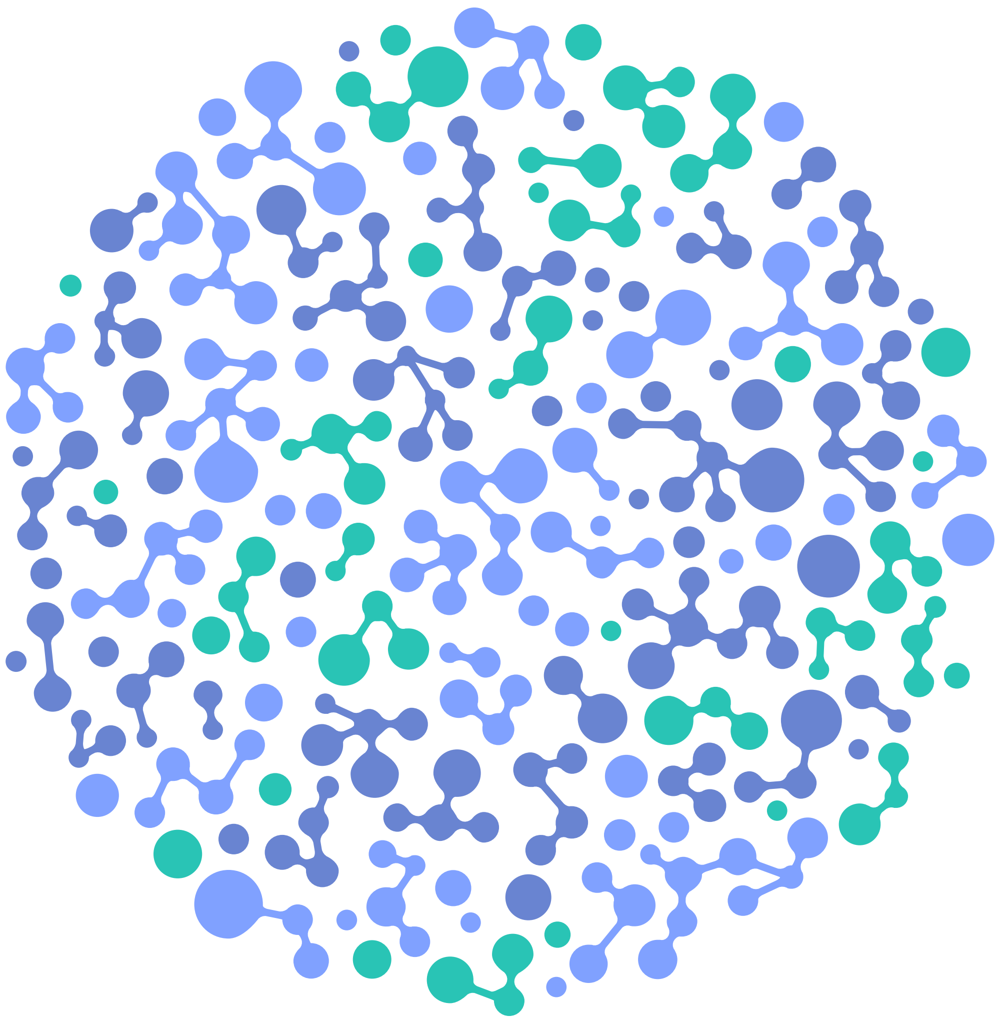
Deloitte.



Life Sciences Industry Accounting Guide

Consolidation

March 2021

Other Deloitte Publications

Other Deloitte publications, such as our Roadmap Series, are available on the Deloitte Accounting Research Tool (DART), a comprehensive online library of accounting and financial disclosure literature. The Roadmap series includes titles on the following topics:

Business Combinations

Business Combinations — SEC Reporting Considerations

Carve-Out Transactions

Comparing IFRS Standards and U.S. GAAP

Consolidation — Identifying a Controlling Financial Interest

Contingencies, Loss Recoveries, and Guarantees

Contracts on an Entity's Own Equity

Convertible Debt

Current Expected Credit Losses

Debt

Distinguishing Liabilities From Equity

Earnings per Share

Environmental Obligations and Asset Retirement Obligations

Equity Method Investments and Joint Ventures

Equity Method Investees — SEC Reporting Considerations

Fair Value Measurements and Disclosures (Including the Fair Value Option)

Foreign Currency Transactions and Translations

Guarantees and Collateralizations — SEC Reporting Considerations

Impairments and Disposals of Long-Lived Assets and Discontinued Operations

Income Taxes

Initial Public Offerings

Leases

Noncontrolling Interests

Non-GAAP Financial Measures and Metrics

Revenue Recognition

SEC Comment Letter Considerations, Including Industry Insights

Segment Reporting

Share-Based Payment Awards

Statement of Cash Flows

Transfers and Servicing of Financial Assets

Contents

Preface

The life sciences ecosystem encompasses a wide array of entities that discover, develop, and manufacture health care products. Such entities include pharmaceutical manufacturers; biotechnology companies; medical device, diagnostic, and equipment manufacturers; and service companies such as drug distributors, contract research organizations (CROs), contract manufacturing organizations (CMOs), and health technology companies.

Finance and accounting professionals in the industry face complex issues and must exercise significant judgment in applying existing rules to matters such as research and development (R&D) costs, acquisitions and divestitures, consolidation, contingencies, revenue recognition, income taxes, financial instruments, and financial statement presentation and disclosure. The 2021 edition of Deloitte's *Life Sciences Industry Accounting Guide* (the "Guide") addresses these and other relevant topics affecting the industry this year. It includes interpretive guidance, illustrative examples, recent standard-setting developments (through February 28, 2021), and key differences between U.S. GAAP and IFRS® Standards. In addition, this Guide discusses accounting and financial reporting considerations associated with the coronavirus disease 2019 ("COVID-19") pandemic that apply specifically to the life sciences industry.

Appendix B lists the titles of standards and other literature we cited, and Appendix C defines the abbreviations we used.

We hope this Guide is helpful in navigating the various accounting and reporting challenges that life sciences entities face. We encourage clients to contact their Deloitte team for additional information and assistance.

Contacts

Jeff Ellis
U.S. and Global Audit Leader — Life Sciences
Life Sciences Industry Professional Practice Director
Deloitte & Touche LLP
+1 412 338 7204
jeellis@deloitte.com

Dennis Howell
Senior Communications Partner, Accounting and Reporting Services
Life Sciences Deputy Industry Professional Practice Director
Deloitte & Touche LLP
+1 203 761 3478
dhowell@deloitte.com

Chapter 5 — Consolidation

5.1 Introduction

Life sciences entities enter into a variety of arrangements with other parties to facilitate the research, development, or sale of their IP or products. Because life sciences entities may absorb the risks and rewards of other parties through interests other than those based on traditional voting equity, they must carefully analyze their arrangements with those parties to determine whether to consolidate them. However, it is important to note that the guidance discussed in this chapter is only applicable to arrangements that are structured in a separate legal entity and is not applicable to collaborative arrangements because those arrangements are not primarily conducted through a separate legal entity. See Section 2.2.1 for accounting considerations relevant to collaborative arrangements.

The dual consolidation model under U.S. GAAP, which comprises the variable interest entity (VIE) model and the voting interest entity model, is designed to ensure that the reporting entity that consolidates another legal entity has a controlling financial interest in that legal entity. Under the voting interest entity model, a reporting entity with ownership of a majority of the voting interests of a legal entity is generally considered to have a controlling financial interest in the legal entity. Under the VIE model, the evaluation of whether the reporting entity has a controlling financial interest in a VIE focuses on (1) the obligation to absorb losses of, or the right to receive benefits from, the legal entity that could potentially be significant to the legal entity and (2) the power to direct the activities that most significantly affect the legal entity's economic performance.

5.2 Consolidation Decision Trees

ASC 810-10-05-6 contains a flowchart that consists of a series of decision trees to help reporting entities identify (1) which consolidation model to apply, if any; (2) whether a reporting entity should consolidate a VIE; and (3) whether a reporting entity should consolidate a voting interest entity. See Deloitte's *A Roadmap to Consolidation — Identifying a Controlling Financial Interest* ("Consolidation Roadmap") for a flowchart that incorporates the concepts in the FASB's flowchart and serves as a guide to the consolidation accounting literature.

