

Technical Line

FASB – final guidance

How the new revenue standard affects life sciences entities

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What you need to know

- ▶ Life sciences entities have to use more judgment and may need to make more estimates than they do today.
- ▶ Life sciences entities have to update their policies, systems and controls to meet the new requirements, even though their pattern of revenue recognition may not change. The standard also requires more interim and annual disclosures.
- ▶ We don't anticipate further significant changes to the recognition and measurement principles in the new revenue standard, so life sciences entities should focus on implementation. Many entities are finding that implementation requires significantly more effort than they expected.
- ▶ While many transactions between parties to collaborative arrangements are in the scope of ASC 808, the FASB has added a project to its agenda to clarify when these transactions should be accounted for under the new revenue standard. Life sciences entities with collaborative arrangements should monitor developments.

Overview

The 2018 effective date¹ of the new revenue recognition standard² (the standard) issued by the Financial Accounting Standards Board (FASB) is fast approaching. As life sciences entities work on implementation, they need to consider all developments. For example, the FASB amended its guidance in the standard on accounting for licenses of intellectual property (IP), identifying performance obligations, assessing collectibility and measuring noncash consideration. In addition, the Joint Transition Resource Group for Revenue Recognition (TRG)³ generally agreed on several issues that may affect the life sciences industry.

This publication highlights key aspects of applying the standard to life sciences arrangements, addresses significant changes to legacy practice and reflects the latest implementation insights.

This publication, which contains a summary of the standard in the appendix, supplements our [Financial reporting developments \(FRD\) publication, *Revenue from contracts with customers \(ASC 606\)*](#), and should be read in conjunction with it. The views we express in this publication may evolve as implementation continues and additional issues are identified.

Collaborative arrangements

In certain life sciences arrangements, a counterparty may not be a customer of the entity. Instead, the counterparty may be a collaborator or partner that shares in the risks and benefits of developing a product to be marketed. These arrangements generally are in the scope of Accounting Standards Codification (ASC) 808.⁴ However, depending on the facts and circumstances, these arrangements may also contain vendor-customer aspects. Such transactions could be within the scope of the new revenue guidance, at least partially, if the collaborator or partner meets the definition of a customer for at least some aspects of the arrangement. Therefore, the parties to such arrangements need to consider all of the facts and circumstances to determine which transactions have a vendor-customer relationship that is subject to the new guidance.

The FASB did not provide further guidance in the new revenue standard for determining whether certain collaborative arrangements would be in the scope of the new guidance. To help entities with assessing the scope of collaborative arrangements, the FASB added a narrow-scope project to its agenda in November 2016 to clarify when transactions between parties to collaborative arrangements are in the scope of the revenue standard. In doing so, the FASB noted that today, some entities apply the revenue guidance to some or all of the elements in collaborative arrangements, while others develop policies that may not be consistent with or analogous to the revenue guidance.

ASC 808 states that when payments between parties in a collaborative arrangement are not within the scope of other authoritative accounting literature, the income statement classification should be based on an analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational and consistently applied accounting policy election. The FASB noted⁵ in the Background Information and Basis for Conclusions of Accounting Standards Update (ASU) 2014-09 that in some circumstances (e.g., when more relevant guidance that could be applied is not available), it may be appropriate for an entity to apply by analogy the principles in the new revenue standard to collaborative arrangements.

How we see it

Today, many life sciences entities apply legacy revenue guidance by analogy to certain transactions with a collaboration partner. Absent further guidance from the FASB, ASC 808 would allow an entity to apply the new revenue guidance by analogy to these types of arrangements if it makes a policy election to do so.

The FASB project to clarify when transactions between parties to collaborative arrangements should be accounted for under the new revenue standard is in the early stages, and it is unclear if or when additional guidance will be issued. Therefore, life sciences entities with collaborative arrangements should monitor developments.

The FASB is considering clarifying when transactions between parties to a collaborative arrangement are in the scope of ASC 606.

Effect of termination clauses on contract duration

Life sciences contracts may include clauses that allow a customer to terminate a contract without penalty, or the customer may be required to pay a termination penalty that is not substantive. The absence of a substantive termination penalty may affect an entity's determination of the length of the contract, the number of performance obligations, the transaction price, the timing of revenue recognition and the required disclosures.

The standard does not explicitly address the effect of termination penalties on the length of the contractual period. However, the TRG generally agreed⁶ that a substantive termination penalty payable by a customer is evidence of enforceable rights and obligations on the part of both parties throughout the period when the substantive termination penalty applies.

The amount, nature and purpose of the termination penalty are factors to consider when determining whether the termination penalty is substantive. TRG members observed that the determination of whether a termination penalty is substantive, and what the enforceable rights and obligations are under a contract, requires judgment and consideration of the facts and circumstances. If the termination penalty is not substantive, the contract may be shorter than the stated contractual term. For example, entities may be required to account for contracts with stated terms as shorter-term contracts, such as month-to-month, if the parties to the contracts can terminate them without paying a substantive penalty, even if the stated terms are for multiple years.

Some life sciences contracts have stated terms of multiple years but also have cancellation provisions, allowing the customer to terminate the contract. If the customer terminates the contract, it is common for any payments made under the contract to be nonrefundable and for all rights conveyed under the license of IP to revert back to the entity, along with any know-how developed or obtained during the contract, upon (or shortly after) termination. Life sciences entities have questioned whether the reversion of a license of IP represents a substantive termination penalty that would indicate that the contract duration may align with the stated contract term (rather than through the date that the customer could terminate the contract). Life sciences entities should monitor developments on this issue.

How we see it

Life sciences entities should carefully evaluate the terms in their contracts with customers, including all substantive termination penalties, to determine the period in which enforceable rights and obligations exist in the contract. The evaluation of substantive termination penalties is critical because the conclusions on the enforceable rights and obligations in a contract, including contract duration, can affect the identification of performance obligations and determination and allocation of the transaction price.

Identifying performance obligations

Promised goods and services

When identifying performance obligations in a contract, the first step is to identify the promised goods or services. To do so, a life sciences entity should consider whether the customer has a reasonable expectation that the life sciences entity will transfer certain goods or services. If it does, the life sciences entity is likely to view those goods or services as promises that are part of the negotiated exchange. The life sciences entity needs to distinguish between the promised goods or services that transfer to a customer and the activities that are more administrative in nature. That is, the activities that a life sciences entity must undertake to fulfill a contract and that do not transfer a good or service to the customer are not promised goods or services.

As entities assess whether promised goods or services are performance obligations, the standard allows them to disregard promises that they determine to be immaterial in the context of a contract. As a result, life sciences entities that make this election do not need to aggregate and assess immaterial items at the entity level. For example, in an arrangement to sell medical equipment to a hospital and provide basic education and training services on the product, a medical technology entity may determine that the education and training services are immaterial in the context of the contract through an evaluation of qualitative factors (e.g., the lack of complexity of the education and training services) and quantitative factors.

Free goods and services

Some items that are considered marketing incentives or incidental goods or services under legacy GAAP have to be evaluated under the new standard to determine whether they are promised goods or services in the contract. Although an entity might not consider them to be the main items that the customer contracts to receive, the FASB concluded⁷ that they are goods or services for which the customer pays, and the entity should therefore evaluate whether they are separate performance obligations. If they are separate performance obligations, the entity allocates a portion of the transaction price to those free goods or services and recognizes that revenue when those free goods or services are transferred to the customer.

For example, a medical technology entity may provide a product and a free service in a contract with a customer. The medical technology entity likely needs to allocate a portion of the transaction price to the service (unless the medical technology entity determined that the service was immaterial in the context of the contract based on qualitative and quantitative factors).

Government vaccine stockpile programs

Life sciences entities may participate in government vaccine stockpile programs under which they produce vaccines and bill the government but hold the goods until requested. Under Securities and Exchange Commission (SEC or Commission) guidance specific to certain types of vaccine stockpile programs,⁸ entities participating in these programs may recognize revenue when the general criteria for revenue recognition are met (e.g., when certain vaccines are placed into the stockpiles), even if certain criteria that normally apply to "bill-and-hold" arrangements are not met.

The SEC staff has indicated that it is evaluating the stockpile program guidance in light of the new standard, but the Commission has not yet updated or amended this guidance. If the SEC doesn't change the guidance, life sciences entities should continue to recognize revenue based on the Commission guidance and provide the disclosures required for these transactions. If the SEC rescinds the guidance, life sciences entities would have to evaluate the full revenue model, including the bill-and-hold guidance in the standard, to identify all of the promised goods and services under the contract and to determine whether those promises are distinct. Life sciences entities would also need to consider the nature of the identified performance obligation(s) (e.g., to manufacture and deliver a specified quantity of vaccines or to stand ready to provide unexpired vaccines, when and if needed) to determine the timing of control transfer of the goods and/or services.

