

<b>CSL™</b>	Review and Approval of Meetings, Congresses, Sponsorships and Engagement with HCPs	
	Doc #: ICO-SOP-BI-COMOPS-01	Version: 1.0
	Effective Date: January 15, 2019	Supersedes:

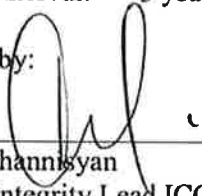
**Applicable to:** Review and approval of Meetings, Congresses, Sponsorships and Engagement with HCPs in ICO ComOps.

**Supports:** ICO-POL-BI-COMOPS-01 Policy on Meetings, Congresses, Sponsorships and Engagement with HCPs

**Note:** ICO-SOP-BI-COMOPS-01 is a Regional TEMPLATE to be used as a guidance to be adjusted by each affiliate's objective need based on external requirements and internal structure.

Revision Interval: 3 years

Authored by:

  
 Bella Hovhannisyán  
 Business Integrity Lead ICO

Approved by:

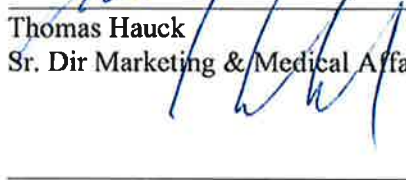
  
 Juan Feliu  
 Ex. Sr. Dir Latin America ICO


  
 Camilla Shen  
 Ex. Sr. Dir Eastern Central ICO

  
 Markus Stämpfli  
 VP and GM ICO Com Ops

 15. 01. 2019  
 Gunnar Philipp  
 Dir Medical Affairs ICO

  
 Thomas Hauck  
 Sr. Dir Marketing & Medical Affairs, ICO

 15.1.19  
 Niklaus Kraehenbuehl  
 Ex. Dir. Associate General Counsel, ICO

	Review and Approval of Meetings, Congresses, Sponsorships and Engagement with HCPs	
	Doc #: ICO-SOP-BI-COMOPS-01	Version: 1.0
	Effective Date: January 15, 2019	Supersedes:

**Applicable to:** Review and approval of Meetings, Congresses, Sponsorships and Engagement with HCPs in ICO ComOps.

**Supports:** ICO-POL-BI-COMOPS-01 Policy on Meetings, Congresses, Sponsorships and Engagement with HCPs

**Note:** ICO-SOP-BI-COMOPS-01 is a **Regional TEMPLATE** to be used as a guidance to be adjusted by each affiliate's objective need based on external requirements and internal structure.

Revision Interval: 3 years

Authored by:

\_\_\_\_\_  
 Bella Hovhannisyan  
 Business Integrity Lead ICO

Approved by:

  
 \_\_\_\_\_  
 Juan Feliu  
 Ex. Sr. Dir Latin America ICO

\_\_\_\_\_  
 Gunnar Philipp  
 Dir Medical Affairs ICO

\_\_\_\_\_  
 Camilla Shen  
 Ex. Sr. Dir Eastern Central ICO

\_\_\_\_\_  
 Thomas Hauck  
 Sr. Dir Marketing & Medical Affairs, ICO

\_\_\_\_\_  
 Markus Stämpfli  
 VP and GM ICO Com Ops

\_\_\_\_\_  
 Niklaus Kraehenbuehl  
 Ex. Dir. Associate General Counsel, ICO

## 1. Purpose

This SOP establishes an integrated process covering the conception, the preparation, the review and the approval, the execution and the post-execution of CSL BEHRING Intercontinental Commercial Operations ("ICO") activities with external stakeholders. It supports ICO Policy on Meetings, Congresses, Sponsorships and Engagements with HCPs and must be complied with in conjunction and is integrated with other related processes (e.g., approval of materials, contract management, purchasing, travel and expenses, etc).

It is intended to be a business instrument and to ensure compliance with laws, regulations and codes such as:

- The EFPIA Code of Practice on the Promotion of Medicines ("EFPIA Code"), the IFPMA code and applicable national code adopting the minimum standards required by the EFPIA Code and the IFPMA Code; and local (country) Industry Codes;
- the Foreign Corrupt Practices Act 15 U.S.C. 78 dd-1 ("FCPA") and any other applicable anti-bribery or anti-corruption laws and regulations.
- Any other laws, regulations and codes covering bribery, money laundering, conflict of interests, inappropriate influence, and inappropriate promotion.

