EXECUTIVE SUMMARIES FROM SELECTED SESSIONS AT:

16TH LIFE SCIENCES
ACCOUNTING & REPORTING
CONGRESS

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HIGHLIGHTS FROM THE 16TH ANNUAL LIFE SCIENCES ACCOUNTING & REPORTING CONGRESS

Throughout the 16th Annual Life Science Accounting & Reporting Congress, leaders from across Deloitte & Touche LLP, along with leaders from life sciences companies, board members, and regulators, shared insights and best practices on some of the most important issues facing accounting leaders in life sciences companies.

A brief description of each of these sessions is provided below. A more detailed executive summary follows.

Industry Fireside Chat

Jeff Ellis led a discussion with board members of life sciences companies about how COVID-19 has affected the life sciences industry. The panelists shared their thoughts about the most critical issues confronting boards at this time, the importance of risk oversight, and the increasing importance around ESG (environmental, social, and governance) issues. The panelists also stressed the importance of board and management teams evaluating the quality of earnings and working collaboratively on M&A and IPO transactions.

Intercompany Reporting

Deloitte's Katie Glynn and Benjamin Reese did a deep dive on intercompany accounting (ICA), with a specific focus on the use of ICA in life sciences companies. They shared a model and an end-to-end ICA framework to improve intercompany accounting processes. They also highlighted steps that companies can take to improve ICA outcomes.

101 Boot Camp

This year's Boot Camp consisted of a panel from Deloitte that focused on some of the implications of the COVID-19 pandemic on accounting. The panelists looked at impairment considerations, contract and revenue recognition considerations, internal control considerations, and SEC reporting and disclosure considerations.

They also examined how COVID-19 has affected the close process and discussed the near-term and longer-term organizational implications of working remotely, closing virtually, and adopting technologies to streamline and automate key processes, while creating more flexible, agile work environments.

INDUSTRY FIRESIDE CHAT

EXECUTIVE SUMMARY

FEATURED SPEAKERS: Neil Dimick, Chair, Mylan's Audit Committee; Member of Mylan's Executive and Finance Committees; Former Chief Financial Officer, AmerisourceBergen Corporation; Barbara Duncan, Biotech Board Member; Former Chief Financial Officer, Intercept Pharmaceuticals, Inc.

IDEAS THAT MATTER

- In today's environment, boards must **accelerate** their work related to risk oversight, ESG issues, technology, and more.
- The board and management must **work hand in hand** to determine the quality of earnings, timing for an IPO, and success of acquisitions.

KEY TAKEAWAYS

Uncertainty generated by COVID-19 has accelerated the urgency of the board's work.

COVID-19 has shown that the future of business is virtual, distributed, digital, and unbound. Boards and management must accelerate their work and become familiar with new risks. This means "fast-forwarding" 10 years in a short period of time. Neil Dimick recommended that boards:

- **Recheck the "tone at the top."** Key concerns include creating culture and trust virtually. Boards also must ask tough questions about what companies have accomplished in the new virtual environment. Communication is the most important tool that boards have.
- **Re-examine the board's composition.** The world has changed, but boards haven't kept pace.
- **Evaluate how the board works with management.** Today's environment is raising new questions for businesses. For example, as critical employees return to the office, they will be working in buildings with lower occupancy. What are the safety implications?

"From the board's perspective, we need to accelerate what we're doing to deal with the uncertainty. The future is virtual, distributed, digital, and unbound. How do we accelerate and become familiar with the risks?"

Neil Dimick, formerly of AmerisourceBergen

Boards are grappling with changing expectations around ESG.

It is important for boards to define what environmental, social, and governance (ESG) means for their company. Investors care about the term, but there are no official rules related to ESG. Management must be involved and must incorporate ESG into SEC filings in coherent ways that avoid "greenwash."