Participation on a joint steering committee

Life sciences entities often enter into collaborative research and development (R&D) arrangements with counterparties that include multiple promised goods and services. It is common for an arrangement to include provisions that call for the development of and participation on a joint steering committee (JSC) to make decisions about the collaborative activities. For example, a biotechnology (biotech) entity that has a revenue contract with a pharmaceutical (pharma) entity could be required to participate on a JSC in addition to licensing a product candidate and performing R&D services.

Participation on a JSC should be evaluated to determine whether it is a promised service in the arrangement. This determination may require judgment based on a careful evaluation of the facts and circumstances (e.g., whether participation on the JSC is required or optional, whether the life sciences entity can terminate its participation at any time). If participation on the JSC is determined to be a promised service in the arrangement, the life sciences entity has to consider whether that promised service is distinct from other promised goods or services (e.g., whether other parties could perform the service, whether participation on the JSC requires unique skills or expertise that results in a significant integration of goods and services).

Determining whether a promise is distinct

Under the standard, life sciences entities have to first identify the promised goods or services in the contract and determine which ones (or which bundles of goods or services) are distinct (i.e., a separate performance obligation, which is the unit of accounting for purposes of applying the standard). A good or service is distinct if both (1) the good or service is capable of being distinct, and (2) the promise to transfer the good or service is distinct within the context of the contract. The standard provides three factors that are intended to help entities identify when promises in a bundle of promised goods or services are *not* separately identifiable and, therefore, should be combined into a single performance obligation. These three factors include: (1) the presence of a significant integration service, (2) the presence of significant modification or customization or (3) whether the promised goods or services are highly interdependent or highly interrelated. Life sciences entities may need to apply significant judgment when determining whether a promise is distinct, especially to determine whether a promised good or service is distinct in the context of the contract.

Case E in Example 11⁹ in the standard addresses a common situation for medical technology entities that sell equipment and specialized consumables for use in the equipment. In the example, the equipment doesn't require significant customization or modification. The entity is the only producer of the consumables, but the consumables are sold separately. The entity concludes that the equipment and consumables are distinct promises because it can satisfy each of them independently of the other. Medical technology entities will need to carefully evaluate the terms of their contracts with customers to determine whether equipment and specialized consumables are distinct performance obligations. Significant judgment will likely be needed in many cases.

Application of the series of distinct goods and services provision

After identifying the distinct goods or services in a contract, life sciences entities will need to determine whether any of those distinct goods or services represent a series of distinct goods or services that must be combined and accounted for as a single performance obligation. Life sciences entities may need to evaluate this guidance when assessing R&D, manufacturing or other services provided to customers. Determining whether an entity's promise is a single combined performance obligation comprising goods or services that are not distinct from one another or a single performance obligation comprising a series of distinct goods or services is important because the determination can affect the allocation of variable consideration and the accounting for contract modifications and changes in the transaction price.

Distinct goods or services have to meet certain criteria in the standard to be accounted for as a series, including the requirement that they be substantially the same. To determine whether the distinct goods or services are substantially the same, life sciences entities first determine the nature of the promised goods or services. If the nature of the promise is the delivery of a specified amount of services, the entity evaluates whether each service is distinct and substantially the same. If the nature of the promise is the act of standing ready or providing a single service for a period of time (i.e., because there is an unspecified amount of services to be delivered), the entity evaluates whether each time increment, rather than the underlying activities, is distinct and substantially the same.

Life sciences entities are required to evaluate whether certain promises meet the criteria to be accounted for as a series.

When evaluating whether the series provision applies to R&D services, a life sciences entity may determine that the series provision does not apply because the daily R&D services that are provided are not distinct (i.e., the R&D services provided throughout the development period are dependent on and interrelated with the R&D services provided on other days). This would result in the R&D services being accounted for as a single combined performance obligation or multiple performance obligations (but not under the series provision). In contrast, a life sciences entity may determine that the series provision applies because the nature of the overall promise is to provide a daily R&D service that is distinct and that its performance of the overall promise to provide R&D services each day is substantially the same (assuming the other series provision criteria are met). This could be the case even though the life sciences entity performs a number of different activities to provide R&D services throughout a day and from day to day (e.g., enrollment of patients, laboratory testing, opening/closing clinical trial sites, preparation of regulatory filings).

If promised goods or services are required to be accounted for as a series of distinct goods or services, any variable consideration received for providing the goods or performing the services (e.g., milestone payments received for completing a phase of R&D services) should be recognized as the life sciences entity provides those specific services if certain criteria are met (see Step 4 of the standard). Consider the following example:

Illustration 1 – Accounting for R&D services that are a single combined performance obligation versus a single performance obligation under the series provision

Biotech agrees to perform R&D services over a three-year period. In exchange, Pharma agrees to pay Biotech a fixed monthly payment for the R&D services and a \$5 million milestone payment upon the enrollment of 100 patients in a phase II clinical trial.

Analysis:

If Biotech concludes that all of the R&D services to be provided over the three-year period are a single performance obligation comprising **non-distinct** services, the milestone would be included in the transaction price (subject to the constraint on variable consideration) and recognized based on the single measure of progress determined for the entire period of performance of the R&D services. This may result in a portion of the milestone being recognized as revenue throughout the R&D services period, including during the development period after the milestone is achieved.

Conversely, if Biotech concludes that the R&D services are a single performance obligation comprising a series of **distinct** services, Biotech may be able to recognize the milestone payment as it enrolls patients in the clinical trial if certain criteria are met. Assuming those criteria are met and the Biotech concludes that the milestone should be included in the transaction price (because it is not constrained), the \$5 million milestone payment is allocated directly to Biotech's efforts to perform the distinct services that led to the enrollment of the 100 patients. The entire \$5 million milestone amount is recognized as revenue during the period when Biotech performed the distinct R&D services that led to the enrollment of the 100 patients (i.e., no revenue from the milestone payment would be recognized during the development period after the milestone is achieved).

How we see it

A life sciences entity needs to first determine the nature of its promise to the customer when evaluating whether any of its promises are distinct and meet the criteria to be accounted for under the series provision. This evaluation may require significant judgment, and life sciences entities need to consider all of the facts and circumstances of the arrangement.

Customer options for additional goods or services

Some contracts give the customer an option to purchase additional goods or services (e.g., consumables for use with medical devices, additional R&D services, manufacturing), which may be priced at a discount or may even be provided free of charge.

When a life sciences entity grants a customer an option to purchase an additional good or service, that option is a separate performance obligation only if it provides a material right to the customer that the customer would not receive without entering into the contract (e.g., a discount that exceeds the range of discounts typically given for that good or service to that class of customer in that geographical area or market). In those cases, the customer in effect pays the life sciences entity in advance for a future good or service. If an entity concludes that a customer option for additional goods or services provides a material right, the option itself is deemed to be a performance obligation in the contract, but the underlying goods or services are not accounted for until the option is exercised.

If a customer has the option to acquire an additional good or service at a price that reflects the standalone selling price for that good or service, that option does not provide the customer with a material right. In these cases, the life sciences entity has made a marketing offer that it should account for when the customer exercises the option to purchase the additional good or service. However, if the contract includes variable consideration (rather than a customer option), a life sciences entity may need to estimate at contract inception the variable consideration expected over the life of the contract.

Determining whether a customer option is a material right will require significant judgment. See Questions 4-12 through 4-14 in our [FRD, Revenue from contracts with customers \(ASC 606\)](#), for further discussion.

Consider the following example:

Illustration 2 – Accounting for a customer option

A medical device manufacturer contracts with its customer to provide a cancer-screening device, perform installation services and provide 50 consumable cartridges to be used with the device. The medical device manufacturer also offers the customer an option to purchase up to 50 additional consumable cartridges in the future at a 25% discount from the list price. The medical device manufacturer generally sells its products at the list price (i.e., undiscounted).

Analysis:

The medical device manufacturer likely will conclude that the customer option for the discounted consumable cartridges is a material right and therefore is a separate performance obligation. That's because the medical device manufacturer does not sell the replacement cartridges at a discount on a standalone basis or offer discounts to new customers that have not entered into a similar contract.

Conversely, if the contract did not provide a discount for the additional consumable cartridges (i.e., the customer option to purchase up to 50 additional cartridges was at the medical device manufacturer's standalone selling price), the medical device manufacturer would likely determine that the customer option for additional consumable cartridges was not a material right and therefore would account for it as a separate contract when the customer exercises the option to purchase the additional consumable cartridges.

How we see it

Contracts in the life sciences industry often include contingent deliverables, such as manufacturing and marketing services that will be provided upon the successful development and approval of a product candidate.