## 2. Scope

The owner of this SOP is the ICO Business Integrity ("ICO BI").

This SOP relates to the activities covered by

- ICO-POL-BI-COMOPS-01 Policy on Meetings, Congresses, Sponsorships and Engagements with Healthcare Professionals

It covers related activities, physical or virtual,

1. initiated by any function in Country in ICO, or at Regional ICO level,
2. involving stakeholders (e.g., Health Care Professionals ("HCPs"), Government Officials ("GO"), Health Care Organizations ("HCOs") practicing in a country/countries in ICO regardless of where the event takes place.

It also applies to meetings related to fee-for-service activities such as advisory boards, investigator meetings, speaker trainings, others.

It may also apply to interactions with Patient Advocacy Groups ("PAGs"), Media, other stakeholders.

It applies to all CSL BEHRING employees (and agents/consultants) involved in the above activities, whatever the function (Marketing, Sales, Medical, Medical Scientific Liasons ("MSL"), Market Access, etc).

This SOP does not apply to:

- One-to-one contacts and visits (e.g., senior Medical visiting top KOLs), unless part of a specific program, in which case the overall program must be approved.
- Ordinary One-to-One Calls.
- Opportunity Meetings, i.e. meetings that are not planned in advance.
- Internal meetings (although contracts with HCPs, GOs and other Stakeholders providing services for such meetings must be approved according to the CSL BEHRING contract management process).
- Investigator Initiated Studies (IIS), non-interentional studies or market research studies.

Activities out of scope of the SOP do not require prior approval under this SOP.

## 3. General Requirements

### 3.1 Classification of Activities

The List (non-exhaustive) of activities subject to approval under this SOP, i.e. activities in scope, can be found in Appendix II.

### 3.2 Process Requirements

#### 3.2.1 General Approval Requirements

All activities in scope must be approved according to this SOP before they are executed.

The process is based on the approval of a Specific Activity Approval Brief, which can be found under Appendix III, made of two main sections, corresponding to the key phases of the process:

- Review and Approval: the detailed information and documentation of the project on which the Review and Approval is based.
- Close out: Project execution documentation and final controls.  
It includes a Checklist of all the documentation needed whether at the time of Approval (e.g., list of invitees), or following the approval or the event (e.g. minutes, sign-in sheets).

All required documentation must be mandatorily collected and uploaded into an online environment (e.g., Companion) to support the approval and closure of the activity. This documentation is necessary to prove that all engagements, services and other interactions with stakeholders or other third parties, for which CSL BEHRING will make payments, are legitimate and commensurate to the value received and adequate to satisfy the related original and approved CSL BEHRING need.

Activities where different functions conduct distinct activities (e.g., promotional booth by Marketing and non-promotional satellite symposium by Medical at the same congress), each function must be responsible for the activity under their responsibility.

Approval of an activity must be obtained before it can take place or any final invitation can be sent or any engagement can be made. Contracts can only be signed after the approval of an activity and before the activity execution. All activities must be cancelled if Approval is not obtained. Exceptionally, final bookings for privately-owned venues (i.e., meeting space and accommodation) can be made, subject to cancellation clauses, prior to the Approval.

The initiator must check that the final program is aligned with CSL BEHRING rules and external requirements, and should this not be confirmed, this should be escalated to ICO Business Integrity to assess whether the activity must be cancelled. The initiator must refer to ICO Policy on Meetings, Congresses, Sponsorships and Engagement with HCPs for guidance.

All payments must be in line with CSL BEHRING Table of Authorization.

#### 3.2.1 Specific Approval Requirements

For **major congresses** where the final program is not available, Approval may be exceptionally granted based on a past year program and on the basis of an advanced draft of the program, in order to allow early arrangements and invitations.

If the information **changes significantly** during the course of the approval process, a new Approval must be sought. Significant changes include but are not limited to changes in venue, location, strategy, material budget variations (e.g. 20% increase), materials changes in the participants' list (e.g. 20% decrease or increase), rationale for scientific program, etc. Significant changes and any other changes must be duly reflected and documented by the initiator.