5.3 Industry Issues

The discussions and examples below contain guidance on consolidation matters that frequently affect life sciences entities. The guidance cited is not intended to be all-inclusive or comprehensive; rather, it provides targeted considerations that are most relevant to the industry. To complete a consolidation analysis, entities must consider all facts and circumstances and use significant judgment. The examples cited will be beneficial in introducing concepts as you approach the evaluation of variable interests.

5.3.1 Business Scope Exception to the VIE Model

When determining whether it is required to consolidate a legal entity under ASC 810-10, a reporting entity should evaluate whether (1) it qualifies for a general scope exception to the consolidation guidance or (2) the legal entity qualifies for a scope exception to the VIE model. The most frequently cited scope exception in ASC 810-10 is the so-called business scope exception to the VIE model. (For a list of all general scope exceptions to the consolidation guidance and a list of all scope exceptions to the VIE model, see Chapter 3 of Deloitte's Consolidation Roadmap.)

The business scope exception is two-pronged and premised on both (1) the legal entity's characteristics (i.e., whether it is a business as defined in ASC 805, and its activities) and (2) the reporting entity's relationship with the legal entity (i.e., the extent of involvement by the reporting entity in the design or redesign of the legal entity, whether the legal entity is designed so that substantially all of its activities either involve or are conducted on behalf of the reporting entity and its related parties, and whether the reporting entity and its related parties provided more than half of the subordinated financial support). A common oversight in evaluating the applicability of the business scope exception is merely assessing whether a legal entity meets the definition of a business and failing to determine whether any of the four conditions in ASC 810-10-15-17(d) are met. Two of these conditions, which may be especially relevant to life sciences entities, are further discussed in Sections 5.3.1.1 and 5.3.1.2 below.

5.3.1.1 Whether Substantially All of the Activities Either Involve or Are Conducted on Behalf of the Reporting Entity and Its Related Parties

A reporting entity should base its determination of whether substantially all of a legal entity's activities either involve or are conducted on behalf of the reporting entity and its related parties on the design of the legal entity and should compare the nature and extent of the activities between the reporting entity and the legal entity with the **entire set** of the legal entity's activities. For this determination, related parties include all parties identified in ASC 810-10-25-43 except for de facto agents as described in ASC 810-10-25-43(d). Generally, if 90 percent or more of the legal entity's activities are conducted on behalf of a reporting entity and its related parties, it is presumed to be "substantially all" of the legal entity's activities. However, less than 90 percent is not a safe harbor. While a variety of conditions may indicate that substantially all of the activities of a legal entity are conducted on behalf of a reporting entity and its related parties, in the context of the life sciences industry, one such condition would be when a reporting entity holds the rights to products that result from the R&D of a legal entity.

Example 5-1

A joint venture entity (Entity P) is formed by two unrelated parties, Enterprises U and G. Each investor has a 50 percent equity interest. Entity P's activities consist solely of developing pharmaceutical products, and the reporting entity, U, has the rights to the resulting products. As currently designed, P represents a development arm of U's business because it is so closely aligned with U in appearance and purpose. Therefore, substantially all of P's activities either involve or are conducted on behalf of U and, accordingly, the business scope exception cannot be applied by U.

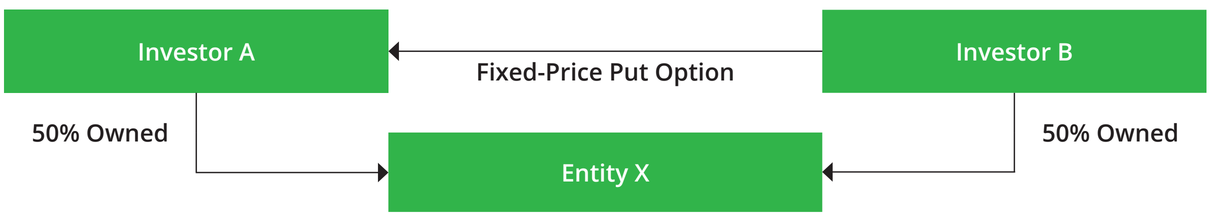
5.3.1.2 Additional Subordinated Financial Support — Put and Call Options

A put or call option in an agreement between equity owners of a life sciences legal entity (e.g., between joint venture partners) can have an impact on whether a reporting entity meets the condition in ASC 810-10-15-17(d)(3) and, therefore, on whether it can apply the business scope exception. The examples below illustrate situations in which (1) a put option (purchased by one investor from the reporting entity) results in the reporting entity's ineligibility for the business scope exception since the reporting entity effectively provides more than half of the total equity, subordinated debt, and other forms of subordinated financial support to the legal entity and (2) a call option would not have the same impact.

Example 5-2

Put Option

Investor A and Investor B form Entity X with equal contributions of equity. Investor B purchases a put option from A that permits it to put its interest in X to A at a fixed price.

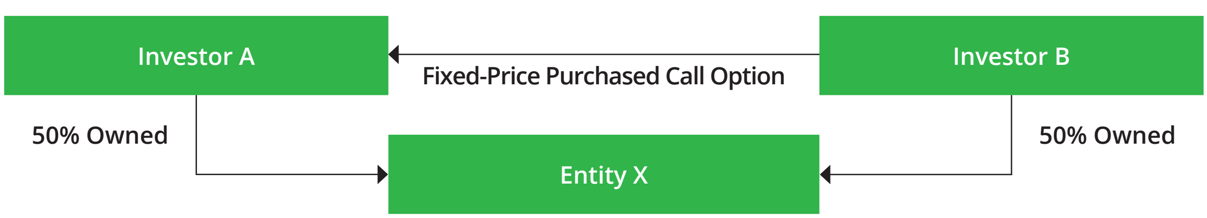


The fair value of the fixed-price put option should be considered additional subordinated financial support provided by A to X because A will absorb expected losses of X upon exercise of that put option (i.e., it meets the definition of subordinated financial support in ASC 810-10-20). Therefore, A would consider the fair value of the fixed-price put option (presumably the price paid) in determining whether the condition in ASC 810-10-15-17(d)(3) is met. If the fair value of the put option is greater than zero, A would meet this condition and therefore would not be able to use the business scope exception since the fair value of the equity provided by A and the fair value of the put option written by A would constitute more than half the total of the equity, subordinated debt, and other forms of subordinated financial support to the legal entity.

Example 5-3

Call Option

Investor A and Investor B form Entity X with equal contributions of equity. Investor A purchases a call option from B that permits it to call B's interest at a fixed price (the call option's strike price is at or above the fair value of the equity interest at inception of the option).



Example 5-3 (continued)

The fair value of the fixed-price call option should not be considered additional subordinated financial support to X because A will not absorb expected losses of X upon exercise of that call option (i.e., the option does not meet the definition of subordinated financial support in ASC 810-10-20). Investor A can exercise its call and obtain additional residual returns of X, but the call option does not expose it to additional expected losses. Therefore, A would not consider the fair value of the fixed-price call option in determining whether it meets the condition in ASC 810-10-15-17(d)(3). Investors A and B would not meet this condition since the fair value of the equity provided by each investor would not constitute more than half of the total of the equity, subordinated debt, and other forms of subordinated financial support to the legal entity. To use the business scope exception, A and B must determine whether the other conditions in ASC 810-10-15-17(d) are met.

5.3.2 Identifying Variable Interests

One of the first steps in assessing whether a reporting entity is required to consolidate another legal entity is to determine whether the reporting entity holds a variable interest in the legal entity being evaluated for consolidation. If a reporting entity determines that it does not have a variable interest in the legal entity, no further analysis is required. That is, that reporting entity is not required to consolidate the legal entity or provide any of the VIE disclosures related to the legal entity. While there are many forms of variable interests, all variable interests will **absorb** portions of a VIE's variability (changes in the fair value of the VIE's net assets exclusive of variable interests) that the legal entity was designed to create. An interest that **creates** variability would not be considered a variable interest.

The FASB established a two-step "by-design" approach for the identification of variable interests. Under this approach as outlined in ASC 810-10-25-22, the reporting entity would (1) "[a]nalyze the nature of the risks in the legal entity" and (2) "[d]etermine the purpose(s) for which the legal entity was created and determine the variability (created by the risks identified in Step 1) the legal entity is designed to create and pass along to its interest holders." ASC 810-10-20 defines variable interests in a VIE as "contractual, ownership, or other pecuniary interests in a VIE that change with changes in the fair value of the VIE's net assets exclusive of variable interests."

