

# Best practice for communicating R&D progress to investors and the public



Developed in collaboration with



Simmons & Simmons

## What is the purpose of this guide?

Ensuring investors and the wider public are well informed and confident about bioscience is crucial to the success of individual companies and the sector as a whole.

This is a best practice guide for bioscience companies on how to maintain understanding and trust through their communications. It has been produced through consultation with the BIA membership and the investment community and focuses primarily on the communication of R&D progress.

*“The UK bioscience sector is booming. We attract over one third of all European venture capital funding and have an active public market that is taking an ever-greater interest in the investment opportunities that our sector has to offer.*

*To establish the UK as the third global bioscience cluster we need investors and the public to be well informed and confident about the great science our companies are doing. That’s why we have produced this new guide to help spread the good communications practice that we’ve identified throughout the BIA membership.*

*We hope our members big and small find it useful as they plan and execute their own communication strategies.”*

**STEVE BATES OBE**  
CEO, BIA

## **Disclaimer**

Bioscience companies must take responsibility for their own communications. The BIA does not police or oversee individual communications or seek to enforce this guide, but strongly encourages bioscience companies to use this guide to maintain high standards of communications about R&D progress in the bioscience sector.

The legal content in this guide is provided by Simmons & Simmons LLP and is for general information about English law only as at: December 2017. Specific advice should be taken in individual circumstances.



**Bioscience companies are subject to laws and corporate governance rules**

## How does this guide fit with the legal requirements for investor communications?

Bioscience companies are subject to laws and corporate governance rules that impact their communications with investors and others. These apply generally to listed/publicly traded companies and, in different ways, to private companies and are not specific to the bioscience sector.

Listed or publicly traded companies, such as those on the Main Market or AIM, must announce inside information without delay when required by the Market Abuse Regulation and, where applicable, the AIM Rules, unless an exemption applies. Compliance with these requirements is not the subject of this guide.

### Standard of communications

The broad effect of securities law and corporate governance rules for a listed/publicly traded company is that communications must be of a high standard and must be:

- **correct when issued**
- **not misleading**
- **without omission**
- **consistent as to content and the pattern of communications**
- **updated for previous forward-looking statements and expectations**
- **fair, balanced and understandable (clear)**

This guide is not a substitute for compliance with applicable legal and governance rules. It is designed to help bioscience companies also meet sector best practice and to apply their communications to the R&D process in particular. For the purposes of this guide, it is therefore a given that bioscience companies meet the legal and governance rules applicable to them, including the communication of inside information consistent with the reasonable investor test. This guide should be treated as supportive, but not determinative, of compliance with applicable legal and governance rules.

*“Deciding when and what to disclose can be complex and require significant judgement. However, companies which communicate effectively with external stakeholders can build stronger relationships with their shareholder base, helping them develop and mature in a sustainable way.”*

**JAMES CLARK**  
HEAD OF TECH AND LIFE SCIENCES, EQUITY PRIMARY MARKETS, LONDON STOCK EXCHANGE

## The BIA's best practice principles for communicating R&D progress

Building on the legal and governance requirements companies must follow, the BIA recommends bioscience companies follow the sector's best practice principles. Communications should be:



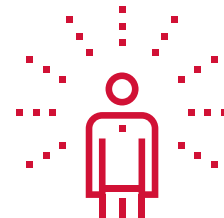
**Well prepared**



**Consistent**



**Fair, balanced and understandable (clear)**



**Mindful of the impact on members of the public to whom it is personally relevant**

These principles apply to public and private bioscience companies. Although focussed on the communication of R&D, they can be applied generally to the communication of other scientific aspects of business activity, including in services and tools companies.

Private companies are not subject to the legal obligations about when to make public announcements to their investors, but these best practice principles can valuably be applied to their communications about R&D to maintain the understanding and trust of their shareholders, stakeholders and potential investors and licensees, both now and in readiness for an IPO or some other corporate or licensing transaction.