#### 3.2.3 Initiators and Reviewers

Initiators are fully accountable for applying the process correctly and for the preparation, completeness, accuracy, approval, finalization, and archiving of the activity. They are fully accountable for the execution of the event in accordance with the approved Specific Activity Approval Brief (Appendix III) and all applicable

laws, regulations, codes and CSL BEHRING policies and procedures. They can delegate tasks to any necessary support functions , but they remain accountable for the overall activity.

The Initiator must not be same as any reviewer/approver. In such cases, approver is the direct manager of the Initiator, unless otherwise approved and documented by ICO Business Integrity (Compliance).

Each reviewer/approver has the duty to review/approve all activities on the basis of their functional competence, the applicable CSL BEHRING strategy (e.g., Brand Plan for Marketing, Medical Plan for Medical, etc.), and applicable laws, regulations, codes and CSL BEHRING policies, procedures and ethical standards, while considering the activity in its entirety and complexity and taking into account the impact it can have on CSL BEHRING’s reputation and image.

Reviewers can consult any other functions (e.g., ICO Business Integrity Department, ICO Legal, etc.) for advice at any time. Reviewers may delegate the responsibility to review and approve (e.g., long leaves) to a colleague in the same function and with the consent of their supervisor but they remain accountable. Review must be completed within 5 working days.

**3.2.4 Other Process Requirements**

As detailed in the Checklist, elements approved under other processes (e.g. materials, contracts) must be referenced through the specific ID number of the applicable process (e.g. Concur, Companion, Compass, SAP).

It is compulsory to insert into attendance sign-in sheets a “data privacy” notice. The standard text is available under Appendix IV. The standard text must be adjusted by country based on specific data privacy applicable laws and regulations.

**3.2.5 Agreements with external stakeholders (e.g., HCPs, GOs, HCOs, etc.)**

Agreements with stakeholders whether in the context of an activity (e.g., Advisory Boards, speaker services, internal training, etc.) or not (e.g., simple consultancy) must be concluded in accordance with the relevant CSL BEHRING processes and must be approved accordingly through Companion.

**4. Procedure**

**Preparation of the Specific Activity Approval Brief**

Initiator	<ul style="list-style-type: none"> <li>• Initiates the Specific Activity Approval Brief and completes it with all the required information following Specific Activity Approval Brief (Appenix III) indications.</li> <li>• Allocates the appropriate finance project tracking system (e.g., SAP) aligned to the P&amp;L Classification. For congresses with problematic hospitality elements, initiates process in compliance with ICO Policy on Meetings, Congresses, Sponsorship and Engagement with HCPs by writing to congress organizers and requests for modification or cancelation of these elements. Completes and documents this process in parallel and before CSL BEHRING participation.</li> <li>• If participants (e.g., delegates) or service providers (e.g., advisors or speakers) from another country are required for the planned activity, consults with his / her functional counterpart in the country where a delegate or service provider are coming from to verify what hospitality, contractual or additional CSL BEHRING local approval requirements apply to those individuals and inserts information into the Specific Activity Approval Brief. May liaise with local CSL BEHRING contact of the country where the participans are coming from/engaged from to initiate preparation.</li> <li>• Signs Specific Activity Approval Brief to certify the accuracy and completeness of the details reported and compliance with the applicable Laws, Regulation and Codes as well as CSL BEHRING Procedural Documents, in particular that elements such as hospitality</li> </ul>
-----------	---

	, selection criteria, Fair Market Value ("FMV") are in line with Country Industry Code and CSL BEHRING applicable policies and procedures.
--	--

### Sourcing Process (when applicable)

Initiator	<ul style="list-style-type: none"> <li>If required by CSL BEHRING procurement policies, contacts Procurement and provides them with approved Specific Activity Approval Brief to initiate sourcing process.</li> </ul>
Procurement	<ul style="list-style-type: none"> <li>If required by CSL BEHRING procurement policies, obtains and reviews proposals from preferred suppliers and identifies the most suitable options.</li> </ul>
Initiator	<ul style="list-style-type: none"> <li>If required by CSL BEHRING procurement policies, contacts suppliers, obtains and reviews proposals and quotes and identifies the most suitable options.</li> <li>Triggers contract approval process for venues i.e., meeting space and accommodation (contract and PO required). For the avoidance of doubt, no invitations or any engagements with any other external stakeholders (e.g., HCPs, GOs, HCOs, etc.) can be made at this stage.</li> <li>Ensure a HCPs / agencies are entered as contractual partners in Companion.</li> <li>Gathers from Procurement/Vendor all applicable elements, e.g., cost estimates, etc.</li> </ul>