It is often simple to identify whether a contract or arrangement is a variable interest. A good rule of thumb is that most arrangements on the credit side of the balance sheet (e.g., equity and debt) are variable interests because they absorb variability as a result of the performance of the legal entity. However, identifying whether other arrangements (e.g., derivatives, leases, and decision-maker and other service-provider contracts) are variable interests can be more complex. The table below contains a very limited list of examples of what may be considered variable interests.

Examples of Variable Interests	Illustrative Fact Patterns
Long-term liabilities of a legal entity (e.g., fixed-rate debt, floating-rate debt, mandatorily redeemable preferred stock)	Company A (the reporting entity) lends Company D, a biotech firm, $50 million in the form of a five-year fixed-rate unsecured loan. Company A, as a debt holder, absorbs the variability in the value of D's net assets exclusive of variable interests because A is exposed to D's ability to pay (i.e., credit risk) and may also be exposed to interest rate risk depending on the design of the legal entity.
Equity of a legal entity (e.g., mezzanine equity, preferred stock, common stock, partnership capital)	Company S (the reporting entity) invests $89 million in Company M, a CRO. The equity investment was made in common stock and is considered equity at risk under ASC 810-10-15-14(a) (which is further discussed below). Company S's interest in M is a variable interest that absorbs the variability associated with changes in M's net assets exclusive of variable interests.

(Table continued)

Examples of Variable Interests	Illustrative Fact Patterns
Guarantees written by a reporting entity[1]	Company C (the reporting entity) provides a guarantee to a medical device company, Company B, on the $2 billion fair value of all medical device IP held by B. Company C must pay B for any decreases in value of this IP. The guarantee agreement transfers all or a portion of the risk of specified assets (IP) to C; thus, C has a variable interest in B.
Put options written by a reporting entity for a price other than fair value (e.g., fixed-price) and similar arrangements on specified assets owned by the legal entity[2]	Company H (the reporting entity) writes a put option to Company W allowing W to sell its medicinal compound in development for a fixed price at a later date. Company H has a variable interest in the specified assets of W since H is exposed to variability in the values of the medicinal compound.
Stand-alone call options written by the legal entity on specified assets owned by that legal entity[3]	Company S writes a call option on its wholly owned interest in a treatment in phase II clinical trials to Company D (the reporting entity), allowing D to acquire the interest for a fixed price at a later date. Because D participates in the positive variability of the specified assets of S, D possesses a variable interest in those specified assets.
Fees paid to a decision maker or service provider	Company S pays a fee to Company R (the reporting entity) to distribute S's products. The fee arrangement requires S to pay R all profits earned on the distribution of the products. The fee arrangement is designed to transfer substantially all of the residual returns and risks of ownership of S's products to R, the decision maker. In accordance with ASC 810-10-55-37C, R's earned fee represents a variable interest in S.
Contingent payments made to a reporting entity	Company C (the reporting entity) holds rights to a pharmaceutical drug. Company W obtains a license from C to produce, market, and sell the drug, and C will earn a royalty based on W's sales. Company C holds a variable interest in W because it absorbs variability through the royalty.

The table below lists examples (not all-inclusive) of what generally would not be considered variable interests.

Examples of Nonvariable Interests	Illustrative Fact Patterns
Assets of the legal entity	Company D (the reporting entity) owes $100 million to Company P as part of an existing loan agreement. Although the loan receivable asset generates value to the investors of P, the loan receivable is not a variable interest to D. Assets typically are the major source of a legal entity's variability and are therefore not considered variable interests.
Contingent payments made to a legal entity	Company E (the reporting entity) enters into an agreement with Company C to continue the R&D of a phase I drug held by C. In exchange for the drug's achievement of milestones, such as FDA approval and the achievement of specified sales levels, E will make milestone payments and pay C royalties. Company E is not exposed to the variability in C and therefore does not possess a variable interest through its milestone or royalty payments.

[1] ASC 810-10-25-55 and 25-56 indicate that variable interests in a specified asset whose value is less than half of the total fair value of a VIE's assets are not considered variable interests in that legal entity unless the reporting entity also holds another interest in the legal entity. In addition, a variable interest in a specified asset of a VIE could result in consolidation of a "silo" within the VIE. For further discussion, see Section 4.3.11 and Chapter 6 of Deloitte's Consolidation Roadmap.

[2] See footnote 1.

[3] See footnote 1.

Discussion of the by-design approach for identifying variable interests, along with a more expansive list of examples of variable interests, is included in Chapter 4 of Deloitte's Consolidation Roadmap.

5.3.3 Determining Whether a Legal Entity Is a VIE

To determine which consolidation model a reporting entity should apply to evaluate its variable interest in a legal entity, the reporting entity must determine whether the legal entity is a VIE. This determination must be made upon the reporting entity's initial involvement with a legal entity and reassessed upon the occurrence of a reconsideration event.

Legal entities can differ in structure as well as legal form (e.g., corporations compared with limited partnerships and similar entities), which affects the method used to understand their design and purpose. In simple terms, the distinction is based on the nature and amount of the equity investment and the rights and obligations of the equity investors. If a legal entity has sufficient equity investment at risk to finance its operations, and those equity investors, through their equity investment at risk, make decisions that direct the significant activities of the legal entity, consolidation based on majority voting interest is generally appropriate. However, if equity is not sufficient, or the equity investors do not control the legal entity through their equity investment, the VIE model is used to identify the appropriate party, if any, to consolidate.

To qualify as a VIE, a legal entity needs to satisfy only one of the following characteristics:

- The legal entity does not have sufficient equity investment at risk.
- The equity investors at risk, as a group, lack the characteristics of a controlling financial interest.
- The legal entity is structured with disproportionate voting rights, and substantially all of the activities are conducted on behalf of an investor with disproportionately few voting rights.

Sections 5.3.3.1 through 5.3.3.3 below discuss a brief list of considerations specifically relevant to life sciences entities for determining whether a legal entity is a VIE. Since this list is not all-encompassing, we encourage you to refer to Chapter 5 of Deloitte's Consolidation Roadmap during your analysis.

5.3.3.1 Sufficiency of Equity

A legal entity is not a VIE under this criterion if its total equity investment at risk is sufficient to finance its activities without additional subordinated financial support. To determine whether there is sufficient equity investment at risk to permit the legal entity to finance its activities without additional subordinated financial support, a reporting entity must perform the following three steps:

- *Step 1* — Identify whether an interest in a legal entity is considered GAAP equity.
- *Step 2* — Determine whether the equity investment is "at risk" on the basis of the equity investment population.
- *Step 3* — Determine whether the identified equity investment at risk is sufficient to finance the legal entity's operations without additional subordinated financial support.

Sections 5.3.3.1.1 through 5.3.3.1.4 below highlight certain considerations related to steps 2 and 3.

5.3.3.1.1 Determining Whether the Equity Investment Is "At Risk"

An interest classified as equity may not have the substantive characteristics of equity. Since the VIE consolidation framework is intended to apply to entities whose voting interests may not be the most appropriate determining factor in the identification of which party should consolidate, the FASB reasoned that equity interests that are not "at risk" should not be included in the sufficiency-of-equity test. To be considered part of the equity investment at risk, equity interests must:

- Participate significantly in profits and losses.
- Not be issued in exchange for subordinated interests in other VIEs.
- Not be received from the legal entity or by parties involved with the legal entity unless that party is a parent, a subsidiary, or an affiliate of the investor that is required to be included in the same set of consolidated financial statements as the investor.
- Not be financed by the legal entity or other parties involved with the legal entity unless that party is a parent, a subsidiary, or an affiliate of the investor that is required to be included in the same set of consolidated financial statements as the investor.

Further, equity investments acquired by an equity investor in exchange for promising to perform services cannot be included in equity investment at risk, because the equity is received in lieu of a fee for services performed. Similarly, equity investments acquired as a result of past services performed are not considered equity investment at risk.

Example 5-4

Three investors form Entity X to conduct R&D activities. Entity X issues equity with a par amount of $15 million ($5 million to each investor). Investor A contributes $5 million in cash. Investor B issues a guarantee that the fair value of the compound at the completion of the R&D activities will be at least $90 million. Investor C enters into an agreement with X to provide research scientists who will each work for 500 hours to complete the activities.

Only A's $5 million in equity is considered equity at risk because B and C received their equity as payment from X for the guarantee (promise to stand ready) and the performance of services, respectively.

