



## TS Toolkit

# TS Support Tools

For sales training and educational  
purposes only  
Proprietary and confidential  
Not for dissemination



# TONE FROM THE MIDDLE RBM Toolkit

## Index

### **SUPPORT TOOLS**

**Steps to Good Ethical Decision Making**

**Therapeutic Specialist Compliance Assessment  
for RBM Therapeutic Specialist Dialogue**

**Guide to Investigations**

**Compliance Resources and Contacts**

# Steps to Good Ethical Decision Making

Many compliance infractions result from individuals making decisions without full knowledge of the compliance requirements, or they make poor ethical decisions. As leaders, you want to avoid situations where a Therapeutic Specialist makes a poor ethical choice and then says *“I didn’t know”* or *“I misunderstood”* or *“I thought it was the right thing to do.”* Therapeutic Specialists need to know what they can’t do, but importantly they also need to be self-sufficient and make good ethical decisions on what they *“can do”* when they face compliance situations that may not seem clear cut during the course of their business day.

To help you train and coach your TSs on how to make good ethical and compliant decisions on a consistent basis, below are some important steps on how to make good ethical decisions *all the time*.

## Steps to Good Ethical Decision Making

---

### 1 Be a Master and be Alert

- Become a master of the compliance policies and procedures so that you know when you might be facing a potential compliance risk.
- Always be alert; ask yourself if there is something about the situation that makes you uncomfortable.

### 2 Examine the Situation

- Potential issues may disappear upon closer examination of the situation, or may change significantly.
- Evaluate the situation from different perspectives; what is the context?
- Ask yourself if you are well prepared to make a decision; could personal feelings, biases, or self-interests affect your ethical judgment?

### 3 Refer to the Standards

- When possible, always refer to Sunovion’s Code of Conduct and Ethics, the Sunovion policies and any other relevant company standards.

# Steps to Good Ethical Decision Making

## Steps to Good Ethical Decision Making

---

### 4 Test the Options

Before acting, evaluate different options with these questions:

- 🟡 Regulatory test—Do I put myself or Sunovion at risk for non-compliance with the FDA?
- 🟡 Harm test—Could patients, customers or others be potentially harmed?
- 🟡 Trust and Reputation test—What will be the impact on the Sunovion's reputation and business relationship with this HCP? Will I build or damage the trust I have with my customer?
- 🟡 Publicity test—Would I want this conduct to be published in the newspaper?
- 🟡 Organization test—What would Compliance or Legal counsel say about this conduct?
- 🟡 Colleague test—What might my supervisor and peers say about this conduct?
- 🟡 Defensibility test—Could I defend this conduct before a committee of peers?
- 🟡 Reversibility test—Would I still think my choice was good if I were adversely affected by it?

### 5 Reach Out

- 🟡 If possible and appropriate, discuss the situation with your manager or peers before acting.
- 🟡 As needed, contact the Compliance Department for their opinion.

### 6 Document, Document, Document

- 🟡 Always accurately document what the situation was and the decision that was made.

### 7 Learn and Improve

- 🟡 Could this situation have been prevented? What could you do to prevent such a situation again and make it less likely that you would have to make such a decision?
- 🟡 Is there any way to have more support next time?
- 🟡 Is there anything that the organization might need to change? (e.g. possible policy changes)

# Steps to Good Ethical Decision Making

## GOOD ETHICAL AND COMPLIANT DECISION MAKING IN ACTION

Frank scheduled lunch with a very important targeted physician in his territory. He had not had much success seeing this physician other than a quick introduction at the nurse's station. As he was setting up the lunch, the receptionist commented that the doctor often is so busy at lunch that he sometimes is not able to come to the lunch or comes very, very late. Frank knew the Sunovion guidelines for lunch with a customer and emphasized with the receptionist and the office manager that he would need to make a product presentation to the physician to meet his company's requirements for providing a meal. They assured Frank that they would have the physician attend the lunch.

