



Life Sciences

Accounting and Financial Reporting Update —
Interpretive Guidance on Consolidation

March 2017

Consolidation

Introduction

Life sciences entities enter into a variety of arrangements with other parties to facilitate the research, development, or sale of their intellectual property or products. Because life sciences entities may absorb risk 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. The dual consolidation model, which comprises the VIE¹ model and the voting interest entity model, is designed to ensure that the reporting entity that consolidates another legal entity has (1) the right and obligation to absorb the other legal entity's returns and losses and (2) the power to direct the activities that most significantly affect the other legal entity.

After more than four decades of little change, the accounting guidance on consolidation has been evolving rapidly over the past 15 years. [ASU 2015-02](#)² is the latest chapter in the consolidation evolution story. While the ASU did not introduce any new models, its changes eliminated two of the existing models (FIN 46(R) and EITF Issue 04-5), requiring all entities to be evaluated as either a voting interest entity or a VIE. Further, under the ASU, the evaluation of whether a VIE should be consolidated is still based on whether the reporting entity has both (1) power and (2) potentially significant economics.

Some key highlights of the ASU's changes are as follows:

- The Statement 167 deferral for interests in investment companies (and certain similar entities) has been eliminated, thereby removing the risks-and-rewards-based consolidation model under FIN 46(R) from U.S. GAAP.
- The limited partnership model in ASC 810-20 has been eliminated. Instead, limited partnerships will be VIEs unless the limited partners have substantive kick-out or participating rights. Although more limited partnerships will be VIEs, it is less likely that a general partner will consolidate a limited partnership.
- The guidance on fees paid to a decision maker or service provider has been amended. Specifically, it is less likely that the fees themselves would be considered a variable interest, that a legal entity would be a VIE, or that a decision maker would consolidate the legal entity.
- The ASU significantly amends how variable interests held by a reporting entity's related parties or de facto agents affect its consolidation conclusion. In addition, the ASU will result in less frequent performance of the related-party tiebreaker test (and mandatory consolidation by one of the related parties) than under the previous VIE models.

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](#) (the "Consolidation Roadmap") for a flowchart that incorporates the concepts in the FASB's flowchart and serves as a guide to the consolidation accounting literature.

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

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

ASU 2015-02 affects all entities with variable interests in other entities. Reporting entities must document their considerations of the new guidance and how it affects any previous consolidation conclusions or their identification of other legal entities as VIEs. For public business entities, the guidance in ASU 2015-02 became effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2015. For entities other than public business entities, the guidance is effective for annual periods beginning after December 15, 2016, and interim periods beginning after December 15, 2017. Early adoption is allowed for all entities (including during an interim period), but the guidance must be applied as of the beginning of the annual period containing the adoption date. A reporting entity may apply the ASU's amendments by using a full retrospective or a modified retrospective approach. Under a full retrospective approach, the reporting entity would retrospectively apply the ASU to one or more years presented in its financial statements and record a cumulative-effect adjustment to retained earnings as of the beginning of the first year presented. Under a modified retrospective approach, the reporting entity would record a cumulative-effect adjustment to equity as of the beginning of the period of adoption. In selecting a transition option, a reporting entity should consider, among other factors, the effort required to recast previous periods and the impact on the financial statements presented.

After issuing ASU 2015-02, the FASB issued [ASU 2016-17](#), which amends the guidance in ASU 2015-02 on interests held through related parties that are under common control. Under ASU 2015-02 before the adoption of ASU 2016-17, a reporting entity that held an interest in another entity under common control was required to consider that related party's interest in a VIE as its own (e.g., if the related party held a 40 percent interest in the VIE, the reporting entity would include the full 40 percent interest in its assessment even if it held only a nominal interest in the related party). Under ASU 2016-17, a reporting entity considers its indirect economic interests in a VIE held through related parties that are under common control on a proportionate basis, in a manner consistent with its consideration of its indirect economic interests held through related parties that are not under common control. For further information, see Deloitte's November 1, 2016, [Heads Up](#).

Industry Issues

The discussions and examples below contain guidance on consolidation matters that frequently affect life sciences entities or are expected to affect life sciences entities upon adoption of ASU 2015-02. The guidance cited is not intended to be all-inclusive or comprehensive; rather, it provides targeted considerations related to the application of the standard 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 any newly acquired variable interests or perform reassessments under the new standard's amendments to existing guidance.