Under the new standard, life sciences entities are required to evaluate whether a contingent good or service represents (1) a customer option to purchase additional goods or services that is a material right, (2) a variable quantity of goods or services that generates variable consideration that is considered in the estimation of the transaction price for the contract or (3) a customer option to purchase additional goods or services that is not a material right and therefore is accounted for as a separate contract when the customer exercises the option to purchase the additional goods or services. This determination likely requires significant judgment and may result in a life sciences entity accounting for a contingency as a component of the initial contract, either in the form of the material right or variable consideration.

Under legacy GAAP, a contingent deliverable often is not accounted for before the resolution of the contingency if considerable uncertainty exists about the outcome of the contingency and the fee for the contingent good or service is consistent with the contingent deliverable's estimated selling price.

Life sciences entities are required to evaluate contingent goods or services at contract inception.

Variable consideration

Life sciences entities commonly enter into arrangements with customers that include variable consideration. To apply the guidance on variable consideration, life sciences entities need to evaluate the facts and circumstances of each contract (or type of contract) and likely need to apply more judgment than they do under legacy GAAP. The timing of revenue recognition also may change.

Forms of variable consideration

Variable consideration is defined broadly and can take many forms (e.g., discounts for prompt payment, rebates, credits, price concessions, outcomes-based pricing, milestone payments, performance bonuses). Variable consideration can result from explicit contract terms or can be implied by a life sciences entity's past business practices or intentions when it entered into a contract. It is important for a life sciences entity to appropriately identify and evaluate the different instances of variable consideration included in a contract because it will need to separately estimate and apply a constraint (as discussed below) to all variable consideration.

Life sciences entities that provide rebates and/or discounts to customers whose orders meet specific volume thresholds have to determine whether to apply the guidance on variable consideration or the guidance on customer options. As discussed in Question 4-14 of our [FRD, Revenue from contracts with customers \(ASC 606\)](#), if a volume rebate or discount is applied prospectively, we believe it generally will be accounted for as a customer option rather than as variable consideration. This is because the consideration for the goods or services in the initial contract is not affected by future purchases, and the volume rebates or discounts affect only the price of future (optional) purchases. If this is the case, life sciences entities will need to evaluate whether the option to purchase future goods or services is a material right and therefore is required to be accounted for as a separate performance obligation, as discussed above.

However, we believe a volume rebate or discount that is applied retrospectively should be accounted for as variable consideration because the final price of each good or service sold depends on the customer's total purchases subject to the rebate program. That is, the consideration is contingent on the occurrence or non-occurrence of future events. These concepts are illustrated in Example 24¹⁰ in the standard.

Life sciences entities should keep in mind that the definition of variable consideration is broad, and they need to evaluate whether contract terms other than those specific to their rebate or discount programs create variable consideration that needs to be separately evaluated (e.g., if the goods subject to a rebate program are also sold with a right of return).

Estimating variable consideration and applying the constraint

To include variable consideration in the estimated transaction price, a life sciences entity must conclude that it is "probable" that a significant reversal of the cumulative revenues recognized under the contract will not occur in future periods when the uncertainty related to the variable consideration is resolved. This requirement, known as the variable consideration constraint, is aimed at preventing the over-recognition of revenue.

Variable consideration estimation methods

A life sciences entity is required to estimate variable consideration using either the "expected value" method or the "most likely amount" method, depending on which method better predicts the amount of consideration to which it will be entitled.

Under the expected value method, life sciences entities determine the expected value of variable consideration using the sum of probability-weighted amounts in a range of possible amounts under the contract. To do this, a life sciences entity needs to identify the possible outcomes and the probabilities of those outcomes.

The FASB indicated in the Basis for Conclusions of ASU 2014-09¹¹ that this method may better predict expected consideration when an entity has a large number of contracts with similar characteristics (e.g., returns). This method also may better predict consideration when an entity has a single contract with a large number of possible outcomes. The FASB clarified in the Basis for Conclusions of ASU 2014-09¹² that an entity preparing an expected value calculation is not required to consider all possible outcomes, even if it has extensive data and can identify many possible outcomes. Instead, the FASB indicated that, in many cases, a limited number of discrete outcomes and probabilities can provide a reasonable estimate of the expected value.

Under the most likely amount method, life sciences entities will determine the amount of variable consideration using the single most likely amount in a range of possible amounts. The FASB indicated in the Basis for Conclusions of ASU 2014-09¹¹ that this method may be the better predictor when an entity expects to be entitled to one of two possible amounts. That would be the case if a life sciences entity is entitled to receive all or none of a milestone payment for successfully completing a stage of clinical development or if a life sciences entity grants a discount if a customer pays within a stated period of time.

Life sciences entities should consider all information (historical, current and forecasted) that is reasonably available to them when applying either of these methods. They will likely have to update accounting policies, accounting systems and/or internal control over financial reporting to estimate variable consideration. For example, a life sciences entity may need to update its documentation, processes and controls for calculating rebates on product sales to estimate these rebates using the expected value method or the most likely amount method.

Illustration 3 – Estimating variable consideration and applying the constraint

Biotech enters into an arrangement with Pharma under which Biotech provides a license to a product candidate that is starting phase II clinical studies and performs R&D services for a specified period of time. Assume that these two promises are determined to be distinct. Biotech receives an up-front payment upon execution of the arrangement and may receive milestone payments upon (1) enrollment of a specified number of patients in a phase II clinical study, (2) completion of phase III clinical studies, (3) regulatory approval in the US and (4) regulatory approval in the European Union.

Analysis:

Under the standard, Biotech will include in the transaction price the up-front payment and its estimate of the milestone payments it expects to receive. The amount of consideration that Biotech can include in the transaction price is limited to amounts for which it is probable that a significant reversal of cumulative revenues recognized under the contract will not occur in future periods.

Because the milestone for patient enrollment only has two possible outcomes (e.g., Biotech enrolls or doesn't enroll the specified number of patients), Biotech determines that the most likely amount method is the better predictor of the milestone payment. It then determines that it can include the amount associated with the enrollment milestone in the transaction price because it is probable that doing so will not result in a significant revenue reversal, based on its prior experience with enrolling participants in similar studies, clinical trial results on the product candidate to date and the significance of the milestone payment compared to the cumulative revenues expected to be recognized under the contract at the time of the enrollment milestone.

Due to the significant uncertainty associated with the other future events that would result in milestone payments, however, Biotech initially determines that it cannot include these amounts in the transaction price (i.e., the other milestone payments are fully constrained at contract inception). At the end of each reporting period, Biotech will update its assessment of whether the milestone payments are constrained by considering both the likelihood and magnitude of a potential revenue reversal.

How we see it

Life sciences entities may recognize revenue related to some bonuses and milestone payments sooner than they do under legacy GAAP because the new standard requires them to include in the transaction price the consideration to which they expect to be entitled, after applying the variable consideration constraint. This will be a change in practice for life sciences entities that, under legacy GAAP, generally do not recognize revenue that is contingent on a future event, such as achieving a milestone, until that event occurs because the sales price is not "fixed or determinable," as required by SEC Staff Accounting Bulletin Topic 13.

However, we expect life sciences entities to conclude in many instances that the variable consideration constraint prevents them from recognizing bonuses and milestone payments that are contingent on regulatory approval (e.g., Food and Drug Administration (FDA) approval of a new drug) until the uncertainty associated with these payments is resolved.

Questions will likely arise about how to apply the variable consideration constraint to specific fact patterns, including how to determine whether it is probable that a significant revenue reversal will not occur.

Rights of return

Life sciences entities often provide customers with a right to return a transferred product for a specified period of time after sale. A right of return creates variability in the transaction price that a life sciences entity needs to estimate.

A life sciences entity will recognize the amount of consideration it expects to return to customers as a refund liability. The standard also requires a return asset to be recognized at the time of the initial sale (when recognition of revenue is deferred due to the anticipated return), if an entity expects to receive the returned product in salable or reparable condition. This return asset represents an entity's right to recover the goods returned by the customer. Life sciences entities have to present the return asset (if recognized) separately from both the refund liability (i.e., on a gross basis) and inventory.

Consider the following example, which is similar to Example 22¹³ in the standard:

Illustration 4 – Right of return

Pharma enters into 50 contracts with customers. Each contract includes the sale of a product for \$100 (50 products × \$100 = \$5,000 total consideration). Cash is received when control of a product transfers. Pharma's return policy allows a customer to return products six months before expiration and up to 12 months after expiration.

Pharma decides to use the portfolio approach described in ASC 606-10 through 10-4 to estimate the variable consideration. Pharma has significant experience in estimating returns for this product and customer class. Pharma decides to use the expected value method and estimates variable consideration of \$4,700 (\$100 × 47 products not expected to be returned).

Pharma considers the variable consideration constraint and determines that although the returns are outside its influence, it has significant experience in estimating returns for this product and customer class. Pharma concludes that it is probable that a significant reversal in the cumulative amount of revenue recognized (i.e., \$4,700) will not occur over the return period.

Upon transfer of control of the 50 products, Pharma does not recognize revenue for the three products that it expects to be returned. Pharma records revenue of \$4,700 and a refund liability of \$300. No return asset is recorded because the product cannot be resold.