5.3.3.1.2 Determining Whether the Identified Equity Investment at Risk Is Sufficient to Finance the Legal Entity's Operations Without Additional Subordinated Financial Support

Once the amount of equity investment at risk is quantified, a reporting entity must determine whether the equity investment at risk is sufficient to finance the legal entity's operations without additional subordinated financial support. If not, the legal entity is a VIE. The purpose of this assessment is to identify whether a legal entity is sufficiently capitalized. Merely having at-risk equity is not enough; the legal entity must be able to finance its operations with the equity investment at risk. The reporting entity must use judgment to determine sufficiency since the various risk tolerances, investment objectives, and liquidity requirements of investing can influence the level of capital in a legal entity.

5.3.3.1.3 Existence of Subordinated Debt

In a qualitative assessment of the sufficiency of equity investment at risk, the existence of subordinated debt is a factor indicating that a legal entity's total equity investment at risk may not be sufficient to absorb expected losses. That is, by virtue of its subordination, subordinated debt is expected to absorb expected losses beyond a legal entity's equity investment at risk. However, the existence of subordinated debt should not be considered determinative in itself; an evaluation of the sufficiency of equity at risk should be based on all facts and circumstances.

In the evaluation of whether equity investment at risk is sufficient, consideration should also be given to whether the entity has outstanding, or could issue, investment-grade debt since such debt is typically issued only when third parties deem a legal entity to be sufficiently capitalized. If debt is subordinated to other variable interests, equity investment at risk may be insufficient to finance the legal entity's operations. The determination of whether debt represents subordinated financial support is based on how that debt absorbs expected losses compared with other variable interests in the legal entity. If the terms of the debt arrangement cause the debt to absorb expected losses before or at the same level as the most subordinated interests (e.g., equity, other subordinated debt), or the most subordinated interests are not large enough to absorb the legal entity's expected losses, the debt would generally be considered subordinated financial support. However, investment-grade debt is a variable interest that would generally not be considered subordinated financial support because investment-grade debt generally indicates that third parties deem the legal entity to be sufficiently capitalized.

Example 5-5

Entity D is formed with $50 of equity and $50 of long-term debt. The long-term debt consists of two issuances: Debt A, $45, and Debt B, $5. Debt B is subordinate to Debt A. Because D was recently formed, it could not obtain senior debt (Debt A) in an investment-grade form.

In a qualitative assessment, the existence of subordinated debt is a factor indicating that D does not have sufficient equity at risk. That factor should be considered along with all other facts and circumstances (e.g., a 50 percent ratio of equity at risk frequently exceeds expected losses). If the qualitative assessment is inconclusive, a quantitative analysis (i.e., calculation of expected losses/residual returns) should be performed to determine whether D is a VIE.

Assume that D was a VIE at formation. Two years after its formation, D engages in additional business activities beyond those that were considered at formation and is an established, profitable business. Given its desire to further expand its business, D issues a new tranche of debt (Debt C) whose rank is identical in seniority (e.g., priority in liquidation) to that of Debt B. Because of D's stable financial condition, the tranche of debt is rated investment-grade. Given the identical priority in liquidation of Debt B and Debt C, one can infer that Debt A (which is senior to Debt B) and Debt B would be rated investment-grade as well. No other debt securities are outstanding, and no other evidence of subordinated financial support (e.g., guarantees) is noted. Assume that a reconsideration event under ASC 810-10-35-4(c) has occurred because the additional business activities increase D's expected losses. Therefore, the variable interest holders must determine whether D is still a VIE.

In a qualitative assessment, D's ability to issue investment-grade debt that has the same priority in liquidation as Debt B is one factor indicating that D, as of the reconsideration date, has sufficient equity at risk. That is, in the absence of other forms of subordinated financial support, D would not have been able to obtain an investment-grade rating on the new debt if its existing equity at risk was not sufficient. However, all other facts and circumstances existing as of the reconsideration date should be considered. If the qualitative assessment is not conclusive, a quantitative analysis should be performed to determine whether D is a VIE as of the reconsideration date.

5.3.3.1.4 Development-Stage Entities

Since life sciences entities frequently require varying levels of funding to complete a product candidate's R&D, it is important for such entities to understand the "sufficiency of the equity investment at risk" characteristic in the VIE analysis when evaluating the funding of each R&D phase.

Before the adoption of ASU 2014-10,[4] certain entities could qualify for specialized accounting under ASC 915 as development-stage entities. Such entities were, by definition, in a stage of development as

[4] ASU 2014-10 eliminated the specialized approach for considering sufficiency of equity investment at risk for development-stage entities. The ASU is effective for PBEs for annual periods beginning after December 15, 2015, and interim periods therein. For entities other than PBEs, the guidance is effective for annual periods beginning after December 15, 2016, and interim periods beginning after December 15, 2017. As a result of these effective dates and early adoption, virtually all entities have adopted the ASU. Reporting entities that have historically applied this exception should consider the impact of ASU 2014-10 on their historical conclusions.

opposed to conducting operations in accordance with their principal plan. Accordingly, those qualifying entities differed in nature from other entities, often being capitalized only to the extent required to perform a specific task related to development.

Although ASU 2014-10 removed the concept of a development-stage entity, we believe that it is still necessary to consider the design of a legal entity in the determination of whether its equity investment at risk is sufficient. That is, considering only the legal entity's current stage of development may be appropriate in the assessment of sufficiency of equity. Specifically, if a legal entity is in the development stage **and** there is substantial uncertainty about whether the legal entity will proceed to the next stage, it may be appropriate to consider only the current stage in the sufficiency assessment. This approach is consistent with the assessment of power of a multiple-stage entity.

A reporting entity should initially assess whether a development-stage entity is a VIE on the date on which it first becomes involved with the legal entity. This assessment must be reconsidered upon the occurrence of any of the events in ASC 810-10-35-4. For a development-stage entity, this would include, but not be limited to:

- Funding of additional equity.
- Commencement of additional activities (e.g., entering a subsequent "phase" of development).

Example 5-6

Entity D is a development-stage entity. Investor A and Investor B each contributed $1 million of equity financing to D. Entity D's current activities consist of product development and marketing surveys ("phase I"). Upon successful completion of phase I, D plans to commence test marketing (i.e., selling the products in selected areas) ("phase II"). During the final phase of D's development stage, it plans to engage in limited-scale production and selling efforts ("phase III"). Entity D's by-laws allow A and B to fund additional equity upon the completion of phase I and phase II. However, it is not certain that D will proceed to phase II.

In the assessment of whether D has sufficient equity at risk under ASC 810-10-15-14(a), only the current phase of D's development needs to be considered. Thus, if, at inception, the $2 million of equity capital is deemed sufficient to finance phase I, D would be considered to have sufficient equity investment at risk. This determination should be reassessed at the commencement of phase II and phase III, upon the funding of additional equity financing, or upon the occurrence of any of the events in ASC 810-10-35-4.

5.3.3.2 Equity Investors, as a Group, Lack the Characteristics of a Controlling Financial Interest

A reporting entity determines whether it holds a **controlling financial interest** in a legal entity differently under the VIE model than it does under the voting interest entity model. The voting interest entity model focuses on the voting rights conveyed by equity interests. Since the holder of an interest other than equity may control the legal entity, the voting interest entity model may not yield an appropriate consolidation conclusion if the equity interests collectively do not possess the characteristics that are typical of equity interests. Accordingly, a legal entity is considered a VIE if the at-risk holders **as a group**, through their equity investment at risk, lack any of the following three qualities, which are the "typical" characteristics of an equity investment:

- The power to direct the most significant activities of the legal entity.
- The obligation to absorb the expected losses of the legal entity.
- The right to receive the expected residual returns of the legal entity.

The rights of the equity investor group must be a characteristic of the equity interest itself and not a characteristic of other interests held by the current holders of the equity interest. Each individual equity investment at risk need not possess all three characteristics, but the total equity investment at risk must possess them all. By implication, as long as the group of equity investors possesses these three characteristics, the failure of any one at-risk equity investor to possess the characteristics would not make the legal entity a VIE.

Example 5-7

Company S holds the patent to a phase II drug, which represents 80 percent of the fair value of the assets held by S. Company S issues to B a fixed-price call option on the phase II drug that is exercisable in one year. The right of S to receive the expected residual returns is effectively capped because of B's ability to participate in the upside through its call option. Consequently, S is a VIE.