Scope Exceptions to the Consolidation Guidance — Business Scope Exception

After the identification of a potential variable interest in a legal entity, a reporting entity should evaluate whether it can apply the scope exceptions to the VIE model. The most frequently cited exception is the so-called business scope exception. (For a list of all consolidation and VIE scope exceptions, see Chapter 3 in 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 (2) the reporting entity's relationship with the legal entity (e.g., 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 assess any of the conditions outlined in the second prong of the test. Two of the more common relationships that must be analyzed are described below.

Substantially All of the Activities Either Involve or Are Conducted on Behalf of the Reporting Entity

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. 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 circumstances may indicate that substantially all of the activities of a legal entity are conducted on behalf of a reporting entity, in the context of the life sciences industry, one such circumstance would be when a reporting entity holds the rights to products that result from the R&D of a legal entity.

Example

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 U's behalf and, accordingly, the business scope exception cannot be applied by U.

Additional Subordinated Financial Support — Put and Call Options

Put and call options may exist in agreements between equity owners in a life sciences legal entity (e.g., between joint venture partners). Such options can have an impact on whether a reporting entity meets the condition in ASC 810-10-15-17(d)(3) and, therefore, on whether the reporting entity 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 — 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 — 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 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.

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 a reporting entity holds a variable interest in the legal entity being evaluated for consolidation. If a reporting entity 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 an entity's variability (changes in the fair value of the entity's net assets) 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 (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 determine whether an 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, determining 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.

Types of Variable Interests	Illustrative Examples
Long-term liabilities of a legal entity (e.g., fixed-rate debt, floating-rate debt, mandatorily redeemable preferred stock)	Aspen Co. (the reporting entity) lends Dunne Co., a biotech firm, \$50 million in the form of a five-year fixed-rate unsecured loan. Aspen Co., as a debt holder, absorbs the variability in the value of the legal entity’s assets because Aspen Co. is exposed to Dunne Co.’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)	Schrute LP (the reporting entity) invests \$89 million in Michael Co., a contract research organization. The equity investment was made in common stock and is considered equity at-risk under ASC 810-10-15-14(a). Schrute LP’s interest in Michael Co. is a variable interest that absorbs the variability associated with changes in Michael Co.’s net assets.
Guarantees written by a reporting entity ³	Costanza Inc. (the reporting entity) provides a guarantee to a medical device company, Ball Investments Inc., on the \$2 billion fair value of all medical device intellectual property held by Ball Investments Inc. Costanza Inc. must pay Ball Investments Inc. for any decreases in value of this intellectual property. The guarantee agreement transfers all or a portion of the risk of specified assets (intellectual property); thus, Costanza Inc. has a variable interest in Ball Investments Inc.
Put options written by a reporting entity and similar arrangements on specified assets owned by the legal entity ⁴	Hermanos LLC (the reporting entity) writes a put option to White Inc. allowing White Inc. to sell its medicinal compound in development for a fixed price at a later date. Hermanos LLC has a variable interest in the specified assets of White Inc.
Stand-alone call options written by the legal entity on specified assets owned by that legal entity ⁵	Sterling Inc. writes a call option on its wholly owned interest in a treatment in phase II clinical trials to Draper LP (the reporting entity), allowing Draper LP to acquire the interest for a fixed price at a later date. Because Draper LP participates in the positive variability of the specified assets of Sterling Inc., Draper LP possesses a variable interest in those specified assets.

³ 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, the variable interest could result in consolidation of a “silo” within a VIE. For further discussion, see Section 4.3.11 and Chapter 6 of Deloitte’s [Consolidation Roadmap](#).

⁴ See footnote 3.

⁵ See footnote 3.