### Review and Approval of the Specific Activity Approval Brief

Reviewer	<ul style="list-style-type: none"> <li>Reviews and provides advice on the basis of their functional competence and the applicable CSL Behring strategy (e.g., Brand Plan for Marketing, Medical Plan for Medical, etc.), and all applicable laws, regulations, codes and CSL Behring policies, procedures and ethical standards, while considering the activity in its entirety and complexity and taking into account the impact it can have on CSL Behring reputation and image. Within 5 working days.</li> </ul>
Approver	<ul style="list-style-type: none"> <li>Approves entire Specific Activity Approval Brief on the basis of their functional competence and Approval of Authority (AA), the applicable CSL BEHRING strategy (e.g., Brand Plan for Marketing, Medical Plan for Medical, etc.), and all applicable laws, regulations, codes and CSL BEHRING policies, procedures and ethical standards, while considering the activity in its entirety and complexity and taking into account the impact it can have on CSL BEHRING reputation and image. May require other functions' advice depending on the nature of the activity and advice required (such as Legal, Business Integrity, Medical, etc.). Approves within 5 working days.</li> <li>In case of rejection, routes back Specific Activity Approval Brief to Initiator, with comments to rectify the Specific Activity Approval Brief and re-submit, if appropriate.</li> </ul>
Initiator	<ul style="list-style-type: none"> <li>In case of rejection, with comments, rectifies the Specific Activity Approval Brief and re-submits, if appropriate.</li> <li>Checks all the advice and approvals have been duly obtained and documented including AA.</li> </ul>

**External requirements as applicable**

Initiator	<ul style="list-style-type: none"> <li>• Ahead of execution, ensures the external local requirements are satisfied and performed according to applicable Country Industry Code.             <ul style="list-style-type: none"> <li>• [Employer's consent]</li> <li>• [Co-payment]</li> </ul> </li> <li>• [External notification e.g., notification on sponsorship of HCPs to Congresses to Health Authorities, etc.]</li> <li>• Others</li> </ul>
-----------	---

**Pre-execution**

Initiator	<ul style="list-style-type: none"> <li>• Ahead of the execution ensures all other relevant approvals are obtained according to relevant processes e.g., contract, materials.</li> <li>• Ahead of execution, ensures completeness and accuracy of the Specific Activity Approval Brief, including documents to be obtained at pre-execution stage as required by the Checklist of the Specific Activity Approval Brief.</li> <li>• Ahead of execution, receives registration forms/invitation response and compares with authorized invitation lists.</li> <li>• Maintains regular participant status in order to produce record of final attendance, if applicable.</li> <li>• Ensures activity does not take place if Approval of the Specific Activity Approval Brief has not been obtained.</li> <li>• Ensures that individual HCPs or other stakeholders do not attend unless all necessary requirements have been fulfilled as applicable (e.g., co-payment, employer's approval, final and approved contracts are in place etc.) directly or through country confirmation if organized with the help of other countries and in accordance to internal approvals of those countries.</li> </ul>
-----------	--

**Execution**

Initiator	<ul style="list-style-type: none"> <li>• Executes all elements of the activity in line with the Specific Activity Approval Brief, CSL BEHRING strategy, this SOP, all applicable CSL BEHRING policies, procedures and ethical standards and all applicable laws, regulations and codes.</li> <li>• Ensures the disclosure as per the external local 'Transparency' requirements are taken care of and performed as applicable.</li> </ul>
-----------	---

**Post Execution**

Initiator	<ul style="list-style-type: none"> <li>• Ensures that <b>executed activities are in line with what was approved in the Specific Activity Approval Brief.</b> Highlights any variation and compulsory inserts relevant explanation.</li> </ul>
-----------	---

