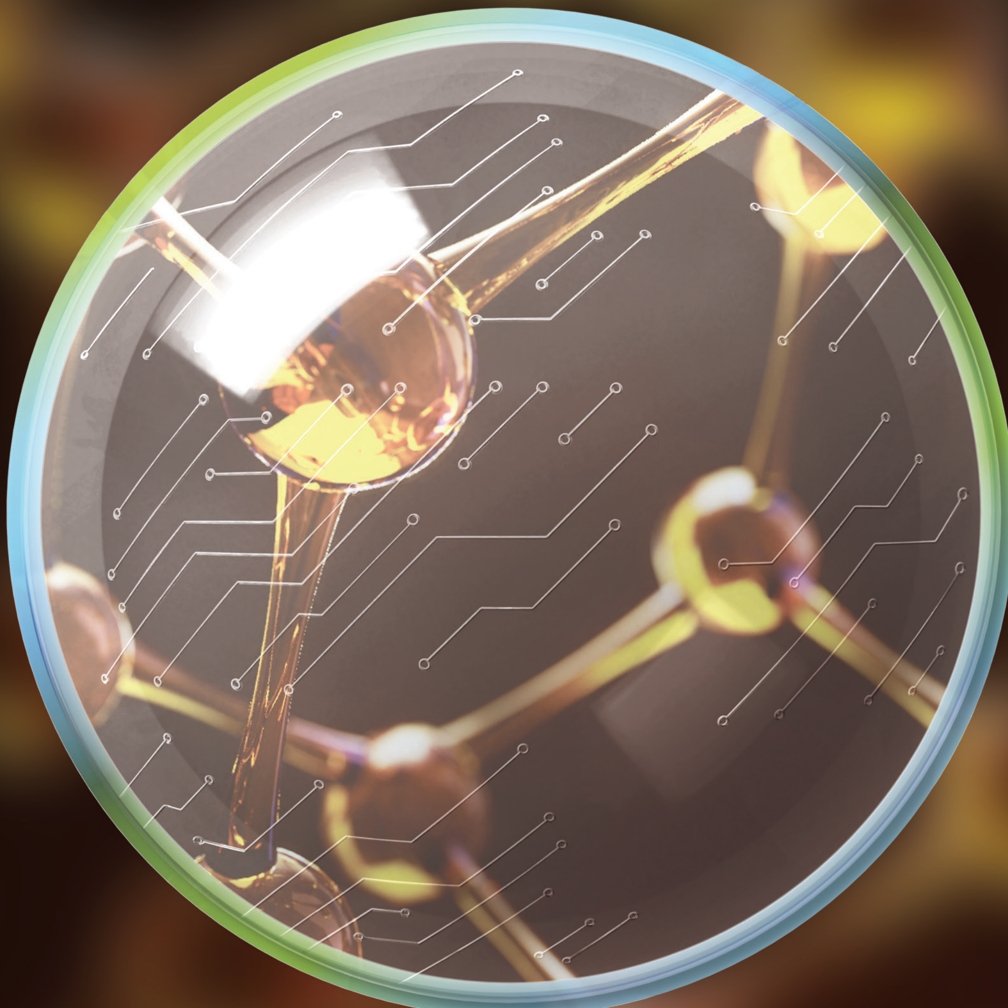

Life Sciences Industry Accounting Guide

Consolidation

March 2024

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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 life sciences 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 2024 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 and rulemaking developments (through March 8, 2024), and key differences between U.S. GAAP and IFRS® Accounting Standards. In addition, this Guide discusses (1) accounting and financial reporting considerations associated with the macroeconomic and geopolitical environment that apply specifically to the life sciences industry, (2) environmental, social, and governance (ESG) matters that have become topics of increased focus, and (3) the impact of the Inflation Reduction Act of 2022 (IRA).

Appendix B lists the titles of standards and other literature we cited, and Appendix C defines the abbreviations we used. Key changes made to this Guide since publication of the 2023 edition are summarized in Appendix D.