How we see it

While treating rights of return as variable consideration under the new standard may not significantly change the timing of revenue recognition compared to legacy GAAP, life sciences entities may have to revise their policies and processes to address the variable consideration constraint.

While returns often have no value for life sciences entities because the products expire or must be destroyed, separately presenting a return asset and a refund liability on the balance sheet will be a change in practice for some medical technology entities. Under legacy GAAP, the carrying value of any product expected to be returned typically remains in inventory and is not subject to separate impairment testing (although inventory is fully expensed at the time of sale if the value of the returned product is expected to be zero).

Distributor and reseller arrangements

Under the standard, life sciences entities that sell their products through distributors, or resellers may recognize revenue sooner than under legacy GAAP. This is because the standard requires entities to estimate variable consideration (i.e., the end sales price) based on the information available at contract inception, taking into consideration the effect of the constraint (similar to the “sell-in” method under legacy GAAP). That is, life sciences entities have to estimate the transaction price, taking into consideration the amounts of returns and other variable components of pricing (e.g., chargebacks). They recognize the amount included in the transaction price as revenue at the time that control of the products transfers to the distributor or reseller.

How we see it

Under the new standard, it is no longer acceptable for life sciences entities that sell their products through distributors or resellers to wait until the product is sold to the end consumer to recognize any revenue (i.e., the “sell-through” method) if the only uncertainty is the variability in the pricing. However, in some cases, the outcomes under the standard and legacy GAAP could be similar if a significant portion of the estimated revenue is constrained.

Under legacy GAAP, many life sciences entities apply the sell-through method and wait until the product is prescribed to a patient or sold to the end consumer to recognize revenue because they do not consider the sales price fixed or determinable until then.

Life sciences entities can no longer wait until a product is sold to an end consumer to recognize revenue from a distributor or reseller if the only uncertainty is variability in pricing.

Significant financing component

To determine whether a significant financing component exists, a life sciences entity will need to consider all relevant facts and circumstances, including (1) the difference between the cash selling price and the amount of promised consideration for the promised goods or services and (2) the combined effect of the expected length of time between the transfer of the goods or services and the receipt of consideration and the prevailing market interest rates.

The standard describes several factors that indicate that there isn't a significant financing component. They include situations when a substantial amount of the consideration promised by the customer is variable, and the amount or timing of that consideration varies based on a future event that is not within the control of the customer or the entity (e.g., a sales-based royalty).

It may be reasonable for a life sciences entity to attribute an adjustment for a significant financing component to one or more, but not all, of the performance obligations in the contract. For example, a life sciences entity that receives an up-front payment as part of the consideration transferred in exchange for a license of functional IP (described below) and R&D services will need to evaluate whether the contract contains a significant financing component associated with the R&D services. If certain criteria are met, the life sciences entity may apply guidance in the standard that requires specific forms of consideration (such as variable consideration or discounts) to be allocated to one or more (but not all) performance obligations to determine how much of the up-front payment relates to the license and how much relates to the R&D services. However, this determination of whether a significant financing component exists will require the use of judgment, especially because cash is fungible.

As a practical expedient, a life sciences entity may decide not to adjust the promised amount of consideration for the effects of a significant financing component if it expects, at contract inception, that the period between the transfer of a promised good or service to a customer and the payment for that good or service will be one year or less.

Licenses of IP

A license provides a customer with rights to use or access an entity's IP. Life sciences entities commonly enter into arrangements with customers that include licenses of IP such as licenses for product candidates or patented drug formulas. The new standard provides guidance for recognizing revenue from licenses of IP and sales-based royalties provided in exchange for licenses of IP that differs in some respects from the guidance for other promised goods and services.

When applying the guidance on licenses of IP, a life sciences entity will have to analyze the facts and circumstances of each contract (or type of contract) and may need to use more judgment than it does under legacy GAAP. The units of accounting and timing of revenue recognition also may change under the standard.

Determining whether a license is distinct

Contracts for licenses of IP frequently include explicit or implicit promises for additional goods or services. Under the standard, an entity must first determine whether the license and additional goods or services are distinct and, therefore, separate performance obligations, by applying the guidance on identifying performance obligations from Step 2 of the standard. Consistent with the guidance in Step 2 of the standard, a license of IP that is not distinct is combined with other goods or services into a single performance obligation. Consider the following two examples, which are similar to Cases A and B in Example 56¹⁴ in the standard:

Illustration 5 – Identifying performance obligations – license is not distinct

Pharma licenses its patent rights to an approved mature drug to a customer for 10 years. Pharma promises to manufacture the drug for five years while the customer develops its own manufacturing capability. There is no expectation that Pharma will undertake activities to change the drug (e.g., to alter its chemical composition). No other entity can perform the manufacturing while the customer develops its manufacturing capability because of the highly specialized nature of the process. As a result, the license cannot be purchased separately from the manufacturing.

Analysis:

Because the customer cannot benefit from the license without the manufacturing, the license and the manufacturing are not capable of being distinct, and the promises are accounted for as a combined performance obligation. The nature of the combined good or service for which the customer contracted is a sole sourced supply of the drug for the first five years.

Illustration 6 – Identifying performance obligations – license is distinct

Assume the same facts as in Illustration 5 above, except that the manufacturing process is not specialized and can be performed by other entities.

Analysis:

Pharma concludes that the promises are capable of being distinct because the customer can benefit from the (1) license together with other readily available resources (i.e., because other entities can provide the manufacturing) and (2) manufacturing together with the license that transfers to the customer up front.

Pharma also concludes that the promises are distinct in the context of the contract because they (1) are not inputs that Pharma integrates into a combined output, (2) do not significantly modify or customize each other and (3) are not highly interrelated or highly interdependent (i.e., the entity will be able to fulfill its promise to transfer the license independently of fulfilling its promise to manufacture the drug for the customer).

As a result, Pharma concludes that the license and the manufacturing should be accounted for as separate performance obligations.

Contractual restrictions

The standard requires life sciences entities to distinguish between contractual provisions that define the attributes of a license of IP (e.g., restrictions of use or geography) and others that represent additional promised goods or services to the customer. Contractual provisions that are attributes of a promised license define the scope of a customer's rights to IP and do not affect whether a performance obligation is satisfied at a point in time or over time. These provisions also don't affect the number of performance obligations in the contract.

Significant judgment will be required to determine whether a contractual provision results in additional promises (e.g., additional licenses) or is an attribute that defines the scope of the license. If a life sciences entity determines that a license contains multiple promises, it has to evaluate whether the promises represent multiple performance obligations. The guidance on contractual restrictions in ASC 606-10-55-64 does not replace the requirement to appropriately identify the goods or services promised to the customer in accordance with Step 2 of the standard.

When analyzing contractual restrictions, a life sciences entity should consider whether a restriction requires it to grant additional rights to the customer at a future date to fulfill its promises under the contract. The presence of such a requirement indicates that there may be multiple promises that need to be accounted for under Step 2 of the standard.

In many life sciences contracts, multiple, distinct rights may be transferred to a customer at the same point in time (e.g., licenses for multiple rights to use product candidates or patented drug formulas) or over the same period of time (e.g., licenses for multiple rights to access brands or trade names). The FASB indicated¹⁵ that an entity is not required to separately identify each set of distinct rights if those rights are transferred concurrently.

How we see it

Licenses in the life sciences industry often restrict where and/or how a customer can use a product candidate or patented drug formula. For example, a license may provide the customer with a right to use a patented drug formula in Country A starting in Year 1 of the contract and Country B starting in Year 2 of the contract. These rights generally are viewed under the standard as multiple promises that are separate performance obligations because additional distinct rights are granted to the customer in Year 2.

Life sciences entities need to apply judgment to determine (based on the requirements in Step 2 of the standard) whether contractual restrictions represent multiple promises to the customer and, if so, whether those multiple promises are distinct.

Effect of contractual restrictions on the distinct analysis

Contractual restrictions that require a customer to obtain goods or services from a specific life sciences entity (e.g., manufacturing, R&D services) are common in contracts in the life sciences industry. As described in Example 11, Case D,¹⁶ of the standard, a contractual restriction that requires a customer to purchase goods or services from the entity (and not from alternate suppliers) does not change the evaluation of whether promised goods or services are distinct if the contractual restriction does not change (1) the characteristics of the goods or services themselves and (2) the entity's promises to the customer.

For example, although a customer may be contractually required to use a life sciences entity to manufacture a drug once it obtains regulatory approval, the contractual requirement does not change the characteristics of the license to the drug or the manufacturing, and it does not change the life sciences entity's promises to the customer (i.e., the contractual requirement does not change the evaluation of whether the license to the drug and the manufacturing are distinct).