	<ul style="list-style-type: none"> <li>• Ensures <b>Companion completion and Filing</b> by obtaining all relevant supporting information and documentation (e.g., minutes, sign-in sheets, records, etc.) and adding to Companion file on the basis of the Checklist of the Specific Activity Approval Brief. Update the Checklist accordingly.</li> <li>• Ensures <b>Post Execution Control</b> by verifying as a minimum the following:             <ul style="list-style-type: none"> <li>○ All services billed were actually received and are as per contractual terms and as per approved Specific Activity Approval Brief.                 <ul style="list-style-type: none"> <li>▪ Proof of Execution obtained and attached for all services detailed in the Specific Activity Approval Brief and in the contracts (see definition)</li> <li>▪ Supporting documentation obtained for any incidental expenses reimbursements as per contractual agreement (e.g., original invoices for HCP reimbursement and limited to the expense items and amounts in the contract).</li> <li>▪ Ensures actual execution is in line with applicable limits for meals, honoraria, travel (e.g., the actual costs, actual number of participants etc.).</li> </ul> </li> <li>○ Ensures supporting documentation is appropriate/valid and consistent with Specific Activity Approval Brief and contracts:                 <ul style="list-style-type: none"> <li>▪ Sign- in sheet contains the signature of all the participants and speakers. Any variance needs to be noted and explained.</li> <li>▪ An invoice is not a proof of service, except for an invoice from booth constructor.</li> <li>▪ The final agenda timelines should match the number of hours of services delivered in the contract.</li> <li>▪ Ensure all the costs have gone to the appropriate project / have been accounted for appropriately as per the Specific Activity Approval Brief information.</li> </ul> </li> <li>○ Verifies that all the pre-execution checks are visible in the supporting information &amp; documentation:                 <ul style="list-style-type: none"> <li>▪ All necessary contracts approved and signed appropriately prior to the event (i.e., none missing signed post event, not appropriately approved etc.).</li> <li>▪ Materials reviewed and approved appropriately prior to the event (i.e., none missing signed post event, not appropriately approved etc.).</li> <li>▪ Local requirements fulfilled and obtained appropriately prior to the event e.g., co-payment, employer's approval, approvals from regulatory authorities, notifications to regulatory authorities within given deadlines (i.e., none missing, not obtained in a timely manner etc.).</li> <li>▪ Local requirements fulfilled and obtained appropriately after the event within given deadlines e.g., reporting to regulatory authorities etc.</li> <li>▪ Specific Activity Approval Brief had been completed and approved appropriately prior to the event and any significant change has been approved.</li> </ul> </li> </ul> </li> <li>• Escalate and report to ICO Business Integrity department any potential issues as appropriate should any issue be uncovered.</li> <li>• Confirms all the tasks above (in the Post-execution of the event) have been completed and activity can proceed to archiving</li> </ul>
--	--



**Archiving of the Specific Activity Approval Brief and related documents**

Initiator	<ul style="list-style-type: none"> <li>Archives in Companion (or similar) the activity related supporting documents (See Appendix III-Checklist) . Formal documents which need to be retained in a paper version, will continue to be physically archived in paper version, however a reference or a copy of the document shall be uploaded into Companion (or similar).</li> </ul>
-----------	---