5.3.3.3 Nonsubstantive Voting Rights

Although intended to clarify ASC 810-10-15-14(b)(1), ASC 810-10-15-14(c) is generally considered a separate condition in the assessment of a VIE. ASC 810-10-15-14(c)(2) explains that the provision "is necessary to prevent a primary beneficiary from avoiding consolidation of a VIE by organizing the legal entity with nonsubstantive voting interests." Thus, ASC 810-10-15-14(c) is often referred to as the "anti-abuse provision" since it aims to prevent a legal entity from being structured in a manner in which a party does not have voting control but in substance should be consolidated by a reporting entity that meets the "substantially all" criteria. See Section 5.4 of Deloitte's Consolidation Roadmap for more interpretive guidance on evaluating this criterion.

5.3.3.4 SEC Comment Letter Themes Related to the Determination of Whether a Legal Entity Is a VIE

Example of an SEC Comment

We note from your prior response that you believe you should consolidate [the legal entity] under either the variable interest or voting interest models. Please tell us how you considered ASC 810-10-15-14 in determining whether [the legal entity] has the characteristics of a variable interest entity.

Recent SEC comments on ASC 810 have focused primarily on the VIE model. The SEC staff often asks registrants to (1) explain their involvement with, and the structure of, VIEs and (2) provide detailed support for their conclusions about whether an entity is a VIE (including the consolidation model they ultimately used). In addition, the SEC staff may ask registrants to discuss any events affecting their previous consolidation conclusion (e.g., events that result in deconsolidation).

5.3.4 Determining the Primary Beneficiary of a VIE

The primary beneficiary of a VIE is the party required to consolidate the VIE (i.e., the party with a controlling financial interest in the VIE). The analysis for identifying the primary beneficiary is consistent for all VIEs. Specifically, ASC 810-10-25-38A requires the reporting entity to perform a qualitative assessment that focuses on whether the reporting entity has both of the following characteristics of a controlling financial interest in a VIE:

- *Power* — The power to direct the activities of the VIE that most significantly affect the VIE's economic performance.
- *Economics* — The obligation to absorb losses or the right to receive benefits of the VIE that could potentially be significant to the VIE.

These two concepts are discussed below. For more detailed information, see Chapter 7 of Deloitte's Consolidation Roadmap.

5.3.4.1 Power Criterion

Although identification of the primary beneficiary requires an evaluation of both characteristics of a controlling financial interest in a VIE, the determination is often based on which variable interest holder satisfies the power criterion since generally more than one variable interest holder meets the economics criterion.

To determine whether it meets the power criterion, the reporting entity must identify the activities that most significantly affect the VIE's economic performance and then determine which variable interest holder has the power to direct those activities. The reporting entity would take the following steps to identify the party with the power to direct the activities that most significantly affect the VIE's economic performance:

- *Step 1* — Evaluate the purpose and design of the VIE and the risks the VIE was designed to create and pass along to its variable interest holders.
- *Step 2* — Identify the activities related to the risks identified in step 1 that most significantly affect the economic performance of the VIE. In certain situations in which multiple unrelated variable interest holders direct different activities, the reporting entity must determine which activity most significantly affects the VIE's economic performance. The party that has the power to direct such activity will meet the power criterion. When making this determination, the reporting entity should consider the activity that results in the most economic variability for the VIE (e.g., expected losses and expected residual returns).
- *Step 3* — Identify the party that makes the significant decisions or controls the activity or activities that most significantly affect the VIE's economic performance. Consider whether any other parties have involvement in those decisions (shared power) or can remove the decision maker (kick-out rights).

While a VIE often performs a variety of activities, the key to determining whether the power criterion has been satisfied is identifying the activities that are most significant to the VIE's economic performance.

5.3.4.1.1 Contingencies

Future power can be conveyed to a variable interest holder only upon the occurrence of a contingent event. Questions have arisen about whether such a variable interest holder can be the primary beneficiary of the VIE before the occurrence of that contingent event. When a party can direct activities only upon the occurrence of a contingent event, the determination of which party has power will require an assessment of whether the contingent event results in a **change in power** (i.e., power shifts from one party to another upon the occurrence of a contingent event) over the most significant activities of the VIE (in addition, the contingent event may change what the most significant activities of the VIE are) or whether the contingent event **initiates** the most significant activities of the VIE (i.e., the VIE's most significant activities only occur when the contingent event happens).

Example 5-8

Entity X is formed by two investors (A and B) to develop and manufacture a new drug. Assume that X is a VIE and that each investor holds a variable interest in X. Investor A has power over the R&D activities to develop and obtain FDA approval for the drug (stage 1), and those activities most significantly affect X's economic performance during that stage. Investor B has the power over the manufacturing process, distribution, and marketing of the drug (as well as protecting its patented formula) if and when FDA approval is obtained (stage 2), and those activities would most significantly affect X's economic performance during that stage. In determining which investor has the power to direct the activities that most significantly affect the economic performance of X, each investor should assess whether the contingent event (FDA approval) results in a **change in power** over the most significant activities of X (in addition, the contingent event may change what the most significant activities of X are) or whether the contingent event **initiates** the most significant activities of X.

Entity X was designed in such a way that there are two distinct stages during its life, and the variable interest holders expect that the second stage will begin only upon FDA approval. Also, the activities and decisions before and after FDA approval are significant to the economic performance of X (in this example, they are different activities directed by different parties). In addition, the variable interest holders conclude that there is substantial uncertainty about whether FDA approval will be obtained and that the approval is outside their control. For these reasons, in the absence of evidence to the contrary, FDA approval would be considered a substantive contingent event that results in a **change in power** from A to B. Therefore, the primary-beneficiary determination should focus on stage 1 activities until the contingent event occurs, and A (the investor that has the power over the R&D activities) would initially have the power to direct the most significant activities of X. If FDA approval is obtained, the primary-beneficiary determination would focus on stage 2 activities, and B (the variable interest holder that has the power over the manufacturing process, distribution, and marketing of the drug) would have the power to direct the most significant activities of X.

5.3.4.2 Economics Criterion

To satisfy the economics criterion in the analysis of the primary beneficiary of a VIE, the variable interest holder must have the obligation to absorb losses of the VIE, or the right to receive benefits from the VIE, that could potentially be significant to the VIE. Said simply, the variable interest holder must have an exposure to the economics of the VIE that is more than insignificant. As a general guideline, the economics criterion would be met if the losses or returns absorbed through the reporting entity's variable interests in the VIE exceed, either individually or in the aggregate, 10 percent of the losses or returns of the VIE under any scenario. However, 10 percent should not be viewed as a bright-line or safe harbor definition of "insignificant." That is, as a result of facts and circumstances, a reporting entity may conclude that the economics condition is met even if the losses or returns absorbed by the reporting entity's interests in the VIE are less than 10 percent. Because more than one variable interest holder typically meets the economics criterion, most of the primary-beneficiary analysis is focused on assessing which variable interest holder or holders have power over the activities that most significantly affect the VIE's economic performance.

5.3.4.3 SEC Comment Letter Themes Related to the Primary-Beneficiary Assessment

Examples of SEC Comments

- Please describe to us the changes in the capital structure of [the legal entity] and in its contractual relationships with [you, as the reporting entity,] that resulted in your conclusion that you are no longer its primary beneficiary and that you should deconsolidate [the legal entity]. Explain to us in appropriate detail how these specific changes support your conclusion that you are no longer the primary beneficiary of the variable interest entity. Refer to the guidance provided in ASC 810-10, including ASC 810-10-35-4.

Examples of SEC Comments (continued)

- Please tell us how you concluded you are the primary beneficiary of [the VIEs] considering your disclosure that the power to direct the activities of the VIEs is shared. In addition, tell us why the general partners of the limited partnerships do not have standalone power given that they only need your consent over certain activities. Please refer to FASB ASC 810-10-25-38D.
- It appears that your conclusion for being the primary beneficiary of the subject entities is based upon your power arising from your capacity as a decision maker ("manager"). Please explain to us, in detail, your consideration of the guidance in ASC 810-10-55-37 to 37D and 55-38.

Given that the SEC staff continues to focus on consolidation conclusions under ASC 810-10, it often asks registrants to discuss the basis for their determination of whether they are the primary beneficiary of a VIE.