We hope the 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
National Office Senior Communications and Consultation 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 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 VIE model, the evaluation of whether the reporting entity has a controlling financial interest in a VIE focuses on (1) the power to direct the activities that most significantly affect the legal entity's economic performance and (2) 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. 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.

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 Roadmap *Consolidation — Identifying a Controlling Financial Interest* 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 provided in ASC 810-10-15-17(d). If a legal entity qualifies for a scope exception to the VIE model, the reporting entity should perform a consolidation analysis under the voting interest entity 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 Roadmap *Consolidation — Identifying a Controlling Financial Interest*.)

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, whether the reporting entity and its related parties provided more than half of the subordinated financial support, and whether the activities of the legal entity are primarily related to securitizations or other forms of asset-backed financings or single-lessee leasing arrangements). 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. In practice, it is not uncommon for a reporting entity to be involved in the design or redesign of a legal entity, which is one condition that would prohibit a reporting entity from meeting this scope exception. Two other conditions in ASC 810-10-15-17(d), 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. That said, in the life sciences industry, it is also important to consider whether there is substantial uncertainty about whether the legal entity will advance to the next stage of development. If such substantial uncertainty exists, the involvement of the reporting entity with the legal entity's current set of activities should then be considered in the determination of (1) the legal entity's purpose and design, (2) whether the legal entity is a VIE, and (3) the primary beneficiary. See Section 5.3.3.1.4 for a discussion of development-stage entities.

In the 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, related parties include all parties identified in ASC 850 and 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.

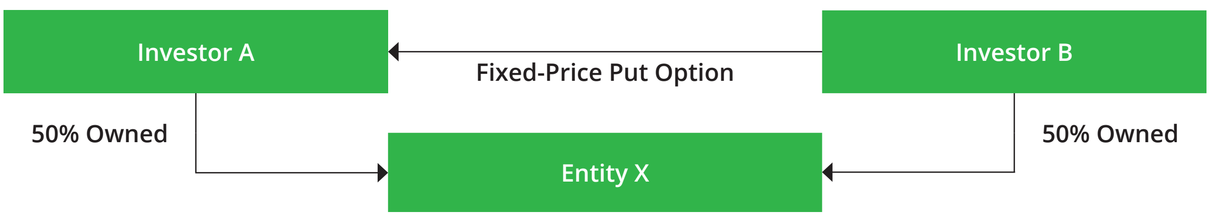
5.3.1.2 Additional Subordinated Financial Support — Put and Call Options

A put or call option 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 of the 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.

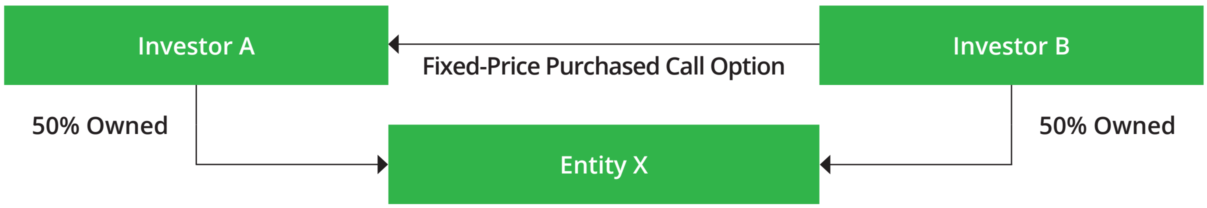


The fair value of the fixed-price put option should be considered additional subordinated financial support provided by A to X because A will absorb expected losses of X upon exercise of that put option (i.e., it meets the definition of subordinated financial support in ASC 810-10-20). Therefore, A would 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 of 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).



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 until 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 option 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, the reporting entity is not required to consolidate the legal entity or provide any of the VIE disclosures related to the legal entity; however, other GAAP may be relevant to the determination of recognition, measurement, and disclosure. ASC 810-10-20 defines variable interests in a legal entity 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." 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.

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.

As a result, 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." The by-design principle is relevant because while a contract or arrangement may absorb certain variability from a legal entity, the contract or arrangement would generally not be a variable interest if the variability absorbed is related to a risk the legal entity was not "designed" to pass on to the interest holder.

