Implementing the new revenue recognition standard
Life sciences

Key issues for implementation

- The new framework introduces a new five-step approach to recognising revenue.
- Companies will need to reassess their revenue streams to understand the impact of these changes.
- This new methodology may lead to changes in when revenue is recognised.
- Disclosure requirements are enhanced.

IFRS 15 Revenue from Contracts with Customers was issued in May 2014. It, together with the FASB’s new revenue standard, Accounting Standards Update 2014-09, Revenue from Contracts with Customers, will replace virtually all existing revenue recognition requirements in IFRS and US GAAP with a single framework.

The new standards provide accounting requirements for all revenue arising from contracts with customers and affect all entities that enter into contracts to provide goods or services to their customers (unless the contracts are in scope of other standards, such as IAS 17 Leases).

Life sciences entities will have some specific issues to consider. These may include:

- Identifying which arrangements with payers will be in the scope of IFRS 15
- Changing processes and controls for making estimates in order to comply with IFRS 15’s requirement for estimating variable consideration
- Identifying and accounting for separate performance obligations in complex arrangements (e.g., bundled R&D and licence contracts)
- Evaluating reseller and distributor arrangements and when revenue should be recognised and whether revenue should be recognised gross or net

EY can assist you with the transition and help you understand the implications for life sciences entities.
What is the change?

IFRS 15 is effective for annual periods beginning on or after 1 January 2017 (or for annual beginning after 15 December 2016 and interim periods therein for public entities reporting under US GAAP). Early adoption is permitted under IFRS but is not permitted for public entities reporting under US GAAP. At their April 2015 meetings, both the IASB and FASB decided to propose a one-year deferral of the effective date for the revenue standards.

IFRS 15 is likely to affect the measurement, recognition and disclosure of revenue, which is typically an entity’s most important financial performance indicator. It is an indicator closely scrutinised by investors and analysts. Gaining an understanding of the effects of the new standard, providing early communication to stakeholders and advanced planning will be critical for a successful implementation.

Entities that do not expect significant changes in the measurement and timing of revenue recognition will, at the very least, need to validate that assumption. Entities will need to identify necessary changes to policies, procedures, internal controls and systems to ensure that revenue transactions are appropriately evaluated through the lens of the new model. Entities with multiple global locations may also need to spend significant amounts of time in multiple markets to ensure that the entire population of relevant contracts has been identified and considered. In addition, entities will need to plan for the significantly expanded disclosure requirements.

For entities that are going to experience a significant change in revenue recognition as a result of the new standard, the implementation effort required will be considerable. Early preparation will be crucial for a smooth transition.

The new five-step model under IFRS15 can be summarised as follows:

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Identify the contract(s) with the customer</th>
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</thead>
<tbody>
<tr>
<td>Step 2</td>
<td>Identify the performance obligations in the contract</td>
</tr>
<tr>
<td>Step 3</td>
<td>Determine the transaction price</td>
</tr>
<tr>
<td>Step 4</td>
<td>Allocate the transaction price to the performance obligations</td>
</tr>
<tr>
<td>Step 5</td>
<td>Recognise revenue when (or as) each performance obligation is satisfied</td>
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</tbody>
</table>
The challenge ahead
Not just an accounting change

With the new standard being applicable to virtually all entities, it is not surprising that changes to the accounting for revenue could affect multiple business functions, as illustrated below.

Because of the potential wide-ranging effects of the new standard, the implementation effort should include functions outside of the finance department, including R&D, manufacturing, IT, legal, sales and marketing, advertising and promotion, human resources, investor relations and senior management. A number of related work streams should be considered in this effort, including:

- Accounting and financial reporting
- Tax
- Business processes and systems
- Change management, communication and training

It will be critical to have strong project management in order to coordinate the roles of the various business functions and to keep the work streams running smoothly and on schedule.