Frank delivered the food at the scheduled time the following week. Unfortunately, the physician had been called away for an emergency and was unable to meet with Frank that day. Frank met with the office staff and discussed his product and the company's coupon program. The office manager assured Frank that if he scheduled another lunch, the physician would surely make time to sit down with Frank.

Frank thought about the situation. He was not permitted to provide a meal without a legitimate presentation with a targeted HCP. Obviously this had been a rare case with the emergency, but he had to consider taking the chance again. On his next visit to the office, he spoke briefly with the physician, but again did not have time for a product presentation. Because he wanted more time to speak with the physician, Frank decided to schedule one more lunch.

Frank again delivered the lunch to the office. This time the physician was in the office, but was 90 minutes behind with his patients. Frank waited over an hour in the lunch room, speaking with the office staff as they grabbed lunch, but the physician never came back to the lunch room. The office manager finally arrived and gave Frank the "bad news". The physician was unable to meet with him today. She offered to reschedule Frank for another lunch in the next few weeks. Frank politely declined.

Frank's in-depth knowledge of the compliance requirements for providing meals to a customer resulted in him making a decision about future meal opportunities with this customer. As important as this targeted physician was, he decided to make the right choice and not schedule lunch anymore in this office.

After the lunch, Frank documented what happened. On his way to the next appointment, he called his RBM to share his experience. The manager agreed with his decision about scheduling future lunches with this physician and asked him to present his story to his peers at their regional conference call.





# Steps to Good Ethical Decision Making

## ETHICAL DECISION MAKING BUILDS CONFIDENCE AND TRUST...EVERYWHERE

Having a solid foundation of ethical decision making allows your Therapeutic Specialist and you to focus on successful sales strategies and impact your business while maintaining the highest standards of compliance excellence and integrity.

Therapeutic Specialists no longer focus on what they *can't do* but have confidence in the strategies they *can do*. This sustains trust in Sunovion with our customers and patients by the ethical decisions our TSs and RBMs make on a daily basis.





# Therapeutic Specialist Compliance Assessment

FOR RBM THERAPEUTIC SPECIALIST DIALOGUE

As Sales colleagues, you know that great sales performance is linked to selling knowledge and skills. Compliance is the same; the right compliance knowledge and skills are needed for great compliance performance. Great selling skills combined with great *compliance* skills will help you drive greater sales performance and it will help enhance the trust and value that you create and bring each day to your customers.

This Compliance Assessment is not a performance evaluation. It is designed to help you evaluate your compliance mindset, compliance comprehension and compliance skills and determine areas of strength and opportunities to improve upon.

## 1 EACH THERAPEUTIC SPECIALIST COMPLETES EACH SECTION OF THE ASSESSMENT

- Section 1—Your mindset; how you think and integrate compliance into your day-to-day selling
- Section 2—Your compliance comprehension; your understanding of key compliance areas
- Section 3—Your compliance skills

■ Be honest—your ability to improve and become a master of compliance will depend on an honest assessment of your strengths and areas to potentially improve upon. This Assessment is just for you; it will not be submitted.

## 2 FOLLOW-UP INDIVIDUAL DISCUSSIONS WITH YOUR MANAGER

■ At the next ride-along/coaching day, discuss the compliance assessment and your 1-2 individual compliance training needs with your RBM and develop an action plan to enhance your compliance mindset, comprehension and skills.

# Therapeutic Specialist Compliance Assessment

FOR RBM THERAPEUTIC SPECIALIST DIALOGUE

## 1 HAVING THE RIGHT COMPLIANCE MINDSET

Compliance excellence also depends on how you think, discuss and integrate compliance into your day-to-day selling activities. Take 5 minutes to assess how you would rate yourself compared to these common characteristics of mastering compliance

	YES / ALWAYS	MAYBE/ SOMETIMES	NO / NEVER
Do you see compliance as potentially adding value to achieving your sales goals?			
Do you see compliance as a barrier to achieving your sales goals?			
When discussing compliance requirements with HCPs and customers, do you express them in a positive tone and explain the rationale and benefits?			
Do you proactively share best practices regarding compliance situations with your manager and teammates?			
Do you proactively look for compliance answers?			
Do you feel confident that you can handle any unexpected compliance situations?			