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.
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 medical device IP held by B. The fair value of the medical device IP is greater than 50 percent of the fair value of B's assets. 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. The fair value of the medicinal compound is greater than 50 percent of W's assets. 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 IPR&D asset for 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. The fair value of the IPR&D asset is greater than 50 percent of S's assets. Because D participates in the positive variability of a specified asset of S, D possesses a variable interest in the specified asset.
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 all profits earned on the distribution of the products to R. 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.

[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 Roadmap *Consolidation — Identifying a Controlling Financial Interest*.

[2] See footnote 1.

[3] See footnote 1.

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

Examples of Arrangements That Are Not Variable 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 a license (or purchase) agreement with Company C to (1) continue the R&D of a phase I drug that had been under development by C before the agreement and (2) commercialize the drug when and if regulatory approval is received. 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.

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 Roadmap *Consolidation — Identifying a Controlling Financial Interest*.

5.3.3 Determining Whether a Legal Entity Is a VIE

To determine which consolidation model to apply when evaluating 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 evaluation 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 Roadmap *Consolidation — Identifying a Controlling Financial Interest* 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.

For step 1, it is important to remember that only an equity interest can be considered equity investment at risk, although not all equity interests will be considered equity investment at risk. That is, an interest classified outside the equity section (permanent or temporary) of a legal entity's balance sheet is not an equity investment that would be considered as part of step 1. 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, commonly referred to as "sweat equity," 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, considering qualitative or quantitative factors in isolation or a combination of the two, 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.

Note that if any amount has only been guaranteed or committed (and not funded) by the equity holder as of the date of the VIE analysis, neither the amount guaranteed nor the fair value of the guarantee is considered equity investment at risk. See Section 5.2 of Deloitte's Roadmap *Consolidation — Identifying a Controlling Financial Interest* for more guidance on evaluating sufficiency of equity.

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.

Example 5-5 (continued)

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 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).

[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.

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, there is substantial uncertainty 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.

Example 5-7

Entity A is a biopharmaceutical entity whose purpose and design is to complete phase III clinical trials. Currently, A is developing a drug candidate that is in phase I clinical trials. At the inception of the phase I clinical trials, A received an additional equity investment from Company X. Upon making that investment in A, X determined that it should assess whether, under ASC 810-10-15-14(a), A has sufficient equity for completing the phase I clinical trials. Although X expects that A will need additional subordinated financial support to conduct phase II and phase III clinical trials, those trials represent the next stages for A as a development-stage entity. There is substantial uncertainty that A will advance to phase II clinical trials for the drug candidate that is currently in phase I trials. Accordingly, any additional subordinated financial support needed for phase II and phase III clinical trials would not be considered in the assessment of the sufficiency of equity for phase I clinical trials given the purpose and design of A.

It may be appropriate for X to consider only the current clinical trial phase of A (i.e., I, II, or III) when assessing whether A has sufficient equity at risk under ASC 810-10-15-14(a) on the basis of A's purpose and design. However, we do not believe that it is appropriate for a reporting entity to bifurcate a clinical development stage into distinct phases (e.g., viewing phase IIa and phase IIb as distinct development stages, respectively) for this evaluation. Also, a reporting entity should take into account the overall purpose and design of the legal entity that is being evaluated for consolidation and the associated risks when performing such an assessment.

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 at risk. For example, an interest outside the equity investment at risk may permit its holder to direct the most significant activities of the legal entity. If that substantively separate interest is held by a party that is also an owner of equity investment at risk, it should not be combined with the equity investment at risk in this analysis because by design, the rights and obligations do not inure to the equity interest itself. 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 5-8

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 Entity 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.

For additional interpretive guidance on the three characteristics discussed above, see Sections 5.3.1 through 5.3.3 of Deloitte's Roadmap *Consolidation — Identifying a Controlling Financial Interest*.