(Table continued)

Types of Variable Interests	Illustrative Examples
Fees paid to a decision maker or service provider	Snow LLC pays a fee to Red Corp. (the reporting entity) to distribute Snow LLC's products. The fee arrangement requires Snow LLC to pay Red Corp. all profits earned on the distribution of the products. In accordance with ASC 810-10-55-37C, the fee arrangement is designed to transfer substantially all of the residual returns and risks of ownership of Snow LLC's products to Red Corp., the decision maker. Red Corp.'s earned fee represents a variable interest in Snow LLC.
Royalties and licenses paid to a reporting entity	Caspian Inc. (the reporting entity) holds rights to a pharmaceutical drug. Wilson Inc. obtains a license from Caspian Inc. to produce, market, and sell the drug, and Caspian Inc. will earn a royalty based on Wilson Inc.'s sales. Caspian Inc. holds a variable interest in Wilson Inc. because it absorbs variability through the royalty.

The table below lists examples of what generally would not be considered variable interests.

Types of Nonvariable Interests	Illustrative Examples
Assets of the legal entity	David Inc. (the reporting entity) owes \$100 million to Prettay LP as part of an existing loan agreement. Although the loan receivable asset generates value to the investors of Prettay LP, the loan receivable is not a variable interest to David Inc. Assets of a legal entity typically are the major source of a legal entity's variability, not an absorber of variability, and are therefore not considered variable interests.
Contingent payments made to a legal entity	Ernie Pharmaceuticals Inc. (the reporting entity) enters into an agreement with Clementine LLC to continue the R&D of a phase I drug held by Clementine LLC. In exchange for the drug's achievement of milestones, such as FDA approval and the achievement of specified sales levels, Ernie Pharmaceuticals Inc. will make milestone payments and pay Clementine LLC royalties. Ernie Pharmaceuticals Inc. is not exposed to the variability in Clementine LLC 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 illustrative examples of variable interests, is included in Chapter 4 of Deloitte's [Consolidation Roadmap](#).

Determining Whether a Legal Entity Is a VIE

To determine which consolidation model to apply when evaluating its variable interest in a legal entity, a reporting entity must determine whether the legal entity is a VIE. This determination must be made upon the reporting entity's initial involvement with the 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.

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.

Below is a brief list of considerations specifically relevant to life sciences entities for determining whether the 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.

The Legal Entity Does Not Have Sufficient Equity Investment at Risk

If a legal entity has sufficient equity investment at risk to finance its operations, and the equity investors 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.

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, 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 (1) participate significantly in profits and losses, (2) not be issued in exchange for subordinated interests in other VIEs, (3) not be received from the legal entity or by parties involved with the legal entity (see example below), and (4) not be financed by the legal entity or other parties involved with the legal entity. Further, equity investments acquired by an equity investor in exchange for promising to perform services cannot be considered 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

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 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.

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.

Existence of Subordinated Debt

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. Consider the example below.

Example

Entity D is formed with \$50 of equity and \$50 of long-term debt. The long-term debt consists of two issuances: (1) Debt A, \$45; and (2) 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 its 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.

Example (continued)

In a qualitative assessment, D's ability to issue investment-grade debt that has the same priority in liquidation as Debt A and 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.

Development-Stage Entities

Life sciences entities frequently require varying levels of funding to complete a product candidate's R&D; understanding "the sufficiency of the equity at risk" to fund each phase of R&D is therefore important to the VIE analysis.

Recognizing the unique funding needs of early-stage entities, the FASB had provided a different framework for evaluating the sufficiency of equity investment at risk for all development-stage entities. ASC 915-10-20 defines a development-stage entity as follows:

An entity devoting substantially all of its efforts to establishing a new business and for which either of the following conditions exists:

- a. Planned principal operations have not commenced.
- b. Planned principal operations have commenced, but there has been no significant revenue therefrom.

Before the adoption of [ASU 2014-10](#),⁶ the following two conditions needed to be present for equity investment at risk to be considered sufficient for a development-stage entity:

- The legal entity must have had sufficient equity to fund its current developmental activity.
- The legal entity must have been legally structured to permit additional equity investment in the future, to fund further development upon completion of the current activity.