How we see it

It is common in the life sciences industry for regulators (e.g., the FDA) to restrict manufacturing to entities with approved facilities and manufacturing processes. Determining how such restriction affects the distinct analysis may require significant judgment.

Careful consideration should be given to factors such as whether a third party would be able to implement the necessary processes and how long it would take for that third party to develop those processes and obtain regulatory approval to manufacture the product. For example, certain products (e.g., some biologics) may be more complex to manufacture than others (e.g., some generic drugs), and it could take longer for a third party to develop the processes and obtain the regulatory approval to do so. This may have a significant effect on the utility of the promised goods or services in the contract (e.g., a license of IP and manufacturing).

Contractual restrictions do not change the evaluation of whether a license of IP and manufacturing are distinct.

Determining the nature of the entity's promise

Entities are required to classify IP as either functional or symbolic to determine whether to recognize the revenue associated with the license of that IP at a point in time or over time. If contracts include multiple licenses of IP (e.g., a contract that grants a license to a drug formula and a license to a brand), entities have to classify each license of IP as either functional or symbolic to determine the appropriate timing of revenue recognition.

Functional IP has significant standalone functionality and derives a substantial portion of its utility (i.e., the IP's ability to provide benefit or value) from that standalone functionality. A licensor's ongoing activities generally do not significantly affect the standalone functionality of functional IP. Examples of functional IP include biological compounds and drug formulas. Revenue from functional IP typically is recognized at a point in time. If the functional IP is not distinct, the licensor combines the functional IP with other goods and services in a single performance obligation and recognizes revenue based on the nature of the combined performance obligation.

Symbolic IP does not have significant standalone functionality because substantially all of its utility is derived from its association with the licensor's ongoing or past support (e.g., activities that support the value of the IP). Examples of symbolic IP include a brand or a trade name. Licenses of symbolic IP always represent a right to access a licensor's IP, and therefore, revenue from symbolic IP is recognized over time as the performance obligation is satisfied.

The following example illustrates how a life sciences entity may determine when to recognize revenue for a license of functional IP:

Illustration 7 – Determining the nature of the entity's promise**Example A**

Assume the same facts as Illustration 5 above.

Analysis:

The license provides a right to use Pharma's IP. Pharma concludes that it is licensing functional IP because the license is for a mature drug that has significant standalone functionality (i.e., it can be used to treat a disease or condition). There is also no expectation that Pharma will undertake activities to change the standalone functionality of the IP.

If the license is the only distinct promise in the contract, revenue is recognized at the point in time that control of the license is transferred to the customer. However, in this example, the license and the manufacturing are combined into a single performance obligation, and Pharma applies the requirements in Step 5 of the standard to determine whether the combined performance obligation is satisfied at a point in time or over time. Pharma will likely determine that the combined performance obligation is satisfied over time up to the end of the fifth year when the manufacturing is complete.

Example B

Assume the same facts as in Illustration 6 above.

Analysis:

Pharma assesses the nature of its promise to grant the license and concludes that the patented drug formula is functional IP because it is a mature drug that can be used to treat a disease or condition. There is also no expectation that Pharma will undertake activities to change the standalone functionality of the IP. Pharma will likely determine that the license is a performance obligation satisfied at the point in time when control of the license is transferred to the customer.

In assessing the timing of recognition of the revenue from the license, Pharma does not consider the manufacturing because it is a separate performance obligation in the contract.

If a life sciences entity is required to bundle a license of IP with other promised goods and services in a contract into a combined performance obligation, it considers the guidance on licenses of IP to determine the nature of its promise to the customer. For example, if the license in Illustration 7, Example A, above provided a right to access the life sciences entity's IP (i.e., symbolic IP), the combined performance obligation will not be fully satisfied until the end of the 10-year license period, which will likely extend the period of revenue recognition beyond the date when the manufacturing is complete.

License arrangements that include sales- or usage-based royalties

Life sciences entities commonly enter into arrangements that require the customer to pay a sales- or usage-based royalty in exchange for a license of IP. For example, a licensee may be required to pay royalties based on a percentage of its drug product sales.

Sales- or usage-based royalties received in exchange for licenses of IP are recognized 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- or usage-based royalty has been allocated is satisfied (in whole or in part). That is, an entity recognizes the royalties as revenue when (or as) the customer's subsequent sales or usage occurs, unless that recognition pattern accelerates revenue recognition ahead of the entity's satisfaction of the performance obligation to which the royalty relates.

The standard requires the royalty recognition constraint to be applied to the overall royalty stream when the sole or predominant item to which the royalty relates is a license of IP (including when no single license is the predominant item to which the royalty relates, but the royalty predominantly relates to two or more licenses in the contract). Entities cannot analogize to it for other situations.

Life sciences entities will need to apply judgment to assess whether a license of IP is the sole or predominant item to which the royalty relates in a combined performance obligation or in relation to other distinct goods or services in a contract. One way for a licensor to make this determination is for it to assess whether the licensee would ascribe significantly more value to the license than to the other goods and services in the contract. For example, in a contract that provides a license of IP and R&D services that are combined into a single performance obligation, a life sciences entity would determine whether the license is the predominant item to which the royalty relates by evaluating whether the customer considers the license significantly more valuable than the R&D services. This determination may require significant judgment based on the facts and circumstances (e.g., the remaining clinical trial studies that need to be completed, the expected size of the market).

The standard requires a royalty stream to be accounted for either entirely under the royalty recognition constraint or entirely under the variable consideration constraint. That is, an entity should not split a single royalty and apply the royalty recognition constraint to a portion of it and the variable consideration constraint to the other portion.

Scope of the sales- or usage-based royalty recognition constraint

The FASB concluded in the Basis for Conclusions of ASU 2016-10¹⁷ that, when entities determine whether to apply the royalty recognition constraint, they should not attempt to determine whether a license of IP is in substance a sale of IP (i.e., a promise that is in the form of a license but has the characteristics of a sale). Therefore, life sciences entities should follow the legal form of a license of IP for purposes of determining whether they can apply the royalty recognition constraint.

It is also important to note that the royalty recognition constraint applies only to licenses of IP for which some or all of the consideration is in the form of a sales- or usage-based royalty. This would include certain types of variable consideration even if payments are not referred to as royalties in the contract but are based on a customer's sale or usage and predominantly related to a license of IP. For example, we generally believe the royalty recognition constraint should be applied to fixed dollar amounts of variable consideration that are contingent on the occurrence of a future event (e.g., sales-based milestone payments), provided that the amounts are determined by reference to sales- or usage-based thresholds.

However, life sciences entities cannot analogize to the royalty recognition constraint for other situations, such as when consideration in a contract is in the form of a sales- or usage-based royalty but there is no license of IP (e.g., royalties paid in exchange for a sale of IP). When the royalty recognition constraint cannot be applied, a life sciences entity follows the general guidance on estimating and applying the variable consideration constraint. Life sciences entities need to apply judgment to determine whether their contracts for licenses of IP contain payments that should be accounted for using the royalty recognition constraint. See Question 8-4 in our [FRD, Revenue from contracts with customers \(ASC 606\)](#), for an illustration and further discussion.

Estimating a sales- or usage-based royalty when there is a lag in reporting

Life sciences entities have questioned whether they can recognize revenue for sales- or usage-based royalties for licenses of IP on a lag if actual sales or usage data is not available at the end of a reporting period. If the sales or usage has occurred and the performance obligation

to which the royalties relate has been satisfied (or partially satisfied), we believe that licensors without actual sales or usage data from the licensee need to estimate the royalties earned in the current reporting period.

The SEC's Chief Accountant noted in a speech¹⁸ that because the FASB did not provide "a lagged reporting exception" in the standard, the reporting of sales- and usage-based royalties may require estimation in some circumstances. This may result in a change in practice for entities that have previously recorded revenue from royalties on a lag (i.e., in a reporting period subsequent to when the underlying sales or usage occurs).

How we see it

Estimating royalties earned in the current reporting period is a significant change in practice for entities that don't have actual sales or usage data from the licensee and report on a lag under legacy practice. Significant judgment is required for these estimates. Licensors without this data need to implement processes and controls to collect data and develop assumptions to make a reasonable estimate.

Recognition of revenue from a license of IP

The standard doesn't allow entities to recognize revenue for a license of IP before they provide the IP or make it available to the customer or before the beginning of the period during which the customer is able to use and benefit from the license. Assuming that all other criteria have been met, a life sciences entity will recognize revenue from a license of functional IP at the point in time when the customer is able to use and benefit from the product or product candidate (i.e., the start of the license period).

Restrictions on a licensee's ability to use and benefit from the license

Renewals of licenses of IP

The standard requires an entity to wait until the beginning of a renewal period to recognize revenue from a renewal of a license of IP. This requirement may change practice for some life sciences entities. For example, assume the same facts as in Illustration 7, Example A, above except that during Year 8 of the 10-year license period, Pharma agrees to renew the license for an additional three years (i.e., through Year 13). Assuming the price of the renewal reflects the license's standalone selling price, the renewal is considered a separate license from the initial 10-year license, and Pharma does not recognize revenue for the renewal performance obligation before the beginning of Year 11 (i.e., the date the renewal period begins). Case B in Example 59¹⁹ in the standard illustrates the revenue recognition for a license renewal.