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 (1) a reporting entity has disproportionately few voting rights and (2) substantially all of the legal entity's activities either involve or are conducted on behalf of the reporting entity (and its related parties except for related parties under ASC 810-10-25-43(d)). A legal entity structured in such a manner would be evaluated under the VIE model. See Section 5.4 of Deloitte's Roadmap *Consolidation — Identifying a Controlling Financial Interest* 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

Examples of SEC Comments

- 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.
- We note that [you, as the reporting entity,] completed the acquisition of an 80% noncontrolling ownership interest in [the legal entity] and that you are accounting for such acquisition using the equity method of accounting. In order to better understand the Company's accounting for this transaction please further tell us the following:
  - How the Company considered the variable interest guidance in ASC 810-10-15-14 and whether the acquisition resulted in an acquired VIE; and
  - If the acquisition did not result in the acquisition of a VIE, how the Company considered the guidance under ASC 810-10-15-8, ASC 810-10-15-8A and ASC 810-10-15-10a such that it resulted in the Company owning 80% of the [legal entity] but not consolidating the [legal 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; (2) provide detailed support for their conclusions about whether an entity is a VIE (including the consolidation model they ultimately used); (3) discuss the basis for their determination of whether they are the primary beneficiary of a VIE (see Section 5.3.4 below); and (4) discuss any events affecting their previous consolidation conclusion (e.g., events that result in deconsolidation). If a registrant determines that a legal entity does not fall under the VIE model, the registrant should then perform a consolidation evaluation under the voting interest entity model.

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 Roadmap *Consolidation — Identifying a Controlling Financial Interest*.

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 substantive participating rights) 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

In situations involving the conveyance of future power 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).

See Section 7.2.9.2 of Deloitte's Roadmap *Consolidation — Identifying a Controlling Financial Interest* for further discussion of contingencies in the power analysis.

Example 5-9

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

- Provide your analysis under ASC 810 supporting your conclusions that (a) [Company A] meets the definition of a variable interest entity and (b) that you are the primary beneficiary.
- 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.
- 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.

5.3.4.4 Initial Measurement of Noncontrolling Interests

For a reporting entity that is deemed to be the primary beneficiary of a VIE, ASC 810-10-30 describes how the assets, liabilities, and noncontrolling interests of the VIE should be initially measured, which can differ depending on the relationship between the primary beneficiary and the VIE. For example, the amount of a noncontrolling interest initially recognized depends on whether the acquired controlling financial interest is in a business, an asset acquisition, or a legal entity under common control.

If a reporting entity obtains control of a legal entity that meets the definition of a business, the reporting entity should account for the transaction as a business combination under ASC 805. Under the business combination guidance, the reporting entity is required to initially recognize the assets and liabilities of, and noncontrolling interests in, the acquired business at fair value. For more information, see Section 5.2.1 of Deloitte's Roadmap *Noncontrolling Interests*.

If the reporting entity acquires a controlling financial interest in a VIE that does not meet the definition of a business, the transaction should be treated as an asset acquisition and accounted for under ASC 810-10-30-4, which requires noncontrolling interests to be initially measured at fair value.

For non-VIE asset acquisitions, we believe that if the legal entity is not a VIE, the acquiring entity in an asset acquisition should include the fair value of any noncontrolling interests remaining as of the date of acquisition in determining the cost to allocate to the assets or group of assets acquired by analogy to the guidance on business combinations in ASC 805-30-30-1. Under that guidance, an acquirer in a business combination must add the fair value of any noncontrolling interests remaining as of the date of acquisition to the consideration transferred to determine the amount recognized for the assets acquired and liabilities assumed. If the acquiring entity in an asset acquisition does not include the fair value of any noncontrolling interests remaining as of the date of acquisition, the assets or group of assets acquired may be recognized at an amount lower than their current fair value. Further, if a reporting entity acquires less than 100 percent of the net assets of a non-VIE legal entity, it should recognize a noncontrolling interest in the legal entity at an amount equal to the noncontrolling interest's proportionate share of the relative fair value of any assets and liabilities acquired. For more information, see Section 5.2.2 of Deloitte's Roadmap *Noncontrolling Interests* and Section C.2.5 of Deloitte's Roadmap *Business Combinations*.