The social justice movement has amplified the pressure for diversity in the boardroom. The boards Barbara Duncan serves on engage in an annual process of evaluating which skillsets, knowledge, and personalities they need. Boards must openly discuss how they are proactively addressing diversity issues. An incremental approach towards diversity might mean supplementing the board with an interim member who is a consultant or a scientific advisory board member.

"When it comes to board diversity, I caution against looking for one person who meets all the criteria and then 'checking the box.' That's not what a company needs. Companies need to take a holistic view of board diversity."

Barbara Duncan, formerly of Intercept Pharmaceuticals

Risk oversight is a board role that is growing in importance.

Five years ago, risk oversight was an agenda item for board discussion. Today, boards have lists, charts, and special committees responsible for nothing but risk oversight. Boards must determine whether they want a separate enterprise risk committee or whether risk assessment will be distributed among committees.

Two growing areas of risk are lawsuits in the life sciences sector and new lease accounting standards. Growing numbers of lawsuits have resulted in significant increases in D&O insurance premiums. With regard to new lease accounting standards, smaller companies lack internal expertise and must hire expensive outside consultants.

Boards and management teams must work collaboratively to make IPOs and M&A transactions successful.

As early stage biotechs consider whether to go public, management can help the board by thinking through the next two to three years for the business. Key concerns include whether the company will be liquid enough for investors to get in and out, as well as managing news flow and presenting data in proper ways. If management comes to the board with a good plan for managing these issues and others, it can make the board decision about an IPO much easier.

Despite today's challenging business environment, the life sciences sector will likely remain a deal-oriented industry. While the volume of deals has decreased, deal complexity remains high. Due diligence is still essential, as is confirming that acquisitions are a strategic fit. Integration is also important. If integration isn't completed, the transaction isn't completed. It is critical that boards use management to help evaluate the acquisition, not months but years after it has been completed.

Both boards and management must evaluate the quality of earnings for their companies.

Quality of earnings is important for both the SEC and investors. While it is essential to follow GAAP as closely as possible, life sciences financial executives have their own ideas of what quality earnings are—and it is not necessarily represented by the audited financials. Many times, adjustments are made to those numbers based on cash generation and EBITDA earnings. It is essential to isolate one-time events and look at the concentration of risk.

Investors must know how much cash a company has on hand, how much can be accomplished with those funds, and what the next inflection point is. It is important to include the chief medical officer or chief scientific officer in discussions about performance measures.

INTERCOMPANY REPORTING

EXECUTIVE SUMMARY

FEATURED SPEAKERS: Katie Glynn, Senior Manager, Risk and Financial Advisory, **Deloitte & Touche LLP**; Benjamin Reese, Manager, Deloitte Risk and Financial Advisory, **Deloitte & Touche LLP**

IDEAS THAT MATTER

- Intercompany accounting is common in life sciences, but few companies think they have leading policies and practices.
- The volume of intercompany transactions is increasing, creating lots of work and offering opportunities for improvement through technology, governance, data centralization, and delivery models.
- Companies can take concrete steps to improve intercompany accounting processes, engaging a wide range of stakeholders to drive greater business value.

KEY TAKEAWAYS

Intercompany accounting (ICA) is widespread in life sciences companies.

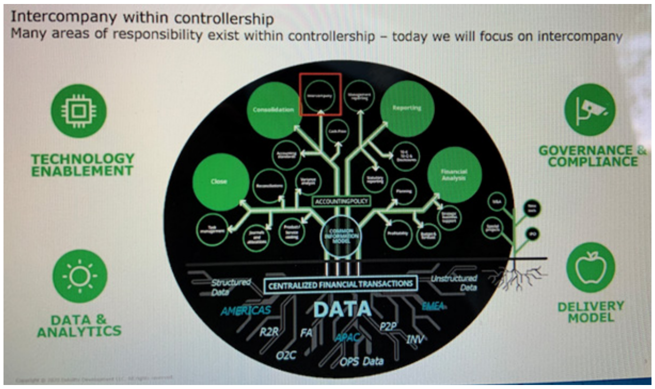
ICA is the reporting and recording of internal financial activity from one legal entity doing business with another legal entity, frequently crossing international borders and currencies. The term comprises activity ranging from fee sharing to sales of the company's core product or services. An understanding of intercompany accounting helps identify opportunities for improvement through process redesign and technology enablement.