List three benefits of compliance:

1.
2.
3.



# Therapeutic Specialist Compliance Assessment

FOR RBM THERAPEUTIC SPECIALIST DIALOGUE

## 2 BUILDING YOUR COMPLIANCE COMPREHENSION

- True understanding and comprehension is ‘being able to accurately describe the details to another person.’
- For each category, write down at least one area in which you could enhance your compliance comprehension, e.g. either a recent situation that came up, a common or recent question from HCPs or customers, or compliance areas you may be uncertain of.

<div>Clinical Messaging<ul style="list-style-type: none"><li>Effectiveness claims</li><li>Safety and fair balance</li><li>Off-label questions</li><li>Use of materials</li><li>Providing prescribing information</li></ul></div>	
<div>Speaker Programs<ul style="list-style-type: none"><li>Invitations</li><li>Cancellations</li><li>Attendees</li><li>Off-label questions</li><li>Monitoring and Speaker Infractions</li><li>Meals and receipts</li></ul></div>	
<div>Lunch and Learns<ul style="list-style-type: none"><li>Ordering food</li><li>Attendees</li><li>Location</li><li>Left-over food</li><li>Medically relevant discussion</li></ul></div>	
<div>Local Exhibits<ul style="list-style-type: none"><li>Contracting process</li><li>Materials used</li><li>Location</li><li>Patient focused exhibits</li><li>Interactions with patients</li></ul></div>	

# Therapeutic Specialist Compliance Assessment

FOR RBM THERAPEUTIC SPECIALIST DIALOGUE

## 2 BUILDING YOUR COMPLIANCE COMPREHENSION

- True understanding and comprehension is ‘being able to accurately describe the details to another person.’
- For each category, write down at least one area in which you could enhance your compliance comprehension, e.g. either a recent situation that came up, a common or recent question from HCPs or customers, or compliance areas you may be uncertain of.

Email, Texts and Social Media

- Use of brand names
- Purpose of email/texts
- Use of Twitter, Facebook

Adverse Event Reporting

- What is an AE?
- What you need to report
- How to report

Sunshine Act

- How to handle questions from HCPs and customers

# Therapeutic Specialist Compliance Assessment

FOR RBM THERAPEUTIC SPECIALIST DIALOGUE

## 3 ENHANCING YOUR COMPLIANCE SKILLS

Compliance skills are similar to selling skills; they are essential to ensuring great compliance performance. In selling you learn about introductory benefit statements, how to deliver clinical messaging, and how to close. In compliance, the following skills will help you achieve great compliance performance. Answer the following questions to determine how well you rate your own compliance skills.

		OFTEN	SOMETIMES	RARELY/NEVER
Decision Making	Do you <u>NOT</u> do something because you are not sure of the compliance requirements?			
	Do you delay decisions because you need to find out the answers?			
	In complex situations, are you confident that you can make a good ethical and compliant decision <i>in the moment</i> ?			
Communications	Do you speak effectively and positively about the rationale and benefits of compliance?			
	Are you careful about your compliance communications and therefore the choice of words and language so that you accurately describe a situation?			
	Do you speak up when you feel there has been a potential violation of compliance policies and procedures?			
Use of Tools	Do you use compliance tools and resources on a daily basis?			
Proactive	Do you think ahead and act proactively to prevent potential issues?			
Consistency	Do you ensure that you apply the compliance requirements consistently to all customers and situations?			
Documentation	Do you appropriately document compliance information in a timely basis?			

# Guide to Investigations

## Investigations

Compliance investigations are an infrequent but important component of the overall Sunovion compliance program. Sunovion conducts compliance investigations when actual or suspected violations of policies are reported. The investigations process is designed to ensure confidentiality, prevent retaliation, accurately and fairly assess what happened, and ensure the situation is resolved and the appropriate corrective action is implemented.