When a reporting entity is deemed to be the primary beneficiary of a VIE and the VIE and reporting entity are under common control, the assets, liabilities, and noncontrolling interests of the VIE should generally be recorded initially at their previous carrying amounts (i.e., a carryover basis should be used with no adjustment to current fair values, and no gain or loss should be recognized) in a manner consistent with the accounting under ASC 805-50-30 for transactions between legal entities under common control. For more information, see Section B.3 of Deloitte's Roadmap *Business Combinations*.

5.3.4.5 Subsequent Measurement of Noncontrolling Interests, Including the Allocation of Income or Loss

As defined in the ASC master glossary, a noncontrolling interest represents the "portion of equity (net assets) in a subsidiary not attributable, directly or indirectly, to a parent." It follows then that the measurement of noncontrolling interests on the reporting entity's balance sheet is affected, in part, by the manner in which a subsidiary's items of income and comprehensive income are attributed to the parent's controlling interest and the noncontrolling interests held by parties other than the parent.

While ASC 810-10 requires a reporting entity to allocate a subsidiary's income or loss and comprehensive income or loss between the controlling and noncontrolling interests, it does not prescribe a specific means for doing so. This lack of detail was acknowledged by the FASB in paragraph B38 of the Background Information and Basis for Conclusions of FASB Statement 160:

> [E]ntities were making attributions before [FASB Statement 160] was issued and . . . those attributions generally were reasonable and appropriate. Therefore, the Board decided that detailed guidance was not needed.

Although items of income or loss and comprehensive income or loss are commonly attributed on the basis of the relative ownership interests of the parent and noncontrolling interests, there are many instances in which it would be inappropriate to attribute income or loss solely on the basis of relative ownership percentages. In the life sciences industry, those instances often include when the controlling interest is in the form of preferred stock. For more information, see Sections 6.2.1 through 6.3 of Deloitte's Roadmap *Noncontrolling Interests*.

5.3.4.5.1 Attributions Disproportionate to Ownership Interests

ASC 970-323

35-16 Venture agreements may designate different allocations among the investors for any of the following:

a. Profits and losses
b. Specified costs and expenses
c. Distributions of cash from operations
d. Distributions of cash proceeds from liquidation.

35-17 Such agreements may also provide for changes in the allocations at specified times or on the occurrence of specified events. Accounting by the investors for their equity in the venture's earnings under such agreements requires careful consideration of substance over form and consideration of underlying values as discussed in paragraph 970-323-35-10. To determine the investor's share of venture net income or loss, such agreements or arrangements shall be analyzed to determine how an increase or decrease in net assets of the venture (determined in conformity with GAAP) will affect cash payments to the investor over the life of the venture and on its liquidation. Specified profit and loss allocation ratios shall not be used to determine an investor's equity in venture earnings if the allocation of cash distributions and liquidating distributions are determined on some other basis. For example, if a venture agreement between two investors purports to allocate all depreciation expense to one investor and to allocate all other revenues and expenses equally, but further provides that irrespective of such allocations, distributions to the investors will be made simultaneously and divided equally between them, there is no substance to the purported allocation of depreciation expense.

Contractual agreements often specify attributions of a subsidiary's profits and losses, costs and expenses, distributions from operations, or distributions upon liquidation that are different from investors' relative ownership percentages.

Although ASC 970-323 was written for equity method investments in the real estate industry, we believe that it is appropriate to refer to this literature for guidance on developing an appropriate method of allocating a subsidiary's economic results between controlling and noncontrolling interests when a contractual agreement, rather than relative ownership percentages, governs the economic attribution of items of income or loss. ASC 970-323 implies that for the attribution of (comprehensive) income or loss to be substantive from a financial reporting perspective, it must hold true and best represent cash distributions over the life of the subsidiary. Reporting entities should focus on substance over form. Further, the reference to the allocation of depreciation expense in the last sentence of ASC 970-323-35-17 is also instructive when guidance in other Codification topics (e.g., the guidance on reporting current-period items of profit or loss related to "partial goodwill" arising from business combinations that occurred before the effective date of ASC 805-10) may result in attribution of specific items of (comprehensive) income or loss on a basis other than the relative ownership percentages of the controlling and noncontrolling interests. For more information, see Sections 6.2.2 through 6.2.2.2.1 of Deloitte's Roadmap *Noncontrolling Interests*.