Important elements of ICA include:

- **Inventory vs. non-inventory:** Inventory (or stock) transactions are raw, semi-finished, or finished materials. Non-inventory (or non-stock) transactions can include R&D charges, royalty payments, loans, or cross charges.
- **Stakeholders.** While accounting is the default owner, ICA extends to teams from controllership, finance, tax, treasury, and statutory reporting—and even to business partners.
- **Room for improvement.** Only 6% of life sciences and healthcare professionals think their companies have a leading global policy around ICA.

The "controllership in the green" model highlights the complexity of ICA, the four enablement areas, and their common challenges.

This model incorporates many practices and maturity models.



The four enablement areas in the model are:

- Technology enablement: Can make processes more effective and efficient.
- Governance and compliance: Includes the control environment and auditing.
- Data and analytics: Enables the organization analytically with a variety of data inputs and centralization of data via a common information model.
- Delivery model: Includes enablement through shared services and a center of excellence (COE).

The volume of ICA is increasing, with pain points leading to reduced efficiency and increased risk. Challenges include the amount of manual work involved, processes for transaction matching and account reconciliation, and having to knit together disparate systems because of legacy M&A.

ICA occurs in a complex, changing, global legal environment. Limited visibility and lack of defined ownership is leading some organizations to move to a COE model to drive intercompany agreements and manage month-end work.

The ICA framework offers opportunities for improvement.

This end-to-end framework breaks intercompany accounting processes into seven manageable elements and enables an assessment of needs and opportunities for improvement.

"To evaluate the various processes within the intercompany accounting framework can be helpful to any organization as they begin their intercompany assessment . . . to break down complex cross problems of intercompany accounting into more manageable parts."

Benjamin Reese, Deloitte & Touche

COMPONENTS OF END-TO-END ICA FRAMEWORK	OPPORTUNITY FOR IMPROVEMENT
1. Governance and Policy	Clearly defined roles and responsibilities, COE, trade services agreements
2. Intercompany Pricing	Necessary to support tax strategies, consider ad hoc vs. defined pricing strategy
3. Data Management	Deal with increasing volume of transactions, standard chart of account coding, reconcile M&A disparities
4. Transaction Management	Intercompany transaction volumes frequently higher than third party, identify where automating can save time
5. Netting and Settlement	Define when to settle books, automated multilateral settlement, treasury systems
6. Reconciliation and Elimination	Automated transaction level systems, manage complex global supply chain
7. Internal and External Reporting	Increase efficiency, streamline through dashboard reporting

Gleaning insights and creating business value from intercompany profit requires overcoming complexity.

Many firms seek to leverage technology to make their processes more efficient, but firms often find that software, such as enterprise resource planning software (ERP), presents gaps. Some organizations upgrade to central finance to consolidate transactional information. Typically, multiple technologies are required for end-to-end automation.

Life sciences presents increasingly complex global supply chains and advantageous tax planning, which can result in the physical flow of goods not matching the financial flow. Complexity can hinder movement along the maturity chain. For example, many SKUs or complex global supply chains with many parties can impede SKU-level tracking.

But increased capabilities associated with intercompany processes can drive more value in business decisions; however, it requires significant stakeholder involvement, especially from manufacturing and procurement. Other opportunities center on improving non-stock intercompany transactions, through process improvements and tools, to manage upfront agreements and workflows to enable partial automation.

Companies can take concrete steps to improve ICA processes and outcomes.

Companies assessing their intercompany process can use the four enabling areas and the seven components of the end-to-end framework. The organization must clarify its goals, as its individual priorities may suggest the areas to push the enterprise to be leading.

"There's a lot of low-hanging fruit getting the right folks involved: treasury, manufacturing, finance, and the planners. It definitely moves on that spectrum."