**5. Roles and Responsibilities**

Roles	Responsibilities
<b>General Manager / Country Manager</b>	<ul style="list-style-type: none"> <li>Initiates, with the support of Process Owner, the local adjustment of the SOP based on objective external and internal needs as applicable and formally approve locally (e.g., through affiliate Compliance Committee). If no substantial adjustments, this SOP can be used but needs to be formally approved at affiliate level (e.g., through affiliate Compliance Committee).</li> </ul>
<b>Process Owner</b>	<ul style="list-style-type: none"> <li>Ensures with support of ICO ComOps proper communication, training, implementation and functioning of this SOP, assess its efficiency and proposes improvements as necessary.</li> <li>Ensures update of the SOP at whenever a change is required.</li> </ul>
<b>Initiator</b>	<ul style="list-style-type: none"> <li>Initiators are fully accountable for applying the process correctly and for the preparation, completeness, accuracy, approval, finalization, and archiving of the Specific Activity Approval Brief. They are fully accountable for the execution of the event in accordance with the approved Specific Activity Approval Brief or standardized relevant forms and all applicable laws, regulations, codes and CSL BEHRING policies and procedures. They can delegate tasks to any necessary support functions (e.g., Purchasing, Event Management, etc.) but they remain accountable for the overall activity.</li> </ul>
<b>Approver</b>	<ul style="list-style-type: none"> <li>One-over-manager of an initiator (e.g., GM is approver for Senior Product Manager initiated activity).</li> <li>Reviews and approves the Specific Activity Approval Brief on the basis of their functional competence, the applicable CSL BEHRING strategy (e.g., Brand Plan for Marketing, Medical Plan for Medical, etc.), AA and all applicable laws, regulations, codes and CSL BEHRING policies, procedures and ethical standards, while considering the activity in its entirety and complexity and taking into account the impact it can have on CSL BEHRING's reputation and image. Within 5 working days.</li> </ul>
<b>Reviewer</b>	<ul style="list-style-type: none"> <li>Marketing: alignment with overall strategy.</li> <li>Medical: compliance with FMV, scientific program and HCPs selection criteria.</li> <li>Market Access: alignment with Market Access strategy if applicable.</li> <li>Legal: compliance with external laws and regulations.</li> <li>Business Integrity (BI): compliance with Industry Codes, internal policies and procedures.</li> <li>Each reviewer, upon initiator or approver request, has the duty to review all activities on the basis of their functional competence, the applicable CSL BEHRING strategy (e.g., Brand Plan for Marketing, Medical Plan for Medical, etc.), and all applicable laws, regulations, codes and CSL BEHRING policies, procedures and</li> </ul>

Roles	Responsibilities
	<p>ethical standards, while considering the activity in its entirety and complexity and taking into account the impact it can have on CSL BEHRING's reputation and image. Within 5 working days.</p> <ul style="list-style-type: none"> <li>For any activity not initiated by Medical, the Medical Review is to be performed on the content of the activity only (i.e., program of the event, agenda of the activity, HCPs selection criteria, FMV, congress relevance). For such activities, the Medical Reviewer is accountable for ensuring that such elements are consistent with laws, regulations, codes, CSL Behring policies, procedures and ethical standards, or practices of good science and medicine. No other element is to be assessed by the Medical Reviewer (such as alignment with the Marketing Strategy, logistics, etc.)</li> </ul>

## 6. Definitions

Term	Definition
<b>Approval Authority (AA)</b>	Authority to approve company's entering into a transaction based on the financial value of the transaction. Refer to Table of Athorization.
<b>External Meetings</b>	Meetings targeted at a non-CSL BEHRING audience. Conversely, internal meetings are meetings targeted at a CSL BEHRING audience (e.g., sales force training), even if some external persons attend as service providers (e.g., an external HCP speaking at an internal training session).
<b>Field Activities</b>	Activities initiated by field forces such as MSLS, Sales Representatives and/or Key Account Managers.
<b>Local Contact</b>	In the countries where hospitality, contractual or additional local approval requirements apply, an individual in the corresponding business unit in those countries will act as a Local Contact and will provide all the necessary information and support
<b>Opprortunity meetings</b>	Meetings which are not planned, but decided on the same day and fall within the scope of ordinary working relationship with an HCP (e.g., sales rep meets an HCP at the hospital within the regular medical visit activity where HCP asks to have a meeting with the hospital department team). All content, with no exception, must be in-label and strictly no off-label content is allowed.
<b>Specific Activity Approval Brief</b>	Specific Activity Approval Brief is a form that summarizes the main elements of an activity.
<b>Proof of execution (service)</b>	<p>Supporting documentation that substantiate the services were provided, such as :</p> <p>For HCP/ other Stakeholders' services</p> <ul style="list-style-type: none"> <li>Advisory Boards: Slides deck (if any) and minutes and sign-in sheet (participation).</li> <li>Satellite symposia: Presentation slides deck and final program of the third party event mentioning the Satellite symposium (ideally the name of the speakers) and CSL BEHRING invitation/flyer.</li> <li>Speaker Presentations in CSL Behring organized standalone events: Presentation slides deck and sign-in sheet and CSL BEHRING invitation.</li> </ul> <p>Sponsorships in 3rd party events</p> <ul style="list-style-type: none"> <li>Booth/Banner: Picture of Booth/banner (The picture must not contain any identifiable individual image, for data privacy reasons). If the picture is not available, then the construction company's invoice/delivery note (other than organizer) for the construction of the booth/banner is acceptable. Advertisements in congress materials and screens: copy of actual congress materials, picture of the screens</li> </ul>