An investigation is a confidential, impartial fact-gathering process that allows Sunovion to evaluate a reported violation and achieve a resolution that is fair and appropriate. Typically, an investigation involves information and document gathering, interviews of those being investigated and witnesses, and a final resolution. The results of an investigation may include additional training and coaching on policies or processes but may also include disciplinary action.

The Compliance and Ethics Department handles all reports of fraud or misconduct, whether actual or suspected and is responsible for ensuring each case is appropriately handled and that the required corrective action takes place.

## REPORTING POTENTIAL VIOLATIONS— YOUR DUTY

All employees are required to report any suspected or potential violations of company policy. Not reporting an actual or potential infraction is also a violation of company policy. All employees can report a potential or suspected violation through their supervisors, Human Resources, Sunovion Compliance and Ethics, Legal or the anonymous Sunovion hot-line at <http://www.ethicspoint.com> or 1-866-886-1348.

Remember, violations of company policy can potentially impact patient safety as well as the trust and reputation of Sunovion with our customers and the public. There can also be serious legal ramifications for those involved and the company. So it is important that you speak up if you feel there has been a breach in policy.

## THE INVESTIGATIONS PROCESS DEMYSTIFIED

### DATA COLLECTION AND INTERVIEWS:

Compliance and Ethics collects relevant documents and typically conducts confidential interviews with those who reported the issue, the person (or people) who the report is about, and others who may have observed or be aware of the reported situation.

Many interviews are conducted over the phone, however, employees may be asked to travel for in-person interviews. Investigations are usually conducted in conjunction with Human Resources or Legal.

Once all the information is gathered, the investigator presents key findings and recommendations and sends this to the Compliance Investigation Committee (CIC). The CIC is composed of Compliance and Ethics, Legal and Human Resources and will make a final decision on the case. Business Leadership is then informed of the decisions and required actions.

### CORRECTIVE ACTION:

Business Leadership is responsible for carrying out the recommended corrective or disciplinary action, including notifying the employee who was investigated and their leadership.

# Guide to Investigations

## SUNOVION NON-RETALIATION POLICY

You may report any misconduct, either openly or anonymously, without fear of retaliation. Sunovion will not discipline, discriminate, or retaliate against any employee who reports a complaint or concern in good faith, or who cooperates in any investigations or inquiry regarding such conduct whether or not such information is ultimately proven to be correct. Moreover, Sunovion will not tolerate any adverse action or retaliation taken against any employee or agent by a supervisor or other employee on account of any compliant or concern raised.

## THE IMPORTANCE OF CONFIDENTIALITY

The investigations process and the results are confidential. Each RBM and TS has a responsibility to keep the contents of the investigations confidential. Only the people who need to know about an investigation are involved; this helps protect everyone’s privacy. A breach of confidentiality could impact the impartiality and legitimacy of an investigation, and could also disrupt the lives and careers of those involved. Sunovion Compliance and Ethics take extensive precautions to maintain confidentiality around an investigation which allows the outcome to be determined through an impartial process and reduces the risk of retaliation.

## YOUR ROLE IF YOU ARE INVOLVED IN AN INVESTIGATIONS INTERVIEW

COOPERATE AND ACTIVELY PARTICIPATE	<ul style="list-style-type: none"><li>■ You must fully cooperate with an investigation, including accepting requests for interviews with the investigator.</li><li>■ Your active participation is required, including being forthright and answering all questions honestly and disclosing all known information.</li></ul>
MAINTAIN COMPLETE CONFIDENTIALITY	<ul style="list-style-type: none"><li>■ Do not discuss the case—including the fact you are being interviewed or that an interview took place—with anyone other than the investigator, <i>including your regional business manager</i>. A breach of confidentiality can damage the investigations process or expose an employee to retaliation and could have serious disciplinary consequences, including termination.</li><li>■ If a colleague wants to discuss or share information about an investigation with you (whether actual or rumored), do not engage in a discussion. Politely decline and inform them that discussing an investigation can have serious ramifications. In addition remind them that any such investigation would be confidential and that if any investigation is on-going, they wouldn’t be able to speak of it anyway.</li></ul>