Given the potential impact of contractual arrangements (or financial reporting requirements of other Codification topics) on each party's absorption of items of income or loss, we believe that reporting entities should generally perform the following three steps to allocate a subsidiary's income or loss between the parent and noncontrolling interest holders in a manner that reflects the substance of the arrangements:

- *Step 1* — Identify all contractual arrangements between the parent, noncontrolling interest holders, subsidiary, and third parties (or financial reporting requirements of other Codification topics) that have the potential to shift the allocation of income or loss between the parties on a basis other than their relative equity ownership percentages.

- *Step 2* — Allocate the economic results of the subsidiary between the controlling and noncontrolling interests to reflect the contractual arrangements (or the financial reporting requirements of other Codification topics) identified in step 1.
- *Step 3* — Allocate residual items of income and loss (which may differ from net income because of the adjustments made in step 2) between the controlling and noncontrolling interest holders in accordance with each party's pro rata equity ownership interest in the subsidiary.

Note that the sum of the allocations in steps 2 and 3 should equal the reported income or loss of the subsidiary.

In some instances, reporting entities may use the hypothetical liquidation at book value (HLBV) method to achieve the result intended by steps 1, 2, and 3. For further discussion of the HLBV method, see Section 6.2.1 of Deloitte's Roadmap *Noncontrolling Interests*.

Connecting the Dots

We believe that the guiding principle for attributing (comprehensive) income or loss to controlling and noncontrolling interests is to ascertain whether attributions that would otherwise be made in the current year are at significant risk of being unwound in subsequent periods on the basis of a different attribution method being used for subsequent cash distributions. In such instances, professional judgment must be used, and consideration should be given to the facts and circumstances at hand. Preparers should consider consulting with professional accounting advisers.

5.3.5 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 Roadmap *Consolidation — Identifying a Controlling Financial Interest*, 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 Roadmap *Business Combinations*, the primary beneficiary recognizes the identifiable assets acquired (excluding goodwill), the liabilities assumed, and any noncontrolling interests as though the VIE were 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. Similarly, a reporting entity may subsequently measure contingent consideration initially measured at fair value by applying either the guidance on asset acquisitions or the guidance specific to contingent consideration in a business combination.

5.3.6 Other Considerations

Examples of SEC Comments

- 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.
- Please revise to include all of the disclosures required by ASC 810-10-50 regarding variable interest entities for which you have determined you are the primary beneficiary as well as for those entities for which you are not the primary beneficiary. Include in your disclosures the carrying amounts and classification of the VIE's assets and liabilities in the statement of financial position that are consolidated as well as terms of arrangements that could require you to provide financial support to the VIE, including events or circumstances that could expose the reporting entity to a loss in accordance with ASC 810-10-50-3.

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. In light of 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 Roadmap *Consolidation — Identifying a Controlling Financial Interest*, 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 2018-17)

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 entity 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.

5.5 On the Horizon — Developments Related to Reorganization of 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***.

On June 27, 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 meeting minutes, 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." Subsequently, however, as stated in the minutes of the FASB's April 20, 2022, meeting, the Board removed this reorganization project from its technical agenda on the basis of feedback received and added a research project to consider whether a single consolidation model can be established for business entities. Stakeholders are encouraged to monitor activity at the FASB for further developments related to the potential reorganization of the consolidation guidance.