The challenge ahead
What makes this complex?
In addition, consideration must be given to a number of drivers of complexity for each step of the model:

<table>
<thead>
<tr>
<th>Contracts</th>
<th>Identifying performance obligations</th>
<th>Transaction price</th>
<th>Allocation</th>
<th>Recognition timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifying all terms of the contract</td>
<td>Identifying goods and services</td>
<td>Base transaction price</td>
<td>Determining stand-alone selling prices</td>
<td>Transfer of control: point in time or over time</td>
</tr>
<tr>
<td>Combining contracts</td>
<td>Identifying performance obligations</td>
<td>Variable consideration, including bonuses, returns, rebates</td>
<td>Allocating attributable variable consideration</td>
<td>Repurchase provisions</td>
</tr>
<tr>
<td>Contract modifications</td>
<td>Service-type warranties</td>
<td>Constraint</td>
<td>Allocating attributable discount</td>
<td>Bill-and-hold transactions</td>
</tr>
<tr>
<td>Established business practices</td>
<td>Options granting a material right</td>
<td>Significant financing components</td>
<td></td>
<td>Consignment arrangements</td>
</tr>
<tr>
<td>Identifying the customer (e.g., principal vs. agent)</td>
<td></td>
<td>Non-cash consideration</td>
<td></td>
<td>Customer acceptance</td>
</tr>
<tr>
<td>Determining legal enforceability</td>
<td></td>
<td>Payments to customers</td>
<td></td>
<td>Licences</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Changes in transaction price</td>
<td></td>
<td>Measuring progress and transferring control</td>
</tr>
</tbody>
</table>
There are a number of factors that affect how complex and time-consuming your IFRS 15 implementation will be. The diagram below summarises some example factors that you may wish to consider, but this is not an exhaustive list.

<table>
<thead>
<tr>
<th>Less complex</th>
<th>More complex</th>
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<tbody>
<tr>
<td>• Shorter revenue cycle</td>
<td>• Bundled arrangements with multiple inter-related performance obligations e.g., R&amp;D arrangements</td>
</tr>
<tr>
<td>• Single line of business</td>
<td>• Long-term contracts</td>
</tr>
<tr>
<td>• Domestic operations only</td>
<td>• Multiple, diverse businesses</td>
</tr>
<tr>
<td>• Highly centralised</td>
<td>• Global operations</td>
</tr>
<tr>
<td>• Well-controlled process currently provides revenue estimates</td>
<td>• Decentralised</td>
</tr>
<tr>
<td>• No change to existing performance obligations</td>
<td>• Limited estimates required by current revenue recognition process</td>
</tr>
<tr>
<td>• One global ERP</td>
<td>• Changes in the number of performance obligations under new model</td>
</tr>
<tr>
<td>• Strong organisational change management</td>
<td>• Multiple, disparate IT systems</td>
</tr>
<tr>
<td></td>
<td>• Organisation struggles to implement change</td>
</tr>
</tbody>
</table>

There are four key areas to consider when designing an implementation plan for IFRS 15: financial, systems, organisational and transitional impacts. We highlight some key questions to address these changes:

- **Financial**
  - What revenue streams and "unique" contracts exist?
  - What is the magnitude of financial impact to KPIs such as revenue growth, margin and EBITDA?

- **System**
  - Will you need to reconfigure your ERP systems to capture all the necessary financial and operational information, including data needed for transition and disclosures?
  - Will the standard create new book/tax differences and/or methods changes?

- **Organisation**
  - How do your implementation plans benchmark against your competitors?
  - How and when will you communicate to internal and external stakeholders?
  - Does this affect the structure of your contracts with customers?

- **Transitional**
  - Have you considered whether the full retrospective or modified retrospective approach is most appropriate for your organisation?
  - Have you prepared for transitional disclosures?
  - Have you considered how to communicate the transitional impact to stakeholders?
Due to particular types of relationships that life sciences entities have with their customers, entities may need to change certain revenue recognition practices as a result of the introduction of IFRS 15. We summarise some of the key considerations below.

**Identifying the contract with the customer**

Identifying contracts with customers may be complex for entities in the life sciences sector. While many contracts will clearly identify the customer, some life sciences arrangements involve multiple parties, which may complicate the assessment. Key questions to consider when identifying the contract include:

- Does the entity have an agreement with oral or implied terms that are legally enforceable (which may need to be accounted for under the new standard)?
- Is collection probable for the arrangement (which under the new standard is one of the criteria for a contract to exist)?
- Have systems and processes been developed across the various markets to ensure that all contracts in scope of the standard are being identified?
- Given the complexity of identifying the customer in life sciences contracts, is the entity clear about whom the customer is in each of its contractual arrangements?

**Collaboration agreements**

Many entities in the life sciences sector enter into complex arrangements aimed at developing and commercialising products. For example, it is common practice for a biotechnology company and a pharmaceutical company to enter into a collaboration to develop a drug candidate for commercialisation. To determine whether or not this type of arrangement is in scope of IFRS 15 will require judgement by management. Key questions to consider will include:

- Are the entities contracting to work together to develop a candidate such that the risks and benefits are shared?
- Is the biotechnology company, selling or licencing the compound to the pharmaceutical company and also providing R&D services?
- Is the collaboration partner a customer for some or all aspects of the contract?
- Can contracts be considered partially within the scope of IFRS 15 and partially outside the scope?