# Guide to Investigations

## YOUR ROLE IF YOU ARE INVOLVED IN AN INVESTIGATIONS INTERVIEW

BE TRUTHFUL AND DETAILED	<ul style="list-style-type: none"><li>Provide honest, detailed answers and don't misrepresent the situation or information.</li><li>Do not omit information you might consider related to the case but insignificant. Sometimes, information that may seem trivial to you can help the investigator better understand the context of a situation.</li><li>Remember you have a duty under the Code of Conduct to report any potential misconduct even if it is beyond the scope of the investigation.</li></ul>
BE CLEAR AND CLARIFY	<ul style="list-style-type: none"><li>Make sure the investigator understands all the points you are making.</li><li>If the investigator asks a question that is unclear, ask for clarification.</li></ul>
DO NOT RECORD	<ul style="list-style-type: none"><li>Interviews relating to an investigation may not be recorded by the interviewer or the interviewee in any way.</li><li>Recording of an interview is a violation of Sunovion policy and will result in dismissal.</li></ul>
NON-RETALIATION	<ul style="list-style-type: none"><li>If you feel someone is retaliating against you, report it to Compliance and Ethics, HR, the Sunovion Hot-line or Legal immediately.</li><li>You may not retaliate or 'get back' at someone who initiated or participated in the investigative process.</li><li>Retaliation is a violation of company policy that can have serious disciplinary consequences, including termination.</li></ul>
FOLLOWING THE INTERVIEW	<ul style="list-style-type: none"><li>The investigations and resolution process may take some time. While the process is underway, continue with your regular business activities unless otherwise notified and do not discuss the investigation.</li><li>You will not be informed of the disciplinary/corrective outcome of the case, and you should not ask. You should not discuss the investigation in any way after the case is closed.</li><li>For those being investigated, only that person and his/her management will be informed once an outcome action has been decided and carried out.</li></ul>

# Compliance Resources and Contacts

Listed below are the broad range of compliance resources that are available to you. It is important that you are self-sufficient and are able to make compliance-related decisions locally.

For any compliance-related questions, as a first step, become fully knowledgeable of Sunovion policies and procedures. If you still have questions, you can contact your RBM for guidance and clarification. If there are still questions, you can access the compliance resources online. The Compliance and Ethics Department is available to answer questions after you have exhausted all other avenues. It is likely that you will be able to find the answer to the vast majority of your questions via your manager, colleagues, or online resources.

## ON-LINE RESOURCES

<b>Website</b> <a href="http://source.sunovion.com/GA/CorpCompliance/Pages/default.aspx">http://source.sunovion.com/GA/CorpCompliance/Pages/default.aspx</a>	Policies and Procedures
<b>Tone from Middle Support Tools</b> <a href="http://source.sunovion.com">http://source.sunovion.com</a>	List of TFM tools
<a href="http://www.phrma.org/about/principles-guidelines/code-interactions-healthcare-professionals">http://www.phrma.org/about/principles-guidelines/code-interactions-healthcare-professionals</a>	Interactions with Healthcare Professional Guidelines

## COMPLIANCE CONTACTS

<b>Anonymous Compliance Hot-line</b>		1-866-886-1348 or <a href="http://www.ethicspoint.com">http://www.ethicspoint.com</a>
<b>Compliance Department</b>	Matthew D'Ambrosio	matthew.dambrosio@sunovion.com
	Paul Ham	paul.ham@sunovion.com
	Averi Price	averi.price@sunovion.com
	Joe Wholley	joseph.wholley@sunovion.com
<b>Questions about the Sunshine Act</b>	Joe Wholley	joseph.wholley@sunovion.com
<b>Off-Label Inquiries</b>	Medical Information	1-800-739-0565
<b>Adverse Event Reporting</b>	Pharmacovigilance & Risk Management and Quality Complaints & Audits	1-800-737-7226
<b>Educational Grants</b>	Questions about educational grants	<a href="http://www.sunoviongrantsandcontributions.com">www.sunoviongrantsandcontributions.com</a>