*“Transparency and clear communication can help make life sciences companies easier for investors to understand, build trust with the investment community and are critical to attracting additional investment into the sector.”*

**CLARE TERLOUW**  
MANAGING DIRECTOR, CORPORATE BROKING & ADVISORY, NUMIS



### Applying these principles

## How should these principles be applied?

### **Be well prepared**

- Have a communications plan in place. At least annually, it is best to plan communications for key developments affecting the progress of each product that is central to the company's purpose and its ability to generate long-term value
- Run scenario planning for different outcomes in advance of trial results, including how positive, negative, and mixed results will be communicated
- Identify appropriate audiences and channels for communication beyond the issuing of regulatory announcements; for example, direct contact with investors, sales teams, analysts, patient groups and the media
- Be prepared for unexpected releases of information; for example, around the regulatory process, publications or through collaborators or other related third parties
- Be aware of any embargoes that may be out of your control, such as those related to academic publication or scientific conferences

### **Be consistent**

- Establish a pattern in the timings of communications and, if required to deviate, keep your audience updated. Companies can choose voluntarily to communicate more often than legally required, this sets a pattern that investors and others expect to be followed
- Disclose the same level or amount of information in all communications
- Be consistent in the language and scientific and technical terms used
- Be consistent in the structure and order of communications
- Use the same distribution channels to your audience for all communications of that type; for example, use of distributions lists, wires services, websites and social media

### **Be fair, balanced and understandable (clear)**

- Use a title that accurately reflects the content of the communication
- Be transparent and clear about bad news
- Provide a high-quality description and explanation suitable to the audience, without assuming scientific expertise
- Be neither too optimistic, nor too pessimistic, so as to be balanced
- Avoid exaggeration or hype




## **Be mindful of the impact on members of the public to whom it is personally relevant**

- Consider the effect the information may have on patients and their families, clinical trial participants, and others to whom it is personally relevant
- Produce public communications alongside investor communications, using plain English wherever possible and explaining scientific and technical terms that can't be avoided
- Keep clinical trial participants and interested parties informed of progress, results and impact of the research, ensuring consistency with investor communications
- Where possible and relevant, involve patients, patient groups and charities in designing and producing any information intended for a public audience
- Avoid creating unrealistic or premature expectations
- Be mindful of how the information may be presented in the media and take steps to avoid inappropriate reporting
- Have policies and processes in place to deal with incoming inquiries or social media commentary, and respond consistently
- Have a strategy and policies in place for engagement through third parties, such as patient groups and forums and research charities

*“Medical research offers such hope to patients and so communicating the results in a responsible way is essential and ethical. Standing in the shoes of the recipient of medical research and understanding what’s important to them can make all the difference to meeting their expectations and not inflating their hopes.”*

**AISLING BURNAND MBE**  
**CHIEF EXECUTIVE, ASSOCIATION OF MEDICAL RESEARCH CHARITIES**



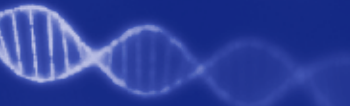
	Communications about			
	Pre-clinical	Phase I	Phase II	Phase III
<p><b>Trigger and timing of announcements</b></p> 	<p>Consider announcing material information which:</p> <ul style="list-style-type: none"> <li>• is a hypothesis-changing result or combination of results</li> <li>• impacts risk-benefit analysis</li> <li>• shows narrowing of the potential commercial opportunity</li> <li>• impacts on use of cash</li> <li>• results in a material change to company strategy or business plan</li> </ul>	<p>Consider announcing information which:</p> <ul style="list-style-type: none"> <li>• impacts on likely risk-benefit; for example, relating to toxicology/dosing</li> <li>• changes the potential commercial opportunity</li> </ul>	<p>Always announce data critical to progress of each of the product(s) which are central to the company's purpose and its ability to generate long-term value</p>	
		<p>For timing, consider announcing:</p> <ul style="list-style-type: none"> <li>• Investigable New Drug (IND) approval</li> <li>• ethics approval</li> <li>• first patient dosing</li> </ul>		
		<p>For timings during trial, consider announcing:</p> <ul style="list-style-type: none"> <li>• interim analysis of emerging data</li> <li>• material changes to previously-made statements</li> <li>• material changes to timeline, costs, and likelihood of success</li> </ul>		
		<ul style="list-style-type: none"> <li>• Establish a pattern for future disclosure</li> </ul>		


*“Building support and trust in Bioscience is an industry wide effort. Clear, timely, consistent and transparent communication is perhaps the most important way to build and maintain trust in our sector. As an investor it has a direct impact on our view of the amount and cost of the capital we invest”*