Distinct rights added through a modification

Life sciences entities frequently modify the terms of arrangements to provide customers with additional rights. The terms of each license of IP are defined by the contract, which establishes the customer's rights (e.g., period of time, area of use). We believe that when a contract for a license of IP is modified, the additional and/or modified license of IP is distinct from the original license because the new and/or modified rights will always differ from those conveyed by the original license.

The standard's contract modification guidance requires a modification in which the additional promised goods or services are distinct to be accounted for on a prospective basis either as a separate contract or a termination of the old contract and creation of a new contract. As discussed above, a life sciences entity cannot recognize revenue for the transaction price allocated to the new license until the customer has the right to use and benefit from it.

Life sciences entities without actual sales or usage data have to estimate the royalties they earned in a reporting period.

Consideration paid or payable to a customer

The standard requires an entity to account for payments made to a customer or another party that purchases the entity's goods or services from the customer, regardless of whether the purchaser receiving the consideration is a direct or indirect customer of the entity. This requirement applies to consideration payable to any purchasers of an entity's products or services at any point along the distribution chain, including customers of resellers or distributors that purchase directly from a life sciences entity (e.g., retail pharmacies, governmental agencies).

Common forms of consideration paid or payable by a life sciences entity to its direct or indirect customers include:

- ▶ Rebates paid to governmental entities (e.g., Medicaid, Medicare, TRICARE, Department of Veterans Affairs, Department of Defense), managed care entities or other health insurers
- ▶ Fee-for-service amounts paid to wholesalers or other resellers
- ▶ Chargebacks paid to wholesalers
- ▶ Prompt payment discounts to wholesalers and specialty pharma companies
- ▶ Patient assistance programs and co-pay assistance

To determine the appropriate accounting treatment for consideration paid or payable to a customer, a life sciences entity must first determine whether the consideration is a payment for a distinct good or service, a reduction of the transaction price or a combination of both. The payment is treated as something other than a reduction of the transaction price only if the entity receives a distinct good or service from the customer in exchange for that payment. See Question 5-22 in our [FRD, *Revenue from contracts with customers \(ASC 606\)*](#), for further discussion.

How we see it

Questions have arisen as to whether a contribution to a not-for-profit or other organization that funds co-pay assistance programs is a form of consideration paid or payable to an indirect customer because the contribution funds may be used by a patient to obtain the entity's products.

Life sciences entities that contribute to not-for-profit or other organizations that may fund co-pay assistance programs should carefully evaluate the facts and circumstances of each contribution to determine whether it represents consideration paid or payable to an indirect customer (i.e., whether it should be accounted for as a reduction of the transaction price from a contract with a customer because the amount is not provided in exchange for a distinct good or service). Life sciences entities will need to apply significant judgment when making this determination.

Transition

The standard requires either a "full retrospective" adoption in which the standard is applied to all of the periods presented or a "modified retrospective" adoption. Certain practical expedients are available if the full retrospective adoption method is used. The modified retrospective adoption method can be applied to all contracts at transition or only to contracts that are not completed as of that date.

The standard considers a contract to be completed at transition if all (or substantially all) of the revenue has been recognized under legacy GAAP. When evaluating which contracts are complete, life sciences entities need to consider all potential contract revenues in the assessment, including contingent amounts that may be received at a future date (e.g., royalties, milestones). In the Basis for Conclusions of ASU 2016-12,²⁰ the FASB explained that in certain circumstances in which less than 100% of the revenue from a contract was recognized under legacy GAAP, an entity could recognize the remaining revenue (e.g., an adjustment to the sales returns reserve) in accordance with legacy GAAP. This determination requires life sciences entities to apply judgment in some cases.

Presentation and disclosure

Presentation

When either party to a contract has performed, an entity presents the contract in the statement of financial position as a contract asset or a contract liability, depending on the relationship between the entity's performance and the customer's payment. Members of the TRG generally agreed²¹ that contract assets and liabilities should be determined at the contract level and not at the performance obligation level. That is, an entity does not separately recognize an asset or liability for each performance obligation within a contract but aggregates them into a single contract asset or liability.

Under the standard, entities do not have to use the terms "contract asset" or "contract liability" but have to disclose sufficient information to allow users of the financial statements to clearly distinguish between unconditional rights to consideration (e.g., receivables) and conditional rights to receive consideration (e.g., contract assets, unbilled receivables).

When a life sciences entity expects to refund some or all of the consideration received (or receivable) from a customer, it records a refund liability. We believe that a refund liability does not typically meet the definition of a contract liability because a refund liability generally does not represent an obligation to transfer goods or services in the future. However, as discussed in the Basis for Conclusions of ASU 2016-20,²² an entity should determine whether a contract refund liability should be characterized as a contract liability based on the specific facts of circumstances of the arrangement. When a life sciences entity concludes that a refund liability is not a contract liability, it should present the refund liability separately from any contract liability (or asset), and the refund liability is not subject to the disclosure requirements for contract assets and liabilities included in ASC 606-10-50-8 and 50-10. See Question 10-4 in our [FRD, Revenue from contracts with customers \(ASC 606\)](#), for further discussion.

Disclosure

For public entities (as defined in the standard), disclosures include qualitative and quantitative information about contracts with customers, significant judgments made to apply the standard and costs to obtain or fulfill a contract. Nonpublic entities can choose to provide the same or streamlined disclosures.

Required qualitative and quantitative disclosures about contracts with customers include information about performance obligations, contract assets and contract liabilities.

The standard also requires disclosure of significant accounting estimates and judgments made in determining the transaction price and amounts allocated to performance obligations. For life sciences entities, this may include information about estimating the standalone selling price of promised goods or services, estimating variable consideration and allocating variable consideration to a specific part of a contract. These disclosures exceed the requirements for significant accounting estimates under legacy GAAP.

Life sciences entities need to consider contingent amounts that may be received at a future date (e.g., royalties, milestones) when evaluating which contracts are complete.

The standard also expands disclosure requirements for interim financial statements and requires certain disclosures upon transition, depending on the transition method an entity selects (i.e., full retrospective or modified retrospective).

Prior to adopting the standard, life sciences entities that are SEC registrants must make certain disclosures about the potential effects of the standard,²³ including the expected transition method once a decision is made. Nonpublic life sciences entities should consider making similar disclosures.

Some of the specific disclosure requirements that may affect life sciences entities are discussed in further detail below.

Disclosure of disaggregated revenue

The requirement to disclose disaggregated revenue information is intended to illustrate how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors. When determining how to disaggregate revenue, a life sciences entity should consider how information is presented for other purposes, including information presented outside the financial statements (e.g., investor presentations), information reviewed by the chief operating decision maker to evaluate operating segments and information used to evaluate the life sciences entity's financial performance. Categories may include type of services, type of customer, type of contract and geographical location.

The standard states that an entity does not have to duplicate disclosures required by another standard. For example, a life sciences entity that provides disaggregated revenue disclosures as part of its segment disclosures does not have to separately provide disaggregated revenue disclosures if the segment-related disclosures are sufficient to illustrate how the nature, amount, timing and uncertainty of revenue and cash flows from contracts with customers are affected by economic factors. However, the FASB stated in the Basis for Conclusions of ASU 2014-09²⁴ that segment revenue disclosures may not always provide users of financial statements with enough information to help them understand the composition of revenue recognized in the period. If a life sciences entity provides disaggregated revenue disclosures in addition to segment disclosures, the standard requires an entity to explain the relationship between the disclosures.

Disclosure of revenue related to satisfied performance obligations

The standard requires entities to disclose the amount of revenue recognized in the period that relates to amounts allocated to performance obligations that were satisfied (or partially satisfied) in previous periods (e.g., due to a change in transaction price or in estimates related to the variable consideration constraint).

Disclosure of remaining performance obligations

A public entity is required to disclose information about remaining performance obligations, including the amount of the transaction price allocated to performance obligations that are unsatisfied (or partially unsatisfied) as of the end of the reporting period and when it expects to recognize the amount(s) in its interim and annual financial statements. The FASB provided optional exemptions that allow an entity not to make quantitative disclosures about remaining performance obligations in certain situations, including when contracts have an original expected duration of less than one year and when an estimate of the transaction price is made solely for disclosure purposes.

These situations also include: (1) when an entity applies the right to invoice practical expedient in ASC 606-10-55-18, (2) when variable consideration in the contract is due to a sales- or usage-based royalty promised in exchange for a license of IP accounted for under ASC 606-10-55-65 through 65B and (3) when variable consideration is allocated entirely to a

wholly unsatisfied performance obligation or to a wholly unsatisfied promise to transfer a distinct good or service that forms part of a single performance obligation (i.e., a series of distinct goods or services) when certain criteria are met.