5.3.5 Other Considerations

Example of an SEC Comment

We note you consolidate entities in which you have a variable interest and of which you are the primary beneficiary. Please tell us what consideration you gave to disclosing the information required by ASC 810-10-50-2AA regarding your involvement with variable interest entities, the information required by ASC 810-10-50-3 with respect to variable interest entities you consolidate as the primary beneficiary and the information required by ASC 810-10-50-4 with respect to variable interest entities you do not consolidate because you are not the primary beneficiary.

All reporting entities that have a variable interest in a VIE are subject to the disclosure requirements of ASC 810-10. Reporting entities should consider the overall objectives of ASC 810-10-50-2AA and, depending on the circumstances, may need to supplement their disclosures to meet these objectives. Meeting the disclosure requirements can sometimes be challenging because a reporting entity might not be privy to all information about a VIE, especially if the reporting entity is not the primary beneficiary of the VIE but has a variable interest in the VIE and is subject to some of the VIE's disclosure requirements. Given the nature of variable interests often held by life sciences entities in VIEs, it is important for life sciences entities to keep these disclosure requirements in mind when preparing financial statements.

Because this chapter is intended to highlight only some of the complex consolidation issues frequently encountered by life sciences entities, not all consolidation topics are discussed herein. For a comprehensive discussion of consolidation, see Deloitte's Consolidation Roadmap, which elaborates on the topics covered herein and also addresses additional topics that include, but are not limited to, (1) the assessment of related parties in the identification of variable interests and performance of the primary-beneficiary analyses, (2) consolidation evaluations under the voting interest entity model, and (3) special considerations related to limited partnerships and similar entities.

Further, for additional discussion of R&D funding arrangements that involve legal entities, see Section 3.2.1.

5.4 Targeted Improvements to the Related-Party Guidance for VIEs (ASU 2018-07)

In October 2018, the FASB issued ASU 2018-17, which amends two aspects of the related-party guidance in ASC 810. The ASU (1) adds an elective private-company scope exception to the VIE guidance for entities under common control and (2) removes a sentence from ASC 810-10-55-37D regarding the evaluation of fees paid to decision makers to conform that Codification paragraph with the amendments in ASU 2016-17.

5.4.1 Private-Company Alternative

ASU 2018-17 broadens the existing accounting alternative available to private companies by allowing all legal entities under common control to elect not to apply the VIE guidance as long as the reporting entity, the common-control parent, and the legal entity being evaluated for consolidation are not PBEs and meet the criteria in ASC 810-10-15-17AD (added by the ASU). ASC 810-10-15-17AD states, in part:

> A legal entity need not be evaluated by a private company (reporting entity) under the guidance in the Variable Interest Entities Subsections if all of the following criteria are met:
>
> a. The reporting entity and the legal entity are under common control.
>
> b. The reporting entity and the legal entity are not under common control of a public business entity.
>
> c. The legal entity under common control is not a public business entity.
>
> d. The reporting entity does not directly or indirectly have a controlling financial interest in the legal entity when considering the General Subsections of this Topic. The Variable Interest Entities Subsections shall not be applied when making this determination.

ASC 810-10-15-17AE (added by the ASU) provides guidance on applying criterion (a) above and establishes that *solely* for the purpose of applying criterion (a), a private-company reporting entity should consider *only* the voting interest model when determining whether the reporting entity and the legal entity are under common control. That is, a private-company reporting entity should not consider the VIE guidance when determining whether criterion (a) is met.

5.4.2 Evaluation of Fees Paid to a Decision Maker

ASU 2018-17 removes a sentence from ASC 810-10-55-37D to conform the guidance on the consideration of indirect interests held by related parties under common control in the variable interest analysis with the guidance on the consideration of those interests in the primary-beneficiary analysis. Under the amended guidance, such indirect interests should be considered on a proportionate basis rather than considered in their entirety.

5.4.3 Effective Date and Transition

For entities other than private companies, ASU 2018-17 is effective for fiscal years beginning after December 15, 2019, including interim periods therein. For private companies, the ASU is effective for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. Early adoption is permitted. Entities are required to apply the ASU's amendments retrospectively with a cumulative-effect adjustment to retained earnings at the beginning of the earliest period presented.

For more information about ASU 2018-17, see Deloitte's November 19, 2018, ***Heads Up***.

5.5 On the Horizon

5.5.1 Proposed ASU on Reorganizing the Consolidation Guidance

In September 2017, the FASB issued a proposed ASU that would reorganize the consolidation guidance in ASC 810 by creating a new Codification topic, ASC 812, with separate subtopics for the guidance on (1) the VIE model and (2) the voting interest entity model. The proposed ASU states that its goal is to make “navigating and understanding consolidation guidance easier without affecting how consolidation analyses are currently performed.” For additional information, see Deloitte’s October 5, 2017, *Heads Up*.

In June 2018, the FASB met to discuss comment letter feedback on the proposed ASU and decided to continue its existing project on reorganizing ASC 810. In addition, as stated in the FASB’s tentative Board decisions, the Board instructed its staff “to develop nonauthoritative educational material to address the more difficult parts of consolidation guidance with the goal of supporting and supplementing the reorganized authoritative consolidation guidance.”

5.5.2 Primary Beneficiary’s Accounting for IPR&D and Contingent Consideration Recognized Upon Initial Consolidation of a VIE That Is Not a Business

As discussed in Section 10.1.2 of Deloitte’s Consolidation Roadmap, the primary beneficiary of a VIE that is not a business should initially measure and recognize the assets and liabilities of the VIE in accordance with ASC 805-20-25 and ASC 805-20-30, and no goodwill should be recognized. Because goodwill is not recognized, the primary beneficiary recognizes a gain or loss calculated on the basis of the requirements in ASC 810-10-30-4. As further noted in Section C.1.2.1 of Deloitte’s *A Roadmap to Accounting for Business Combinations*, the primary beneficiary recognizes the identifiable assets acquired (excluding goodwill), the liabilities assumed, and any noncontrolling interests as though the VIE was a business and subject to the guidance on recognition and measurement in a business combination. As a result, the assets acquired (excluding goodwill), liabilities assumed, and any noncontrolling interests are measured and recognized the same way as they would be in a business combination. IPR&D and contingent consideration therefore would be recognized at fair value upon acquisition, and the applicable recognition and fair value measurement exceptions would be the same as those for a business combination. However, ASC 810 does not provide guidance on the subsequent accounting for IPR&D and contingent consideration, and the absence of such guidance has led to diversity in practice.

For example, a reporting entity may apply the subsequent accounting guidance for intangible assets acquired in a business combination in ASC 350. Alternatively, a reporting entity may conclude that because the VIE is not a business, it should subsequently account for IPR&D under ASC 730. That is, IPR&D with no alternative future use is recognized as an expense on the acquisition date.

At its May 8, 2019, agenda prioritization meeting, the FASB considered an agenda request to address the diversity in practice related to a primary beneficiary’s subsequent accounting for IPR&D and contingent consideration initially recognized upon consolidation of a VIE that is not a business. As stated in the tentative Board decisions, the FASB affirmed during its September 2, 2020, meeting that the scope of phase 3 of its project on the definition of a business should be expanded to include this issue. Practitioners should monitor the project for any developments that might change current accounting.

Appendix B — Titles of Standards and Other Literature

AICPA Literature

Accounting and Valuation Guides

Assets Acquired to Be Used in Research and Development Activities

Valuation of Privately-Held-Company Equity Securities Issued as Compensation

Audit and Accounting Guide

Revenue Recognition

Clarified Statements on Auditing Standards

AU-C Section 501, "Audit Evidence — Specific Considerations for Selected Items"

AU-C Section 620, "Using the Work of an Auditor's Specialist"

Issues Papers

Identification and Discussion of Certain Financial Accounting and Reporting Issues Concerning LIFO Inventories

86-2, *Accounting for Options*

Other

AICPA Technical Q&A Section 2260.03, "Other Assets; Legal Expenses Incurred to Defend Patent Infringement Suit"