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

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"

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 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*

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Appendix C — Abbreviations

Abbreviation	Description
AETR	annual effective tax rate
AFS	available for sale
AFSI	adjusted financial statement income
AI	artificial intelligence
AICPA	American Institute of Certified Public Accountants
AIN	AICPA Accounting Interpretation of an APB Opinion
AMT	alternative minimum tax
ANDA	abbreviated new drug application
APB	Accounting Principles Board
API	active pharmaceutical ingredient
ARO	asset retirement obligation
ASC	FASB Accounting Standards Codification
ASR	accelerated share repurchase
ASU	FASB Accounting Standards Update
AUD	Australian dollar
BCF	beneficial conversion feature
BEAT	base erosion anti-abuse tax
BEMTA	base erosion minimum tax amount
BPD	branded prescription drug
C&DIs	Compliance and Disclosure Interpretations
CAM	critical audit matter
CAQ	Center for Audit Quality
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CCF	cash conversion feature

Abbreviation	Description
CECL	current expected credit loss
CFC	controlled foreign corporation
CIMA	Chartered Institute of Management Accountants
CMO	contract manufacturing organization
CRO	contract research organization
CSRD	Corporate Sustainability Reporting Directive
DTA	deferred tax asset
DTL	deferred tax liability
EBITDA	earnings before interest, taxes, depreciation, and amortization
ED	exposure draft
EDGAR	SEC electronic data gathering, analysis, and retrieval system
EGC	emerging growth company
EITF	Emerging Issues Task Force
ELOC	equity line of credit
EPS	earnings per share
ESA	energy service agreement
ESG	environmental, social, and governance
ESPP	employee stock purchase plan
ESRS	European Sustainability Reporting Standards
EUR	euros
Exchange Act	Securities Exchange Act of 1934
FASB	Financial Accounting Standards Board
FAST Act	Fixing America’s Surface Transportation Act

Abbreviation	Description
FDA	U.S. Food and Drug Administration
FDII	foreign-derived intangible income
FOB	free on board
FPI	foreign private issuer
FRM	SEC Division of Corporation Finance Financial Reporting Manual
FVO	fair value option
FVTOCI	fair value through other comprehensive income
GAAP	generally accepted accounting principles
GenAI	generative artificial intelligence
GHG	greenhouse gas
GILTI	global intangible low-taxed income
GloBE	Global anti-Base Erosion
GPO	group purchasing organization
HAFWP	how and for what purpose
HFI	held for investment
HFS	held for sale
HVAC	heating, ventilation, and air conditioning
IAS	International Accounting Standard
IASB	International Accounting Standards Board
IBNR	incurred but not reported
ICFR	internal control over financial reporting
IFRIC	IFRS Interpretations Committee
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

Abbreviation	Description
ISSB	International Sustainability Standards Board
IT	information technology
ITC	invitation to comment
JOBS Act	Jumpstart Our Business Startups Act
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
MNE	multinational enterprise
MSL	medical science liaison
NDA	new drug application
NFP	not-for-profit (entity)
NIH	National Institutes of Health
NOL	net operating loss
NOPA	notice of proposed adjustment
NQSO or **NSO**	nonqualified stock 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
PCC	Private Company Council
PIPE	private investment in public equity
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

Abbreviation	Description
R&D	research and development
R&E	research and experimental
REC	renewable energy certificate
REMS	risk evaluation and mitigation strategy
RIM	retail inventory method
ROU	right of use
SaaS	software as a service
SAB	Staff Accounting Bulletin
SEC	U.S. Securities and Exchange Commission
Securities Act	Securities Act of 1933
SEPA	standby equity purchase agreement
SOX	Sarbanes-Oxley Act of 2002
SPAC	special-purpose acquisition company

Abbreviation	Description
SPPI	solely payments of principal and interest
SRC	smaller reporting entity
S&P 500	Standard & Poor's 500 Index
TD	Treasury Decision
TDR	troubled debt restructuring
TRG	transition resource group
TRWG	IFRS Foundation Technical Readiness Working Group
TSA	transition services agreement
USD	U.S. dollars
UTB	unrecognized tax benefit
VIE	variable interest entity
VWAP	volume-weighted average daily market price
XBRL	eXtensible Business Reporting Language