These optional exemptions only apply to the portion of the transaction price that is variable consideration and meets the conditions of the exemptions. If a contract includes both fixed consideration and variable consideration and the variable consideration meets one of the conditions for applying the exemptions, an entity will still be required to disclose the remaining fixed consideration. For example, a guaranteed minimum amount of consideration included in a sales- or usage-based royalty is fixed consideration, and the remaining amount to be recognized under the minimum should be disclosed.

Entities that elect to use any of the standard's optional exemptions that allow them not to disclose the aggregate transaction price allocated to the remaining performance obligations must disclose which optional exemption(s) they are applying, the nature of the performance obligations, the remaining duration of the contract and a description of the variable consideration that has been excluded from the disclosure (e.g., the nature of the variability and how that variability will be resolved).

How we see it

Disclosing the revenue recognized from performance obligations satisfied in previous periods is likely to be a change in practice for life sciences entities. This type of revenue includes sales- or usage-based royalties a life sciences entity receives in a reporting period after it delivers functional IP. Life sciences entities need to make sure they have appropriate systems, policies and procedures and internal controls in place to collect and disclose the required information.

Endnotes:

- ¹ Under US GAAP, public entities, as defined, will be required to adopt the standard for annual reporting periods beginning after 15 December 2017 (1 January 2018, for calendar-year public entities), and interim periods therein. Nonpublic entities will be required to adopt the standard for annual reporting periods beginning after 15 December 2018, and interim periods within annual reporting periods beginning after 15 December 2019. Public and nonpublic entities can adopt the standard as early as the original public entity effective date (i.e., annual reporting periods beginning after 15 December 2016, and interim periods therein). Early adoption prior to that date is not permitted.
- ² Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*, as amended, and created by Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers*.
- ³ The FASB and the International Accounting Standards Board (IASB) created the TRG to help them determine whether more guidance is needed on their new revenue standards (ASC 606 and the IASB's standard IFRS 15 *Revenue from Contracts with Customers*) and to educate constituents. While the group met jointly in 2014 and 2015, only FASB TRG members participated in the meetings in 2016.
- ⁴ ASC 808, *Collaborative Arrangements*.
- ⁵ Paragraph BC56 of ASU 2014-09.
- ⁶ 9 November 2015 TRG meeting; agenda paper no. 48.
- ⁷ Paragraph BC89 of ASU 2014-09.
- ⁸ The SEC issued Interpretive Release, *Commission Guidance Regarding Accounting for Sales of Vaccines and Bioterror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*, in response to public policy concerns and, therefore, this guidance should not be used by analogy for other bill-and-hold arrangements. The release, issued on 5 December 2005, says the exception is limited to a specific list of "enumerated vaccines" related to federal governmental stockpile programs.
- ⁹ ASC 606-10-55-150G through 55-150K.
- ¹⁰ ASC 606-10-55-216 through 55-220.
- ¹¹ Paragraph BC200 of ASU 2014-09.
- ¹² Paragraph BC201 of ASU 2014-09.
- ¹³ ASC 606-10-55-202 through 55-207.

- ¹⁴ ASC 606-10-55-368 through 55-370.
- ¹⁵ Paragraph BC47 of ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*.
- ¹⁶ ASC 606-10-55-150E through 55-150F.
- ¹⁷ Paragraph BC78 of ASU 2016-10.
- ¹⁸ Speech by Wesley R. Bricker, 9 June 2016. Refer to SEC website at <https://www.sec.gov/news/speech/bricker-remarks-35th-financial-reporting-institute-conference.html>.
- ¹⁹ ASC 606-10-55-392A through 55-392C.
- ²⁰ Paragraph BC52 of ASU 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*.
- ²¹ 31 October 2014 TRG meeting; agenda paper no. 7.
- ²² Paragraph BC37 of ASU 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*.
- ²³ Codified in SEC Staff Accounting Bulletin, Topic 11.M, Disclosure of the Impact that Recently Issued Accounting Standards Will have on the Financial Statements of the Registrant when Adopted in a Future Period.
- ²⁴ Paragraph BC340 of ASU 2014-09.

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Appendix: The five-step revenue model and contract costs

The standard's core principle is that an entity recognizes revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to a customer. That principle is applied using five steps that will require entities to exercise judgment when considering the terms of their contract(s) and all relevant facts and circumstances. Entities have to apply the requirements of the standard consistently to contracts with similar characteristics and in similar circumstances. This table summarizes the new revenue model and the guidance for contract costs.

Step 1: Identify the contract(s) with the customer
<p><i>Definition of a contract</i></p> <p>An entity must first identify the contract, or contracts, to provide goods and services to customers. A contract must create enforceable rights and obligations to fall within the scope of the model in the standard. Such contracts may be written, oral or implied by an entity's customary business practices but must meet the following criteria:</p> <ul style="list-style-type: none"> ▶ The parties to the contract have approved the contract (in writing, orally or based on their customary business practices) and are committed to perform their respective obligations ▶ The entity can identify each party's rights regarding the goods or services to be transferred ▶ The entity can identify the payment terms for the goods or services to be transferred ▶ The contract has commercial substance (i.e., the risk, timing or amount of the entity's future cash flows is expected to change as a result of the contract) ▶ 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 <p>If these criteria are not met, an entity would not account for the arrangement using the model in the standard and would recognize any nonrefundable consideration received as revenue only when certain events have occurred.</p> <p><i>Contract combination</i></p> <p>The standard requires entities to combine contracts entered into at or near the same time with the same customer (or related parties of the customer) if they meet any of the following criteria:</p> <ul style="list-style-type: none"> ▶ The contracts are negotiated as a package with a single commercial objective ▶ The amount of consideration to be paid in one contract depends on the price or performance of another contract ▶ The goods or services promised in the contracts (or some goods or services promised in each of the contracts) are a single performance obligation <p><i>Contract modifications</i></p> <p>A contract modification is a change in the scope and/or price of a contract. A contract modification is accounted for as a new contract separate from the original contract if the modification adds distinct goods or services at a price that reflects the standalone selling prices of those goods or services. Contract modifications that are not accounted for as separate contracts are considered changes to the original contract and are accounted for as follows:</p> <ul style="list-style-type: none"> ▶ If the goods and services to be transferred after the contract modification are distinct from the goods or services transferred on or before the contract modification, the entity should account for the modification as if it were the termination of the old contract and the creation of a new contract ▶ If the goods and services to be transferred after the contract modification are not distinct from the goods and services already provided and, therefore, form part of a single performance obligation that is partially satisfied at the date of modification, the entity should account for the contract modification as if it were part of the original contract ▶ A combination of the two approaches above: a modification of the existing contract for the partially satisfied performance obligations and the creation of a new contract for the distinct goods and services

Step 2: Identify the performance obligation(s) in the contract

An entity must identify the promised goods and services within the contract and determine which of those goods and services (or bundles of goods and services) are separate performance obligations (i.e., the unit of accounting for purposes of applying the standard). 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.

A promised good or service represents a performance obligation if (1) the good or service is distinct (by itself or as part of a bundle of goods or services) or (2) the good or service is part of a series of distinct goods or services that are substantially the same and have the same pattern of transfer to the customer.

A good or service (or bundle of goods or services) is distinct if both of the following criteria are met:

- ▶ 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 (i.e., the good or service is capable of being distinct)
- ▶ The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract)

In assessing whether an entity's promise to transfer a good or service is separately identifiable from other promises in the contract, entities will need to consider whether the nature of the promise is to transfer each of those goods or services individually or to transfer a combined item or items to which the promised goods or services are inputs. Factors that indicate two or more promises to transfer goods or services are not separately identifiable include, but are not limited to, the following:

- ▶ 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
- ▶ One or more of the goods or services significantly modify or customize, or are significantly modified or customized by, one or more of the other goods or services promised in the contract
- ▶ 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

If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

Series guidance

Goods or services that are part of a series of distinct goods or services that are substantially the same and have the same pattern of transfer to the customer must be combined into one performance obligation. To meet the same pattern of transfer criterion, each distinct good or service in the series must represent a performance obligation that would be satisfied over time and would have the same measure of progress toward satisfaction of the performance obligation (both discussed in Step 5), if accounted for separately.

Customer options for additional goods or services

A customer's option to acquire additional goods or services for free or at a discount is accounted for as a separate performance obligation if it provides a material right to the customer that the customer would not receive without entering into the contract (e.g., a discount that exceeds the range of discounts typically given for those goods or services to that class of customer in that geographical area or market).