FASB Literature

ASC Topics

ASC 105, *Generally Accepted Accounting Principles*

ASC 205, *Presentation of Financial Statements*

ASC 210, *Balance Sheet*

ASC 220, *Income Statement — Reporting Comprehensive Income*

ASC 230, *Statement of Cash Flows*

ASC 235, *Notes to Financial Statements*

ASC 250, *Accounting Changes and Error Corrections*

ASC 260, *Earnings per Share*

ASC 270, *Interim Reporting*

ASC 275, *Risks and Uncertainties*

ASC 280, *Segment Reporting*

ASC 310, *Receivables*

ASC 320, *Investments — Debt and Equity Securities*

ASC 321, *Investments — Equity Securities*

ASC 323, *Investments — Equity Method and Joint Ventures*

ASC 326, *Financial Instruments — Credit Losses*

ASC 330, *Inventory*

ASC 340, *Other Assets and Deferred Costs*

ASC 350, *Intangibles — Goodwill and Other*

ASC 360, *Property, Plant, and Equipment*

ASC 405, *Liabilities*

ASC 410, *Asset Retirement and Environmental Obligations*

ASC 420, *Exit or Disposal Cost Obligations*

ASC 450, *Contingencies*

ASC 460, *Guarantees*

ASC 470, *Debt*

ASC 480, *Distinguishing Liabilities From Equity*

ASC 505, *Equity*

ASC 605, *Revenue Recognition*

ASC 606, *Revenue From Contracts With Customers*

ASC 610, *Other Income*

ASC 705, *Cost of Sales and Services*

ASC 710, *Compensation — General*

ASC 715, *Compensation — Retirement Benefits*

ASC 718, *Compensation — Stock Compensation*

ASC 720, *Other Expenses*

ASC 730, *Research and Development*

ASC 740, *Income Taxes*

ASC 805, *Business Combinations*

ASC 808, *Collaborative Arrangements*

ASC 810, *Consolidation*

ASC 815, *Derivatives and Hedging*

ASC 820, *Fair Value Measurement*

ASC 825, *Financial Instruments*

ASC 830, *Foreign Currency Matters*

ASC 835, *Interest*

ASC 840, *Leases*

ASC 842, *Leases*

ASC 845, *Nonmonetary Transactions*

ASC 848, *Reference Rate Reform*

ASC 855, *Subsequent Events*

ASC 860, *Transfers and Servicing*

ASC 905, *Agriculture*

ASC 915, *Development Stage Entities*

ASC 930, *Extractive Activities — Mining*

ASC 942, *Financial Services — Depository and Lending*

ASC 944, *Financial Services — Insurance*

ASC 946, *Financial Services — Investment Companies*

ASC 948, *Financial Services — Mortgage Banking*

ASC 954, *Health Care Entities*

ASC 958, *Not-for-Profit Entities*

ASC 960, *Plan Accounting — Defined Benefit Pension Plans*

ASC 985, *Software*

ASUs

ASU 2010-27, *Other Expenses (Topic 720): Fees Paid to the Federal Government by Pharmaceutical Manufacturers* — a consensus of the FASB Emerging Issues Task Force

ASU 2011-06, *Other Expenses (Topic 720): Fees Paid to the Federal Government by Health Insurers* — a consensus of the FASB Emerging Issues Task Force

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ASU 2017-11, *Earnings per Share (Topic 260); Distinguishing Liabilities From Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments With Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception*

ASU 2017-12, *Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities*

ASU 2017-13, *Revenue Recognition (Topic 605), Revenue From Contracts With Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Rescission of Prior SEC Staff Announcements and Observer Comments* (SEC Update)

ASU 2017-14, *Income Statement — Reporting Comprehensive Income (Topic 220), Revenue Recognition (Topic 605), and Revenue From Contracts With Customers (Topic 606)* (SEC Update)

ASU 2018-01, *Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842*

ASU 2018-07, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*

ASU 2018-08, *Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*

ASU 2018-10, *Codification Improvements to Topic 842,* Leases

ASU 2018-11, *Leases (Topic 842): Targeted Improvements*

ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement*

ASU 2018-14, *Compensation — Retirement Benefits — Defined Benefit Plans — General (Subtopic 715-20): Disclosure Framework — Changes to the Disclosure Requirements for Defined Benefit Plans*

ASU 2018-15, *Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* — a consensus of the FASB Emerging Issues Task Force

ASU 2018-17, *Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities*

ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*

ASU 2018-20, *Leases (Topic 842): Narrow-Scope Improvements for Lessors*

ASU 2019-01, *Leases (Topic 842): Codification Improvements*

ASU 2019-04, *Codification Improvements to Topic 326,* Financial Instruments — Credit Losses*, Topic 815,* Derivatives and Hedging*, and Topic 825,* Financial Instruments

ASU 2019-05, *Financial Instruments — Credit Losses (Topic 326): Targeted Transition Relief*

ASU 2019-08, *Compensation — Stock Compensation (Topic 718) and Revenue From Contracts With Customers (Topic 606): Codification Improvements — Share-Based Consideration Payable to a Customer*

ASU 2019-10, *Financial Instruments — Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*

ASU 2019-11, *Codification Improvements to Topic 326,* Financial Instruments — Credit Losses

ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*

ASU 2020-01, *Investments — Equity Securities (Topic 321), Investments — Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815): Clarifying the Interactions Between Topic 321, Topic 323, and Topic 815* — a consensus of the FASB Emerging Issues Task Force

ASU 2020-02, *Financial Instruments — Credit Losses (Topic 326) and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02*, Leases (Topic 842)

ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*

ASU 2020-05, *Revenue From Contracts With Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities*

ASU 2020-06, *Debt — Debt With Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*

ASU 2021-01, *Reference Rate Reform*

Concepts Statements

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

No. 6, *Elements of Financial Statements*

No. 8, *Conceptual Framework for Financial Reporting — Chapter 8,* Notes to Financial Statements

Proposed ASUs

No. 2015-340, *Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance*

No. 2017-210, *Inventory (Topic 330): Disclosure Framework — Changes to the Disclosure Requirements for Inventory*

No. 2017-280, *Consolidation (Topic 812): Reorganization*

No. 2019-500, *Income Taxes (Topic 740): Disclosure Framework — Changes to the Disclosure Requirements for Income Taxes (Revision of Exposure Draft Issued July 26, 2016)*

No. 2019-790, *Derivatives and Hedging (Topic 815): Codification Improvements to Hedge Accounting*

Other

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

FASB Staff *Revenue Recognition Implementation Q&As*

IFRS Literature

IFRS 2, *Share-Based Payment*

IFRS 3, *Business Combinations*

IFRS 5, *Non-Current Assets Held for Sale and Discontinued Operations*

IFRS 9, *Financial Instruments*

IFRS 10, *Consolidated Financial Statements*

IFRS 11, *Joint Arrangements*

IFRS 12, *Disclosure of Interests in Other Entities*

IFRS 15, *Revenue From Contracts With Customers*

IFRS 16, *Leases*

IAS 1, *Presentation of Financial Statements*

IAS 7, *Statement of Cash Flows*

IAS 10, *Events After the Reporting Period*

IAS 12, *Income Taxes*

IAS 17, *Leases*

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

IAS 27, *Separate Financial Statements*

IAS 32, *Financial Instruments: Presentation*

IAS 37, *Provisions, Contingent Liabilities and Contingent Assets*

IAS 38, *Intangible Assets*

IAS 40, *Investment Property*

IRC

Section 78, "Gross Up for Deemed Paid Foreign Tax Credit"

Section 163(j), "Interest; Limitation on Business Interest"

Section 382, "Limitation on Net Operating Loss Carryforwards and Certain Built-In Losses Following Ownership Change"

Section 409A "Inclusion in Gross Income of Deferred Compensation Under Nonqualified Deferred Compensation Plans"

Section 422, "Incentive Stock Options"

Section 423, "Employee Stock Purchase Plans"

PCAOB Literature

Release No. 2017-001, *The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion and Related Amendments to PCAOB Standards*

SEC Literature

CF Disclosure Guidance

Topic 9, "Coronavirus (COVID-19)"

Topic 9A, "Coronavirus (COVID-19) — Disclosure Considerations Regarding Operations, Liquidity, and Capital Resources"

Topic 11, "Special Purpose Acquisition Companies"

Final Rules

No. 34-88365, *Accelerated Filer and Larger Accelerated Filer Definitions*

No. 33-10786, *Amendments to Financial Disclosures About Acquired and Disposed Business*

No. 33-10890, *Management's Discussion and Analysis, Selected Financial Data, and Supplementary Financial Information*

FRM

Topic 1, "Registrant's Financial Statements"

Topic 2, "Other Financial Statements Required"

Topic 3, "Pro Forma Financial Information"

Topic 5, "Smaller Reporting Companies"

Topic 7, "Related Party Matters"

Topic 10, "Emerging Growth Companies"