**Licences**

Entities may find it challenging to determine how to account for arrangements that include a licence and other services. For example, a typical transaction might involve Pharma A entering into a single contract with Pharma B which includes an out-licence of an early stage drug compound for development and commercialisation to Pharma B alongside providing R&D services and manufacturing services to Pharma B.
Implementing the new revenue recognition standard  July 2015

In this scenario, the parties will need to consider whether the licence of intellectual property (IP), R&D services and manufacturing services are distinct in order to apply the new standard appropriately. Key questions to consider include:

- Could Pharma A perform the other services for Pharma B without the licence?
- Could Pharma B obtain the R&D services or the manufacturing services from another provider?
- Is the technology required to perform the R&D services or the manufacturing services so specialised that only Pharma A can provide it?

Depending on the answers to these questions, the licence and the other services may need to be treated as a single performance obligation. Alternatively, if Pharma B could perform the R&D services and manufacturing services on its own or obtain them from another vendor, the licence, R&D services and manufacturing services may be distinct.

It should also be noted that IFRS 15 provides an exception to the variable consideration requirements for sales- and usage-based royalties from licences of IP to recognise revenue when the relevant sales or usage occurs. However, it is not clear whether this exception will also apply to royalties that relate to both licenced IP and other goods or services in a contract (e.g., a contract with two performance obligations, a distinct product candidate licence and R&D services that would be provided over time and would affect the amount of royalties earned). The IASB may propose an amendment to clarify the position and companies should monitor the IASB website for further information.

Estimating variable consideration

Frequently, contracts in the life sciences sector include variability in the amount or timing of a portion of the transaction price. This can be due to rebates, incentives, rights of return, performance bonuses, milestones, future royalties or price concessions. IFRS 15 requires an entity to estimate variable consideration using either the most likely amount method or the expected value method, depending on which method best predicts the amount to which the entity will be entitled. An entity includes in the transaction price the amount for which it is highly probable that a significant revenue reversal will not occur (i.e., a constraint on variable consideration is applied before including variable consideration in the transaction price). Key questions to consider include:

- Which contracts include variable consideration (e.g., a contingency that needs to be resolved before a payment is received)?
- Will an entity’s systems and procedures enable the identification of all variable consideration at contract inception?
- Is there sufficient information and history with similar products on which to estimate variable consideration?
- Is the outcome of a contingency binary?
- Does a future royalty stream relate to a licence of IP?
- Is an identified contingency something that is within the entity’s control or influence? If it is dependent on another party, such as a regulator, it may be difficult to determine the outcome increasing the risk/likelihood of a revenue reversal.
Entities may find it difficult to estimate consideration in a performance-based model where the life sciences entity’s consideration is linked in some way to the performance of the medication. The following provides an example of such an arrangement:

Pharma A recently received regulatory approval to sell Drug A. Pharma A sells Drug A to a hospital network, and the hospital administers the drug to patients. The hospital is required to pay for Drug A upon shipment based upon a contracted price (30-day terms). The hospital is eligible for a 50% refund if, after 90 days, the patient has not had a positive response to the treatment using Drug A (based upon criteria defined in the contract).

Estimating the amount of revenue to recognise and at what point in time will be complex. Key questions to consider will include:

- What is the history of performance of the medication in other territories or patient groups (if any)? Since for a newly launched product such history may not be available, can data of comparable drugs that are already sold in the market be used to derive such estimates?
- What if there are tiered outcomes and associated payments included in the arrangement?
- Are there instances where revenue is currently deferred because fees cannot be reliably measured, that will now be recognised subject to the constraint or because there is a non-refundable floor price or minimum consideration as part of the arrangement?
- For arrangements with variable considerations (likely to be almost all arrangements in the life sciences sector), has it been determined whether the most likely method or expected value method should be used?
- What systems are needed to capture the information necessary to calculate the expected value? What changes are necessary to existing processes, procedures, documentation and controls?

**Reseller and distributor arrangements**

Under the new standard, life sciences entities that sell their products through distributors or resellers may recognise revenue earlier than under current rules. Today, some entities that use resellers wait until the product is sold to the end-customer to recognise revenue, because they do not meet all of the criteria in the risk and rewards model in IAS 18 Revenue to recognise revenue on delivery to the reseller.