This framework was more generous than the approach applicable to entities that did not qualify as development-stage entities since it took into account the life cycle of the legal entity in phases rather than over the entire contemplated life of the legal entity. Under this framework, a reporting entity (1) initially assessed whether a development-stage entity was a VIE on the date the reporting entity first became involved with the legal entity and (2) reconsidered its assessment upon the occurrence of any of the events described in ASC 810-10-35-4. For a development-stage entity, such events would have included, but would not have been limited to:

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

Although the concept of a development-stage entity has been removed in ASU 2014-10, 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, for certain legal entities that met the definition of a development-stage entity under previous guidance, 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

⁶ ASU 2014-10 eliminates the specialized approach for considering sufficiency of equity investment at risk for development-stage entities. That guidance became effective for public business entities for annual periods beginning after December 15, 2015, and interim periods therein. For entities other than public business entities, the guidance is effective for annual periods beginning after December 15, 2016, and for interim periods beginning after December 15, 2017. Early adoption is permitted. Reporting entities that have historically applied this exception should consider the impact of ASU 2014-10 on their historical conclusions.

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 in the primary beneficiary analysis of a multiple-stage entity.

Example

Entity D is a development-stage entity as defined in ASC 915. Investor A and Investor B each contributed \$1 million of equity financing to D. Entity D's current activities consist of early-stage (phase I) drug development. Upon successful completion of phase I, D plans to commence phase II trials. During the final phase of D's R&D stage, it plans to engage in phase III trials. Entity D's by-laws allow A and B to fund additional equity upon the completion of phase I and phase II. Given the low probability of technical and regulatory success of the drug being studied, there is substantial uncertainty about whether D will proceed to phase II of development.

When assessing the sufficiency of equity at risk under ASC 810-10-15-14(a), D need only consider the current phase of its development. 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 described in ASC 810-10-35-4.

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 any of the following three qualities — the “typical” characteristics of an equity investment — are absent from the holders of equity investment at risk **as a group**:

- 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 interests. 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

Stabler Inc. is the sole equity holder in an entity that holds the patent to a phase II drug. The phase II drug represents 80 percent of the fair value of the net assets held by Stabler Inc. Stabler Inc. issues to Benson LLC a fixed-price call option on the phase II drug that is exercisable in one year. The right of Stabler Inc. to receive the expected residual returns is effectively capped because of Benson LLC's ability to participate in the upside through its call option. Consequently, Stabler Inc. is a VIE.

Disproportionate (Nonsubstantive) Voting Rights

Although intended to clarify the previous criteria (equity investors as a group do not possess characteristics of a controlling financial interest), the evaluation of whether disproportionate (nonsubstantive) voting rights exist 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 referred to as the “anti-abuse provision” since it aims to prevent a legal entity from being structured in a manner such that the legal entity does not confer voting control to a reporting entity but in substance should be consolidated by the reporting entity because “substantially all” of the legal entity’s activities either involve the reporting entity or are conducted on the reporting entity’s behalf. See Section 5.4 of Deloitte’s [Consolidation Roadmap](#) for more interpretive guidance on evaluating this criterion.

SEC Comment Letters Related to the Determination of Whether a Legal Entity Is a VIE

Example of an SEC Comment

[P]lease further explain how you concluded [Entity A] was not a VIE pursuant to ASC 810-10-15-14(b). If you determine it is a VIE, please explain how you determined [the registrant] has the characteristics of a controlling financial interest per ASC 810-10-25-38A and provide the basis for consolidation and any other required disclosure pursuant to ASC 810-10-50.

Given that the variable interest model is complex and requires an entity to use significant judgment, the SEC staff frequently requests further information from registrants about how they concluded that an entity either is or is not a VIE.

Identifying 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). Upon the adoption of ASU 2015-02, 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 “power” and “economics.” These two concepts are discussed below. For more detailed information, see Chapter 7 of Deloitte’s [Consolidation Roadmap](#).

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 significant decisions related to the risks identified in step 1 and the activities associated with those risks. In certain situations in which multiple unrelated variable interest holders direct different decisions and 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.

Contingencies

Future power can be converted to a variable interest holder 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

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 such 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.

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 that could potentially be significant to 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 that could potentially be 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. 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 the threshold for meeting the economics criterion is low, most of the primary beneficiary analysis is focused on assessing the reporting entity's power over the significant activities that affect the VIE's performance.

SEC Comment Letters Related to the Primary-Beneficiary Assessment

Example of an SEC Comment

Regarding your conclusion that you are not the primary beneficiary of [Entity A], provide us your analysis of ASC 810-10-25 supporting this conclusion. Indicate for us the activities of [Entity A] that most significantly impact its economic performance and why you concluded that you do not have the power to direct these activities.

