**

Proposed Concepts Statement 2014-200, *Conceptual Framework for Financial Reporting: Chapter 8: Notes to Financial Statements*

## **FASB Statements (Pre-Codification Literature)**

Statement No. 167, *Amendments to FASB Interpretation No. 46(R)*

Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51*

Statement No. 141(R), *Business Combinations*

## **FASB Interpretation (Pre-Codification Literature)**

FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities*

## **FASB Concepts Statements**

No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises*

No. 6, *Elements of Financial Statements*

## **EITF Issues**

Issue 09-4, "Seller Accounting for Contingent Consideration"

Issue 08-1, "Revenue Arrangements With Multiple Deliverables"

Issue 04-5, "Determining Whether a General Partner, or the General Partners as a Group, Controls a Limited Partnership or Similar Entity When the Limited Partners Have Certain Rights"

Issue 01-8, "Determining Whether an Arrangement Contains a Lease"

Issue 00-21, "Revenue Arrangements With Multiple Deliverables"

## **SEC C&DI Topic**

Non-GAAP Financial Measures

## **SEC Regulation G**

"Conditions for Use of Non-GAAP Financial Measures"

## **SEC Regulation S-K**

Item 10(e), "General; Use of Non-GAAP Financial Measures in Commission Filings"

Item 601(b)(10), "Exhibits; Description of Exhibits; Material Contracts"

## **SEC Regulation S-X**

Rule 3-05, "Financial Statements of Businesses Acquired or to Be Acquired"

Rule 4-08(h), "General Notes to Financial Statements; Income Tax Expense"

Article 11, "Pro Forma Financial Information"

## **SEC Staff Accounting Bulletin**

SAB Topic 1.M, "Financial Statements; Materiality"

SAB Topic 13, "Revenue Recognition"

SAB Topic 13.A.4, "Revenue Recognition; Selected Revenue Recognition Issues; Fixed or Determinable Sales Price"

## **International Standards**

IFRS 15, *Revenue From Contracts With Customers*

IFRS 11, *Joint Arrangements*

IFRS 3, *Business Combinations*

IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*

IAS 17, *Leases*

## Appendix B — Abbreviations

Abbreviation	Description
<b>AFS</b>	available for sale
<b>AICPA</b>	American Institute of Certified Public Accountants
<b>ANDA</b>	abbreviated new drug application
<b>API</b>	active pharmaceutical ingredient
<b>APIC</b>	additional paid-in capital
<b>ASC</b>	FASB Accounting Standards Codification
<b>ASU</b>	FASB Accounting Standards Update
<b>BOLI</b>	bank-owned life insurance
<b>C&amp;DI</b>	SEC Compliance and Disclosure Interpretation
<b>CECL</b>	current expected credit loss
<b>CODM</b>	chief operating decision maker
<b>COLI</b>	corporate-owned life insurance
<b>CRO</b>	contract research organization
<b>DCP</b>	disclosure control procedure
<b>DTA</b>	deferred tax asset
<b>DTL</b>	deferred tax liability
<b>EBITDA</b>	earnings before interest, taxes, depreciation, and amortization
<b>EITF</b>	Emerging Issues Task Force
<b>EPS</b>	earnings per share
<b>EU</b>	European Union
<b>FAQ</b>	frequently asked question
<b>FASB</b>	Financial Accounting Standards Board
<b>FDA</b>	Food and Drug Administration
<b>FIFO</b>	first in, first out

Abbreviation	Description
<b>FIN</b>	FASB Interpretation Number (superseded)
<b>FOB</b>	free on board
<b>GAAP</b>	generally accepted accounting principles
<b>IAS</b>	International Accounting Standard
<b>IASB</b>	International Accounting Standards Board
<b>IFRS</b>	International Financial Reporting Standard
<b>IIR</b>	investigator-initiated research
<b>IPR&amp;D</b>	in-process research and development
<b>LIFO</b>	last in, first out
<b>LLC</b>	limited liability company
<b>LP</b>	limited partnership
<b>M&amp;A</b>	merger and acquisition
<b>MD&amp;A</b>	Management's Discussion and Analysis
<b>MDET</b>	medical device excise tax
<b>MSL</b>	medical science liaison
<b>NDA</b>	new drug application
<b>OCI</b>	other comprehensive income
<b>OEM</b>	original equipment manufacturer
<b>PCAOB</b>	Public Company Accounting Oversight Board
<b>PCD asset</b>	purchased financial asset with credit deterioration
<b>PMA</b>	premarket approval
<b>PTRS</b>	probability of technical and regulatory success
<b>Q&amp;A</b>	question and answer

<b>Abbreviation</b>	<b>Description</b>
<b>R&amp;D</b>	research and development
<b>REMS</b>	risk evaluation and mitigation strategy
<b>ROU</b>	right of use
<b>SAB</b>	SEC Staff Accounting Bulletin
<b>SAC</b>	subjective acceleration clause
<b>SEC</b>	Securities and Exchange Commission
<b>TRG</b>	transition resource group
<b>VIE</b>	variable interest entity
<b>WAC</b>	wholesaler acquisition cost

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