Under IFRS 15, life sciences entities will need to first evaluate when control, rather than only the risks and rewards, of the product transfers to the customer. In this respect, they need to assess whether their contracts with resellers are consignment arrangements. In a consignment arrangement, control generally does not transfer (and, therefore, revenue is not recognised) until the reseller sells the product to an end-customer.

If an entity concludes that its contract with a reseller is not a consignment arrangement, deferring revenue until the end-sale has occurred will no longer be acceptable if the only uncertainty is the variability in the pricing and there is some amount that is not deemed highly probable of a significant revenue reversal. Key questions to consider will include:

- Are entities clear on which of their contracts would be accounted for as consignment arrangements under the new standard and which would not?
- Do entities have the necessary systems data and information to determine when to recognise consideration if a change in timing is required compared with current IFRS?
- How will entities determine if the constraint on variable consideration requires a reduction of the transaction price?
The challenge ahead

Why start a diagnostic now?

Developing potential diagnostic activities will help an entity to:

- Build an implementation team and governance protocols with appropriate organisational representation
- Identify key constituencies and prioritise their preliminary requirements, benefits and constraints
- Identify relevant revenue streams and “unique” contracts (many of which may be owned by a local market)
- Understand high-level financial and existing in-flight project impacts (e.g., new IT system roll-outs)
- Make an informed decision on which transition method is preferable and attainable
- Prepare a detailed planning budget to understand the level of human and financial resources required
- Answer stakeholder questions regarding changes and impact
- Participate in sector or geographical working groups to help influence developing practices

How can EY help?

Implementation methodology

Adopting the new standard may seem daunting. It is important to apply a comprehensive methodology for implementing the accounting change. Doing so will help you adopt the standard in an organised and efficient manner that reduces risk and the possibility of costly errors and delays.

A five-phase model for entities implementing this accounting change is recommended.*

There are also four dimensions to consider: accounting and reporting, tax, business processes and systems, and change management, communication and training.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Diagnostic</th>
<th>Design and planning</th>
<th>Solution development</th>
<th>Implementation</th>
<th>Post-implementation</th>
</tr>
</thead>
</table>

**Accounting and reporting**

- Tax

**Business processes and systems**

- Identify accounting, reporting and tax differences and consequences for business process and IT systems

<table>
<thead>
<tr>
<th>Project management</th>
<th>Accounting and reporting</th>
<th>Tax</th>
<th>Business processes and systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify actions, prepare implementation plan and develop solutions across work-streams</td>
<td>Approve and roll out action plan across work-streams</td>
<td>Address deferred items and transition to operational model</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Workstreams</th>
</tr>
</thead>
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</table>

* Note: Certain of our services for an audit client and its affiliates may be more limited in order to comply with applicable independence standards. Please reach out to your EY contact for further information.
The EY Revenue Recognition Readiness (RRR) Tool

We have developed an application that combines structured analysis, such as automation of standard calculations with documentation, and a clear audit trail of key management judgements and estimates through each step of the new model.

The EY RRR tool may help with the (depending on an entity’s needs):

- Identification and documentation of the key contract terms with customers
- Evaluation of the key terms against the requirements of the five-step model
- Consideration and documentation of judgements and conclusions
- Collection of data to support disclosure requirements
EY’s cloud-based site

EY’s cloud-based site provides an easy-to-use “one-stop shop” for all of your project management, information and analytical tool needs.

The implementation methodology and framework on EY’s site can easily be customised to accommodate your project structure and reporting needs (e.g., for business units, work streams, regions, phases, project type, revenue streams and individuals).

Our commitment

EY’s sector-specific insights and understanding of current market trends, combined with our technical experience, will help to successfully deliver your revenue recognition implementation project.

We can provide practical and innovative services to address the financial reporting challenges resulting from changes in the economic and regulatory environment.

Why EY?

EY is ready to support and advise you in your IFRS 15 transition:

› We have teams with the right experience in implementing IFRS 15 for life sciences companies around the world.

› We have direct experience of supporting companies in the life sciences sector applying the new standard.

› In addition to our FAAS team, we bring together experience in all aspects of a transition to IFRS 15, including from our Advisory and Tax teams. We recognise that changing your approach to revenue recognition is much more than just an accounting issue.

› We have developed a detailed approach and methodology for transitions – supported by our tools – that can assist you through each stage of the process.

To access more EY thought leadership on IFRS standards, visit ey.com/IFRS.
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