Because the primary-beneficiary assessment determines whether a registrant will consolidate an entity, the SEC staff will often request further information from registrants about their primary-beneficiary assessment.

Other Considerations

Because this publication is intended to highlight some of the complex issues frequently encountered by life sciences entities, certain consolidation topics are outside its scope. However, such topics are discussed in Deloitte's [Consolidation Roadmap](#); they include (1) the assessment of related parties in the identification of variable interests and performance of primary beneficiary analyses, (2) consolidation evaluations involving voting interest entities, and (3) special considerations for limited partnerships and similar entities. For a summary of the key changes to ASC 810 as a result of ASU 2015-02, see Appendix A of the Consolidation Roadmap.

Recently Issued Accounting Standards Update

In January 2017, the FASB issued [ASU 2017-01](#), which effectively narrows the definition of a business. As a result, fewer entities may qualify for the business scope exception.

Appendix A — Glossary of Standards and Other Literature

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

AICPA Literature

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

FASB Accounting Standards Updates

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FASB ASC Topics and Subtopics

ASC 205, Presentation of Financial Statements

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

ASC 230, Statement of Cash Flows

ASC 230-10, Statement of Cash Flows: Overall

ASC 235, Notes to Financial Statements

ASC 250, Accounting Changes and Error Corrections

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

ASC 280-10, Segment Reporting: Overall

ASC 320, Investments — Debt and Equity Securities

ASC 321-10, Investments — Equity Securities: Overall

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

ASC 325-10, Investments — Other: Overall

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

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

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

ASC 330, Inventory

ASC 330-10, Inventory: Overall

ASC 350, Intangibles — Goodwill and Other

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

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

ASC 450, Contingencies

ASC 450-10, Contingencies: Overall

ASC 450-20, Contingencies: Loss Contingencies

ASC 450-30, Contingencies: Gain Contingencies

ASC 470-10, Debt: Overall

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

ASC 480-10, Distinguishing Liabilities From Equity: Overall

ASC 605, Revenue Recognition

ASC 605-10, Revenue Recognition: Overall

ASC 605-15, Revenue Recognition: Products

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

ASC 605-28, Revenue Recognition: Milestone Method

ASC 605-45, Revenue Recognition: Principal Agent Considerations

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

ASC 606, Revenue From Contracts With Customers

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

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

ASC 730, Research and Development

ASC 730-10, Research and Development: Overall

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

ASC 740, Income Taxes

ASC 740-10, Income Taxes: Overall

ASC 740-270, Income Taxes: Interim Reporting

ASC 805, Business Combinations

ASC 805-10, Business Combinations: Overall

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

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

ASC 805-50, Business Combinations: Related Issues

ASC 808, Collaborative Arrangements

ASC 808-10, Collaborative Arrangements: Overall

ASC 810, Consolidation

ASC 810-10, Consolidation: Overall

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

ASC 810-30, Consolidation: Research and Development Arrangements

ASC 815, Derivatives and Hedging

ASC 820, *Fair Value Measurement*

ASC 825, *Financial Instruments*

ASC 840, *Leases*

ASC 842, *Leases*

ASC 915, *Development Stage Entities*

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

ASC 985-605, *Software: Revenue Recognition*

FASB Proposed Accounting Standards Updates

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

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

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

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

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

Other FASB Proposal

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

FASB Statements (Pre-Codification Literature)

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

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

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

FASB Interpretation (Pre-Codification Literature)

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

FASB Concepts Statements

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

No. 6, *Elements of Financial Statements*

EITF Issues

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

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

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

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

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

SEC C&DI Topic

Non-GAAP Financial Measures

SEC Regulation G

"Conditions for Use of Non-GAAP Financial Measures"

SEC Regulation S-K

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

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

SEC Regulation S-X

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

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

Article 11, "Pro Forma Financial Information"

SEC Staff Accounting Bulletin

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

SAB Topic 13, "Revenue Recognition"

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

International Standards

IFRS 15, *Revenue From Contracts With Customers*

IFRS 11, *Joint Arrangements*

IFRS 3, *Business Combinations*

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

IAS 17, *Leases*

Appendix B — Abbreviations

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

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

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

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