	<p>with the advertisement.</p> <ul style="list-style-type: none"> <li>Indirect evidence such as activity report can also contribute to substantiate the services &amp; activity were properly executed.</li> </ul>
<b>Proof of execution (Attendance)</b>	<ul style="list-style-type: none"> <li>CSL BEHRING events (standalone): sign- in sheet.</li> <li>Non CSL BEHRING events: sign-in sheet or copy of attendance certificate or congress organizer's confirmation for the actual attendees, or a written certification issued by a CSL employee attending an event.</li> </ul>

## 7. Appendices

Appendix	Title
I	Venue/location selection criteria
II	List of Activities (non-exhaustive)
III	Specific Activity Approval Brief
IV	Sign-in sheet

## 8. Forms and Templates

The Forms & Templates can be updated in collaboration with ICO Business Integrity Department.

Form ID	Title
Form 1 (sample)	Specific Activity Approval Brief– incorporated by reference

## 9. References

- IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) Code
- EFPIA (European Federation of Pharmaceutical Industries and Associations) Code of Practice on the Promotion of Medicines ("EFPIA Code")
- Applicable National Pharmaceutical Industry Codes (e.g., AIPM - Russia, CETIFARMA-Mexico, etc.)
- Foreign Corrupt Practices Act 15 U.S.C. 78 dd-1 ("FCPA") and any other applicable anti-bribery or anti-corruption laws and regulations (e.g., UK Bribery Act).
- CSL Behring Code of Responsible Business Practice
- CSL Board Policy 0400- Anti-Bribery and Anti-Corruption
- CSL Global Policy 0013 - Interactions with Health Care Professionals and Health Care Organizations
- CSL Global Policy 0439 -Provision of Gifts and Hospitality
- CSL Global Policy 0410- Community Contributions
- CSL Global Policy 0401- Sourcing and Procurement
- ICO-SOP-MAF-04: Intercontinental Promotional Material Guideline
- CSL Global POLICY "Implementation of the Labelling Governance in Com.Ops."
- CSL BEHRING Guideline "Rules for Information Sharing with external HCPs in Commercial Development
- CSL BEHRING Guideline "Handling of Questions from external Healthcare Professionals "Global Q&A Process"
- ICO-SOP-MAF-06: Response and tracking of Medical Service Requests (MSR) in Intercontinental Region
- CSL GMA-GDL-GMALT-03-AB "Guideline: Set up, planning, preparation and execution of Advisory Board meetings"
- ICO-SOP-MAF-01 Intercontinental Com.Ops. Fair Market Value (FMV) Guidelines for Fee-For-Service engagements with Health Care Professionals
- ICO-POL-BI-COMOPS-01 Meetings, Congresses, Sponsorships and Engagements with HCPs.

## **APPENDIX I – VENUE/LOCATION SELECTION CRITERIA**

Industry Codes standards must prevail when choosing/assessing a venue/location.

The venue/location choice is not an issue of cost but image and reputation, so questionable venues are prohibited even if cheaper than business-like venues. It applies to venues used for accommodation and/or for meetings that do not involve accommodation.

This applies also to activities organized by third parties where CSL Behring intends to sponsor HCPs, have a symposium, have a booth or other activities. In these cases CSL Behring is not responsible for choosing the geographic location/venue but is still responsible for the fact of sending HCPs to such locations or generally to be associated with these locations/venues.

These are the compulsory selection criteria for identifying business hotels/venues/locations:

### **General principle:**

CSL Behring can select hotels/venues that are business oriented and that are conducive to the main purpose of the meeting (i.e., large number of rooms, appropriate equipment and facilities).

### **Geographic location selection:**

CSL Behring cannot select hotels/venues/locations in a view to provide accommodation or organize meetings in geographic locations with a touristy reputation:

- Seaside or archipelago location during high season;
- Ski locations during high season;
- Touristy cities unless they are also capital cities or major business centers in which case stay clear of touristy areas whatever the star rating;
- Locations when festivals, fairs, sports tournaments, major exhibitions, etc.;
- In attraction or entertainment locations, all year;
- For other cases use your ethical sensitivity and your common sense: if desirable for tourists, then stay clear.