Katie Glynn, Deloitte & Touche

Among the concrete steps to be taken in the ICA journey are:

- Planning: Identify the pain points.
- Maturity assessment: Determine how involved cross-functional stakeholders are.
- Define future state vision: Working with the cross-functional team, identify gaps, priorities and risks.
- Foundational readiness: Assess historical practices, law changes, and areas needing clean up.
- ICA process deep dive: Select areas for greatest transformation.
- Develop implementation roadmap: Prioritize and build a roadmap; recognize it's a long-term challenge.
- Technology implementation: Leverage technology enablement to reduce manual steps and increase reliability.

101 BOOT CAMP

EXECUTIVE SUMMARY

FEATURED SPEAKERS: Rich Holtz, Senior Manager, **Deloitte & Touche LLP**; Michael Lombardo, Partner, **Deloitte & Touche LLP**; Laurel Pikulin, Senior Manager, **Deloitte & Touche LLP**; Justin Stappler, Senior Manager, **Deloitte & Touche LLP**

IDEAS THAT MATTER

- COVID-19 is having a considerable effect on accounting reporting considerations.
- This includes impairment considerations, revenue recognition considerations, internal control considerations, and SEC reporting and disclosure considerations.
- The pandemic has also affected virtual closes, is leading to a new normal, will accelerate the use of technology in the close process, and will change the future of controllership.

KEY TAKEAWAYS

Due to COVID-19, preparers must consider triggering events that could require testing for impairment.

Because of the economic disruption and uncertainty caused by COVID-19, preparers must consider whether any "trigger" events could require goodwill and other long-lived intangible assets to be tested for impairment. Among the many potential triggers are a decrease in revenue, a decrease in the market price for a long-lived asset, supply chain disruptions, a sustained decrease in share price, and more.

> "It is important to recognize that certain considerations could be potential triggers requiring testing for impairment."
>
> Michael Lombardo, Deloitte & Touche

While companies routinely use judgment when evaluating or testing assets for impairment, the need to use good judgment is amplified in the current environment. Among the most common impairment considerations are:

- Goodwill. Companies need to be mindful of the goodwill impairment indicators, as detailed in ASC 350. Companies may choose to qualitatively evaluate the impairment indicators or go to the Step 1 quantitative assessment, which seems to be more common. In looking at valuation considerations, there is currently a high degree of uncertainty, and many key variables that impact valuation are currently extremely difficult to predict. EY is encouraging clients to engage in scenario planning, reviewing a wide range of potential scenarios and identifying those scenarios with the highest probability of occurring.

"These unique challenges magnify the need for management teams to scrutinize all available information when developing forward-looking estimates and work to translate expectations of macroeconomic conditions into revisions of estimates of the company's own future cash flows."

Rich Holtz, Deloitte & Touche

- Order of impairment testing. If goodwill and another asset of a reporting unit are tested for impairment at the same time, the other asset should be tested for impairment before goodwill.
- Finite-lived intangible assets. When testing a long-lived asset, companies need to prepare an undiscounted cash flow model, which generally indicates that a long-lived asset is less prone to impairment. However, companies should consider the impact of the pandemic on changes in an asset's useful life or salvage value, and may consider revising depreciation or amortization estimates accordingly.
- In-process research & development (IPR&D). Intangible assets that are not subject to amortization should be tested for impairment annually or more frequently if events or changes in circumstances indicate it is likely the asset is impaired. Because FDA resources have been shifted during the pandemic, work attending to previously submitted applications has been affected, which could impact valuation inputs to IPR&D assets.
- Other considerations include:
    - *Right of use assets* are subject to impairment guidance, meaning that when events or circumstances change that suggest impairment indicators exist, right of use assets should be tested to determine if there is an impairment.
    - *Accounts receivable* are an area that, especially in the current environment, companies need to pay close attention to, with particular attention to geographic regions most affected by COVID.
    - *Inventory* has been affected by COVID as some inventory has expired or become obsolete due to lower demand. Also, plants running at lower capacity could affect allocation of fixed overhead costs.
    - *Investments* include equity investments that do not have a readily determinable fair value, requiring a qualitative assessment to evaluate if the securities are impaired, and equity method investments, where an impairment loss is recognized if the loss is not temporary in nature. Management must use judgment to assess the severity and duration of a decline in fair value.