Interpretive Release

33-10403, *Updates to 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*

Regulation S-K

Item 103, "Business; Legal Proceedings"

Item 201, "Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters"

Item 301, "Selected Financial Data"

Item 302, "Supplementary Financial Information"

Item 303, "Management's Discussion and Analysis of Financial Condition and Results of Operations"

Item 305, "Quantitative and Qualitative Disclosures About Market Risk"

Item 402, "Executive Compensation"

Item 404, "Transactions With Related Persons, Promoters and Certain Control Persons"

Item 407, "Corporate Governance"

Item 503, "Prospectus Summary"

Item 601, "Exhibits"

Regulation S-X

Rule 1-02(w), "Definitions of Terms Used in Regulation S-X (17 CFR part 210); Significant Subsidiary"

Article 2, "Qualifications and Reports of Accountants"

Rule 3-01, "Consolidated Balance Sheet"

Rule 3-02, "Consolidated Statements of Comprehensive Income and Cash Flows"

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

Rule 3-09, "Separate Financial Statements of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons"

Rule 3-10, "Financial Statements of Guarantors and Issuers of Guaranteed Securities Registered or Being Registered"

Rule 3-14, "Special Instructions for Financial Statements of Real Estate Operations Acquired or to Be Acquired"

Rule 3-16, "Financial Statements of Affiliates Whose Securities Collateralize an Issue Registered or Being Registered"

Rule 4-08(g), "General Notes to Financial Statements; Summarized Financial Information of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons"

Rule 4-08(n), "General Notes to Financial Statements; Accounting Policies for Certain Derivative Instruments"

5-02, "Commercial and Industrial Companies; Balance Sheets"

5-03, "Commercial and Industrial Companies; Statements of Comprehensive Income"

Article 8, "Financial Statements of Smaller Reporting Companies"

Rule 10-01(b), "Interim Financial Statements; Other Instructions as to Content"

Article 11, "Pro Forma Financial Information"

Rule 11-01 "Presentation Requirements"

SAB Topics

No. 1.M, "Financial Statements; Materiality"

No. 5.A, "Miscellaneous Accounting; Expenses of Offering"

No. 5.Y, "Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies"

No 11.A, "Miscellaneous Disclosure; Operating-Differential Subsidies"

No. 13, "Revenue Recognition"

No. 14.B, "Share-Based Payment; Transition From Nonpublic to Public Entity Status"

No. 14.D, "Share-Based Payments; Certain Assumptions Used in Valuation Methods"

- No. 14.D.1, "Expected Volatility"
- No. 14.D.2, "Expected Term"

SEC Securities Act of 1933 General Rules and Regulations

Rule 144, "Persons Deemed Not to be Engaged in a Distribution and Therefore Not Underwriters — General Guidance"

TRG Agenda Papers

TRG Agenda Paper 6, *Customer Options for Additional Goods and Services and Nonrefundable Upfront Fees*

TRG Agenda Paper 11, *October 2014 Meeting — Summary of Issues Discussed and Next Steps*

TRG Agenda Paper 41, *Measuring Progress When Multiple Goods or Services Are Included in a Single Performance Obligation*

TRG Agenda Paper 44, *July 2015 Meeting — Summary of Issues Discussed and Next Steps*

TRG Agenda Paper 54, *Considering Class of Customer When Evaluating Whether a Customer Option Gives Rise to a Material Right*

TRG Agenda Paper 55, *April 2016 Meeting — Summary of Issues Discussed and Next Steps*

Superseded Literature

AICPA Statement of Position

96-1, *Environmental Remediation Liabilities*

EITF Issues

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

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

Issue 01-9, "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)"

Issue 01-10, "Accounting for the Impact of the Terrorist Attacks of September 11, 2001"

Issue 02-16, "Accounting by a Customer (Including a Reseller) for Certain Consideration Received From a Vendor"

Issue 08-6, "Equity Method Investment Accounting Considerations"

Issue 09-2, "Research and Development Assets Acquired in an Asset Acquisition"

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

FASB Interpretations

No. 14, *Reasonable Estimation of the Amount of a Loss* — an interpretation of FASB Statement No. 5

No. 48, *Accounting for Uncertainty in Income Taxes* — an interpretation of FASB Statement No. 109

FASB Statements

No. 5, *Accounting for Contingencies*

No. 52, *Foreign Currency Translation*

No. 95, *Statement of Cash Flows*

No. 114, *Accounting by Creditors for Impairment of a Loan* — an amendment of FASB Statements No. 5 and 15

No. 123(R), *Share-Based Payment*

No. 133, *Accounting for Derivative Instruments and Hedging Activities*

No. 141, *Business Combinations*

No. 141(R), *Business Combinations*

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

Appendix C — Abbreviations

Abbreviation	Description
AETR	annual effective tax rate
AFS	available for sale
AICPA	American Institute of Certified Public Accountants
AMT	alternative minimum tax
API	active pharmaceutical ingredient
APIC	additional paid-in capital
ASC	FASB Accounting Standards Codification
ASR	accelerated share repurchase
ASU	FASB Accounting Standards Update
BCF	beneficial conversion feature
BEAT	base erosion anti-abuse tax
BEMTA	base erosion minimum tax amount
BPD	branded prescription drug
CAM	critical audit matter
CCF	cash conversion feature
CECL	current expected credit loss
CFC	controlled foreign corporation
CFR	Code of Federal Regulations
CMO	contract manufacturing organization
CODM	chief operating decision maker
CRO	contract research organization
DTA	deferred tax asset
DTL	deferred tax liability
EBITDA	earnings before interest, taxes, depreciation, and amortization
ED	exposure draft

Abbreviation	Description
EDGAR	SEC electronic data gathering, analysis, and retrieval system
EGC	emerging growth company
EITF	Emerging Issues Task Force
EPS	earnings per share
ESPP	employee stock purchase plan
EU	European Union
EUR	euros
FASB	Financial Accounting Standards Board
FDA	Food and Drug Administration
FDII	foreign derived intangible income
FIFO	first in, first out
FIN	FASB Interpretation
FOB	free on board
FRM	SEC Division of Corporation Finance Financial Reporting Manual
FVTOCI	fair value through other comprehensive income
GAAP	generally accepted accounting principles
GILTI	global intangible low-taxed income
GPO	group purchasing organization
HFI	held for investment
HFS	held for sale
IAS	International Accounting Standard
IASB	International Accounting Standards Board
IBNR	incurred but not reported

Abbreviation	Description
IFRS	International Financial Reporting Standard
IIR	investigator-initiated research
IP	intellectual property
IPO	initial public offering
IPR&D	in-process research and development
IRC	Internal Revenue Code
IRS	Internal Revenue Service
ISO	incentive stock option
IT	information technology
LCD	liquid-crystal display
LIBOR	London Interbank Offered Rate
LIFO	last in, first out
M&A	merger and acquisition
MD&A	Management's Discussion & Analysis
MSL	medical science liaison
NFP	not-for-profit entity
NOL	net operating loss
NQSO	nonqualified stock option
NSO	nonstatutory option
OCA	SEC's Office of the Chief Accountant
OCI	other comprehensive income
OECD	Organisation for Economic Co-operation and Development
OEM	original equipment manufacturer
PBE	public business entity
PCAOB	Public Company Accounting Oversight Board

Abbreviation	Description
PCC	Private Company Council
PP&E	property, plant, and equipment
PRV	priority review voucher
PTRS	probability of technical and regulatory success
Q&A	question and answer
QIP	qualified improvement property
R&D	research and development
R&E	research and experimentation
REMS	risk evaluation and mitigation strategy
ROU	right of use
SaaS	software as a service
SAB	Staff Accounting Bulletin
SEC	Securities and Exchange Commission
SME	small to medium-sized entity
SPAC	special-purpose acquisition company
SPPI	solely payments of principal and interest
SRC	smaller reporting entity
S&P 500	Standard & Poor's 500 Index
TD	Treasury Decision
TRG	transition resource group
USD	U.S. dollars
UTB	unrecognized tax benefit
VIE	variable interest entity
VWAP	volume-weighted average daily market price

The following is a list of short references for the Acts mentioned in this Guide:

Abbreviation	Act
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
Exchange Act	Securities Exchange Act of 1934
FAST Act	Fixing America's Surface Transportation Act
JOBS Act	Jumpstart Our Business Startups Act
Securities Act	Securities Act of 1933
2017 Act	Tax Cuts and Jobs Act of 2017