### **Hotel selection:**

CSL Behring cannot select:

- Any hotel/venue if it has a luxury reputation [e.g., Carlton or Ritz] whatever the star rating.
- Any hotel/venue with luxury facilities such as for e.g. (1) superlative services: extra room services not included in standard, private assistance, (2) luxury meal service: different from standard open buffet or pre-determined menus, (3) luxury rooms: private concept rooms with special amenities/facilities (e.g. access to a private swimming pool).
- Chains with mixed luxury/non-luxury reputation can be used but only if away from tourist context (e.g. near airport, business centers).
- Hotels/venues with significant sports or leisure facilities e.g., golf, spas, private beach, cabarets, casinos, extravagant venues or any significant leisure facilities : theatres, sport venues, casinos, live music, dancing, boats, museums, cabarets, gourmet restaurants, extravagant dinners and similar recreational activities/venues are not allowed (whether for meals, meetings only, etc.)

**Appendix II – List of Activities (non-exhaustive)**

Activities covered by/in line with ICO Policy on Meetings, Congresses, Sponsorships & Engagements with HCPs are classified as follows:

<b>ACTIVITY TYPE</b>	<b>INITIATOR</b>	<b>EXAMPLES (other cases can exist)</b>
<b>A : CSL BEHRING activity in the context of a third party event</b>	<b>Marketing</b>	Promotional Booths Disease Awareness Booths (non-promotional by default) Promotional Symposia Sponsorship of HCPs to Congresses Workshop/Courses Sponsorship of Hospital meetings (Promotional Stand) Other Promotional Activities
	<b>Medical</b>	Satellite Symposia Disease Awareness Booths Med Info Booths Sponsorship of HCPs to Congresses Scientific Exchange at Plenary Session Other Non Promotional Activities
	<b>Others (e.g. Market Access)</b>	Other Non Promotional Activities
<b>B : Standalone events organized by CSL BEHRING</b>	<b>Marketing</b>	Standalone Symposia Launch Events Webcasts Executive Encounters Master Classes Speaker Training (non-promotional by default) Preceptorships Workshops Round Table Forums Disease Awareness meetings (non-promotional by default) Sponsorship of HCPs to CSL BEHRING event Speaker Meeting at hospital Peer to Peer Discussion Other Promotional Activities
	<b>Medical</b>	Disease Awareness Meetings with External Speaker Investigator Meetings Advisory Boards Master Classes/Speaker Training Preceptorships Publication Round Tables Round Table Forum Sponsorship of HCPs to CSL BEHRING event Disease Awareness Medical/MSL presentation with Medical/MSL as Speaker Other Non Promotional meetings in response to an expressed and unsolicited request from HCPs Other Non Promotional Activities
	<b>Others (e.g., Market Access)</b>	Other Non Promotional Activities

## APPENDIX III – Specific Activity Approval Brief



FINAL-Specific  
Activity Approval Brie

**APPENDIX IV – SIGN-IN SHEET TEMPLATE**

*(The sign-in-sheet template is to be used at CSL Behring organized and controlled events. Local adjustment per country Data Privacy regulation is required, please refer to local legal counsel. Should an affiliate receive a data related questions from HCPs sent to affiliate address, please send the question to ICO Business Integrity Lead to liaise with CSL Behring Data Privacy officer).*



In compliance with the provisions of Data Privacy regulation [indicate the applicable regulation] of [date], related to Protection of Personal Data and its provisions, all attendees below expressly authorize the inclusion of their personal data (as collected below) in the files owned by CSL Behring [complete per local legal entity] with corporate domicile at [complete per corporate address] (“CSL”), with the purpose of being used by this company both as proof of execution of the event and for audit purposes. CSL will use the participants’ name and its therapeutic area as confirmation for the attendance and will use this confirmation as proof of execution of the event.

If you have any questions about privacy, or any privacy concerns or complaints, please contact [privacy@cslbehring.com](mailto:privacy@cslbehring.com) or send a letter to [indicate affiliate address].

Activity Name:  
Venue:  
Date:  
Duration:

Participants' First Name	Participants' Last Name	Therapeutic Area	Signature

CSL representative:  
Name:

\_\_\_\_\_

Signature:

\_\_\_\_\_