Principal versus agent considerations

When more than one party is involved in providing goods or services to a customer, an entity must determine whether it is a principal or an agent in these transactions by evaluating the nature of its promise to the customer. An entity is a principal and therefore records revenue on a gross basis if it controls a promised good or service before transferring that good or service to the customer. An entity is an agent and records as revenue the net amount it retains for its agency services if its

role is to arrange for another entity to provide the goods or services. Because it is not always clear whether an entity controls a specified good or service in some contracts (e.g., those involving intangible goods and/or services), the standard also provides indicators of when an entity may control the specified good or service as follows:

- ▶ The entity is primarily responsible for fulfilling the promise to provide the specified good or service
- ▶ The entity has inventory risk before the specified good or service has been transferred to a customer or after transfer of control to the customer (e.g., if the customer has a right of return)
- ▶ The entity has discretion in establishing the price for the specified good or service

Step 3: Determine the transaction price

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer. When determining the transaction price, entities need to consider the effects of all of the following:

Variable consideration

An entity needs to estimate any variable consideration (e.g., amounts that vary due to discounts, rebates, refunds, price concessions, bonuses) using either the expected value method (i.e., a probability-weighted amount method) or the most likely amount method (i.e., a method to choose the single most likely amount in a range of possible amounts). An entity's method selection is not a "free choice" and must be based on which method better predicts the amount of consideration to which the entity will be entitled. To include variable consideration in the estimated transaction price, the entity has to conclude that it is probable that a significant revenue reversal will not occur in future periods. This "constraint" on variable consideration is based on the probability of a reversal of an amount that is significant relative to cumulative revenue recognized for the contract. The standard provides factors that increase the likelihood or magnitude of a revenue reversal, including the following: the amount of consideration is highly susceptible to factors outside the entity's influence, the entity's experience with similar types of contracts is limited or that experience has limited predictive value, the contract has a large number and broad range of possible outcomes. The standard requires an entity to estimate variable consideration, including the application of the constraint, at contract inception and update that estimate at each reporting date.

Significant financing component

An entity needs to adjust the transaction price for the effects of the time value of money if the timing of payments agreed to by the parties to the contract provides the customer or the entity with a significant financing benefit. As a practical expedient, an entity can elect not to adjust the transaction price for the effects of a significant financing component if the entity expects at contract inception that the period between payment and performance will be one year or less.

Noncash consideration

When an entity receives, or expects to receive, noncash consideration (e.g., property, plant or equipment, a financial instrument), the fair value of the noncash consideration at contract inception is included in the transaction price.

Consideration paid or payable to the customer

Consideration payable to the customer includes cash amounts that an entity pays, or expects to pay, to the customer, and credits or other items (vouchers or coupons) that can be applied against amounts owed to the entity. An entity should account for consideration paid or payable to the customer as a reduction of the transaction price and, therefore, of revenue unless the payment to the customer is in exchange for a distinct good or service. However, if the payment to the customer exceeds the fair value of the distinct good or service received, the entity should account for the excess amount as a reduction of the transaction price.

Step 4: Allocate the transaction price to the performance obligations in the contract

For contracts that have multiple performance obligations, the standard generally requires an entity to allocate the transaction price to the performance obligations in proportion to their standalone selling prices (i.e., on a relative standalone selling price basis). When allocating on a relative standalone selling price basis, any discount within the contract generally is allocated proportionately to all of the performance obligations in the contract. However, there are two exceptions.

One exception requires variable consideration to be allocated entirely to a specific part of a contract, such as one or more (but not all) performance obligations or one or more (but not all) distinct goods or services promised in a series of distinct goods or services that forms part of a single performance obligation, if both of the following criteria are met:

- ▶ The terms of a variable payment relate specifically to the entity's efforts to satisfy the performance obligation or transfer the distinct good or service
- ▶ Allocating the variable consideration entirely to the performance obligation or the distinct good or service is consistent with the objective of allocating consideration in an amount that depicts the consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services to the customer

The other exception requires an entity to allocate a contract's entire discount to only those goods or services to which it relates if certain criteria are met.

To allocate the transaction price on a relative standalone selling price basis, an entity must first determine the standalone selling price of the distinct good or service underlying each performance obligation. The standalone selling price is the price at which an entity would sell a good or service on a standalone (or separate) basis at contract inception. Under the model, the observable price of a good or service sold separately in similar circumstances to similar customers provides the best evidence of standalone selling price. However, in many situations, standalone selling prices will not be readily observable. In those cases, the entity must estimate the standalone selling price by considering all information that is reasonably available to it, maximizing the use of observable inputs and applying estimation methods consistently in similar circumstances. The standard states that suitable estimation methods include, but are not limited to, an adjusted market assessment approach, an expected cost plus a margin approach or a residual approach (if certain conditions are met).

Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation

An entity recognizes revenue only when (or as) it satisfies a performance obligation by transferring control of the promised good(s) or service(s) to a customer. The transfer of control can occur over time or at a point in time.

A performance obligation is satisfied at a point in time unless it meets one of the following criteria, in which case it is satisfied over time:

- ▶ The customer simultaneously receives and consumes the benefits provided by the entity's performance as the entity performs
- ▶ The entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced
- ▶ The entity's performance does not create an asset with an alternative use to the entity, and the entity has an enforceable right to payment for performance completed to date

The transaction price allocated to performance obligations satisfied at a point in time is recognized as revenue when control of the goods or services transfers to the customer. If the performance obligation is satisfied over time, the transaction price allocated to that performance obligation is recognized as revenue as the performance obligation is satisfied. To do this, the standard requires an entity to select a single revenue recognition method (i.e., measure of progress) that faithfully depicts the pattern of the transfer of control over time (i.e., an input method or an output method).

Licenses of intellectual property

The standard provides guidance on the recognition of revenue for licenses of intellectual property (IP) that differs from the model for other promised goods and services. The nature of the promise in granting a license of IP to a customer is either:

- ▶ A right to access the entity's IP throughout the license period (a right to access)
- ▶ A right to use the entity's IP as it exists at the point in time in which the license is granted (a right to use)

To determine whether the entity's promise is to provide a right to access its IP or a right to use its IP, the entity should consider the nature of the IP to which the customer will have rights. The standard requires entities to classify IP in one of two categories:

- ▶ **Functional:** This IP has significant standalone functionality (e.g., many types of software, completed media content such as films, television shows and music). Licenses of functional IP generally grant a right to use the entity's IP, and revenue for these licenses generally is recognized at the point in time when the IP is made available for the customer's use and benefit. This is the case if the functionality is not expected to change substantially as a result of the licensor's ongoing activities that do not transfer an additional promised good or service to the customer. If the functionality of the IP is expected to substantively change because of activities of the licensor that do not transfer additional promised goods or services, and the customer is contractually or practically required to use the latest version of the IP, revenue for the license is recognized over time.
- ▶ **Symbolic:** This IP does not have significant standalone functionality (e.g., brands, team and trade names, character images). The utility (i.e., the ability to provide benefit or value) of symbolic IP is largely derived from the licensor's ongoing or past activities (e.g., activities that support the value of character images). Licenses of symbolic IP grant a right to access an entity's IP, and revenue from these licenses is recognized over time as the performance obligation is satisfied (e.g., over the license period).

Revenue cannot be recognized from a license of IP before both (1) an entity provides (or otherwise makes available) a copy of the IP to the customer and (2) the beginning of the period during which the customer is able to use and benefit from its right to access or its right to use the IP.

The standard specifies that sales and usage-based royalties on licenses of IP are recognized when the later of the following events occurs: (1) the subsequent sales 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). This guidance must be applied to the overall royalty stream when the sole or predominant item to which the royalty relates is a license of IP (i.e., these types of arrangements are either entirely in the scope of this guidance or entirely in the scope of the general variable consideration constraint guidance).

Contract costs

ASC 340-40 specifies the accounting for costs an entity incurs to obtain and fulfill a contract to provide goods and services to customers. The incremental costs of obtaining a contract (i.e., costs that would not have been incurred if the contract had not been obtained) are recognized as an asset if the entity expects to recover them. The standard provides a practical expedient that permits an entity to immediately expense contract acquisition costs when the asset that would have resulted from capitalizing these costs would have been amortized in one year or less.

An entity accounts for costs incurred to fulfill a contract with a customer that are within the scope of other authoritative guidance (e.g., inventory, property, plant and equipment, internal-use software) in accordance with that guidance. If the costs are not in the scope of other accounting guidance, an entity recognizes an asset from the costs incurred to fulfill a contract only if those costs meet all of the following criteria:

- ▶ The costs relate directly to a contract or to an anticipated contract that the entity can specifically identify.
- ▶ The costs generate or enhance resources of the entity that will be used in satisfying (or in continuing to satisfy) performance obligations in the future.
- ▶ The costs are expected to be recovered.

Any capitalized contract costs are amortized, with the expense recognized as an entity transfers the related goods or services to the customer. Any asset recorded by the entity is subject to an impairment assessment at the end of each reporting period.