**CHRIS HOLLOWOOD**  
**CHIEF INVESTMENT OFFICER, SYNCONA**







	Communications about			
	Pre-clinical	Phase I	Phase II	Phase III
<b>Include in content of announcements</b> 	<ul style="list-style-type: none"> <li>• Material information (see opposite)</li> <li>• Experiment design and results (including in vitro or in vivo)</li> <li>• Ability and resources to progress; such as changes to cash demands, timelines</li> </ul>	<ul style="list-style-type: none"> <li>• Results – design, endpoints, pharmacokinetic data, link to <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> entry</li> <li>• Intention to publish further data and analysis; for example, about secondary and exploratory endpoints</li> <li>• Explain deviations from previously announced timelines for announcements</li> <li>• Implications for timelines, future trial design, clinical and commercial potential</li> <li>• Ability and resources to progress; for example, changes to cash demands, timelines</li> </ul>		
				<ul style="list-style-type: none"> <li>• Clear on maturity and completeness of the data</li> <li>• Overall implication of headline relative to full results; for example, if the primary end point is not met but there is a clear path to further development</li> </ul>
	<ul style="list-style-type: none"> <li>• Next steps in the R&amp;D and/or regulatory process</li> </ul>			

*“Clear announcements, giving both background and consequence, enable equity analysts to give timely and accurate comment and context on the news for investors in the short period between news release and market open, reducing the potential for misinterpretation and share price overreaction”*

**DR JULIE SIMMONDS**  
**DIRECTOR, EQUITY RESEARCH, PANMURE GORDON & CO**



R&D data and results milestones are critical to a bioscience company's prospects. They must be communicated carefully to enable all audiences, including less specialist investors and media, to quickly and accurately interpret results and their implications.

**When making clinical trial top-line data announcements**

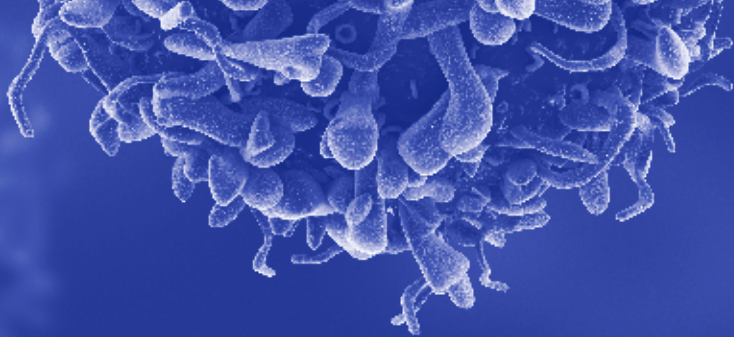
- Disclose up-front the results of a clinical trial against primary end points, do not hide negative results
- Describe the clinical trial design and endpoints, and explain any changes to these from previous communications
- Whenever possible include links to clinical trial registries, such as [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- Indicate any intention and, if known, the timeline for publication of further data and analysis such as a peer-reviewed journal or conference presentation

**When publishing data - academic journals or at conferences**

- Consider the materiality of any new analysis by or connected to the company that will be made public in a journal or at a conference, and disclose any material new information to investors as soon as possible and no later than the time of publishing
- Understand the editorial and publication processes; for example, if there will be pre-publication stage at which data and/or analysis will be widely available for review ahead of full publication
- Be aware of and plan appropriately around embargoes

**When data is published by third parties unconnected to a company**

- Consider announcing when you become aware of any third-party data of material impact, for example, a physician-sponsored study outside the company's direct control
- Explain the potential impact of the new data
- Explain any differences to pre-existing data that has already been made public



## What about the use of social and digital media channels?

Communications about R&D progress through social and digital media can be read by everyone and global transmission is almost instant. The following guidance applies the best practice principles to these communications:

- Establish a corporate social media strategy and policy (what will be communicated, who can communicate, sign off processes and compliance, monitoring and engagement)
- Maintain a consistency of process on each platform
- Maintain a consistency of language and terminology
- Take care to prevent the creation or continuation of false rumours
- Have an internal policy for employees' personal use of social media when communicating or mentioning company matters
- Be aware that in some non-UK jurisdictions, such as the US, you can use social media as the primary method for announcing to investors. Therefore, you should use that method consistently and appropriately

### Where can you find more information?

The BIA has created an online library of resources to support this guide. It will be updated with new content to ensure this guide remains useful and up-to-date as the UK biotech sector grows and evolves.

Go to <http://bia.me/RDcommsguide>

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## BIA Supporters