COVID-19 may affect a company's revenue contracts and revenue recognition.

Companies must consider several items when assessing revenue from contracts. These include collectability, variable considerations such as rebates, returns, and discounts, the estimated transaction price, and any expected changes in the company's ability to perform. A company may also need to consider whether it will be able to achieve milestone payments, performance bonuses, trailing commissions, or any other performance-related fees.

Due to COVID-19, it may be necessary for companies to modify contract provisions, which could include price concessions or purchase commitments. Companies may need to extend payment terms, offer sales incentives, or alter other contract terms—all of which can impact revenue recognition. These complexities can also increase the difficulty of making certain critical estimates.

The disruption from COVID-19 has caused companies to assess their internal control environment.

Disruptions may have affected a company's revenue, supply chain, and infrastructure as well as its risk assessment and risk landscape. This occasion requires that companies assess their internal control processes and systems and their service providers, and that they identify and prioritize those factors that are mission critical. If any changes to internal controls are made, it is essential to update the descriptions of the controls and to communicate these changes in a timely manner.

The pandemic is requiring companies to assess their SEC reporting and disclosure considerations.

Among the considerations requiring attention are:

- Management discussion and analysis (MD&A). Companies should discuss in their MD&A the material quantitative and qualitative impact of COVID-19 on the business with specific focus on the financial impact, results on operations, and liquidity. Life sciences companies may also want to touch on the impact on clinical trial enrollment and on production and launch sites.
- Risk factors. Companies should disclose the most significant risks facing the entity and should consider whether to update previous disclosures to clarify if a risk is no longer hypothetical.

> "Registrants should disclose information about the most significant risks facing the entity or its securities and consider whether to update past disclosures to clarify that a risk is no longer hypothetical and to provide more specificity about the actual and potential future impact of COVID-19."
>
> Laurel Pikulin, Deloitte & Touche

- CARES Act. Companies should consider disclosures about the impact of the CARES Act, which can include the short- and long-term impact of a loan, grant, tax relief, or other assistance on the financial condition, liquidity, or capital resources.
- Non-GAAP measures. Companies may consider reflecting various impact of COVID-19 on their non-GAAP measures. The key requirements for disclosure are related to prominence, reconciliation, clear labeling, usefulness and purpose, and not being misleading.
- Going concern. In the notes to financial statements companies must state if there is substantial doubt about the entity's ability to continue as a going concern.

The future of controllership could involve significant changes.

The past few months have been challenging related to the execution of virtual close and financial reporting. To simplify the close process, Deloitte recommends identifying gaps and thinking about technologies to close the gaps and help the team work more collaboratively.

This unique, challenging moment provides an opportunity to get smarter about digital tools and process improvements to simplify and expedite the close process. Rethinking these processes and leveraging technology is likely to be part of a "new normal" for companies and employees. Recent research shows:

- 65% of employers are looking to improve finance efficiency through automation.
- 42% of employers said their biggest closing challenge when working remotely is collaboration.
- 60% of workers are confident they can do their job remotely.
- 44% of workers want to continue working remotely at least 50% of the time.

These responses paint a picture about the future. The future of controllership will mean changes in roles, staffing models, and recruiting. It will require new ways of empowering teams and engaging employees. Companies on the cutting edge are already making these changes. They are leveraging technology to improve the close process and are creating more flexible work environments.

> "The next 10 years or so, we expect to find the traditional accounting role to move to incorporate continuous automation, automated intelligence, and continuous monitoring."
>
> Justin Stappler, Deloitte & Touche