






Supplier Quick Reference “Getting Started” on Totality

-  Ensure a fully executed contract/statement of work (SOW) is in place with J&J Affiliate for the project before work is initiated.
-  Obtain a J&J Purchase Order (PO) or Check Requisition (CR) number for the project. Confirm a valid Totality project ID is associated with the PO/CR.
-  Register and attend required **HCC Compliance** and **Totality** training for new Suppliers
 - ✓ Training dates & logistics will be posted on the “**Events**” tab of the **Training & Resource** link of the Extranet site.
 - ✓ “On Demand” targeted training modules will also be available in the future on the “**Resources**” tab of the link.
-  Prior to initiating a project involving interaction or “value exchange” with an HCP - Review and understand the **Supplier Compliance Requirements** (below) and **Supplier Totality Process Flow** ([Exhibit A](#))
 - REQUIREMENTS:**
 - ✓ Complete HCP verification checks and secure required documentation of checks and executed HCP contracts
 - ✓ Upload HCP payment/“value exchange” data (i.e, **Standard Data Templates**) into Totality within required timeframes.
 - ✓ Upload all other required **supporting documentation** to demonstrate compliance and proof of service ([Exhibit D](#))
 - ✓ Review project “**Activity Reports**” to validate uploaded HCP payment details associated with the project are complete and accurate
 - ✓ “**Attest**” when all compliance deliverables for the project have been met (i.e., at completion of project).
-  At the start of each new project, ensure consensus with the Project Manager on required project deliverables and party responsible for completion and/or upload to the system:

- ✓ **Compliance Deliverables Matrix** – Defines the documentation requirements by Type of Project/Activity (**Exhibit B**).



Register for Access to the Totality Extranet portal: <https://totalitygateway.inj.com/tpextranet/>

- ✓ Download and complete the “**User Registration Form**” (excel file) from “**Registration**” link on the Extranet Login Page
- ✓ Submit completed form to the Totality mailbox: TG@prdus.inj.com
- ✓ Registration Form must include date completed HCC/Totality training
- ✓ Ensure supplier system firewalls allow emails from TG@prdus.inj.com



Login to the Totality Extranet site – (1st time access)

- ✓ Users must use **Internet Explorer** as the internet browser to access/login to Totality
- ✓ **User Name** = Registration email address
- ✓ Password = User **Temporary** Password (Temporary password will be emailed upon Registration. *User will be prompted to change upon first time login*).



Download the applicable “**HCP Data Template**” and review data field requirements and upload frequency (**Exhibit C**) to ensure clear understanding of all required data/information needed to capture to complete required data upload for the project.



Ensure supplier systems/processes in place to capture all key HCP “value exchange” data & documentation required for project.



Additional resources are available to Totality Extranet / 3rd party Users:

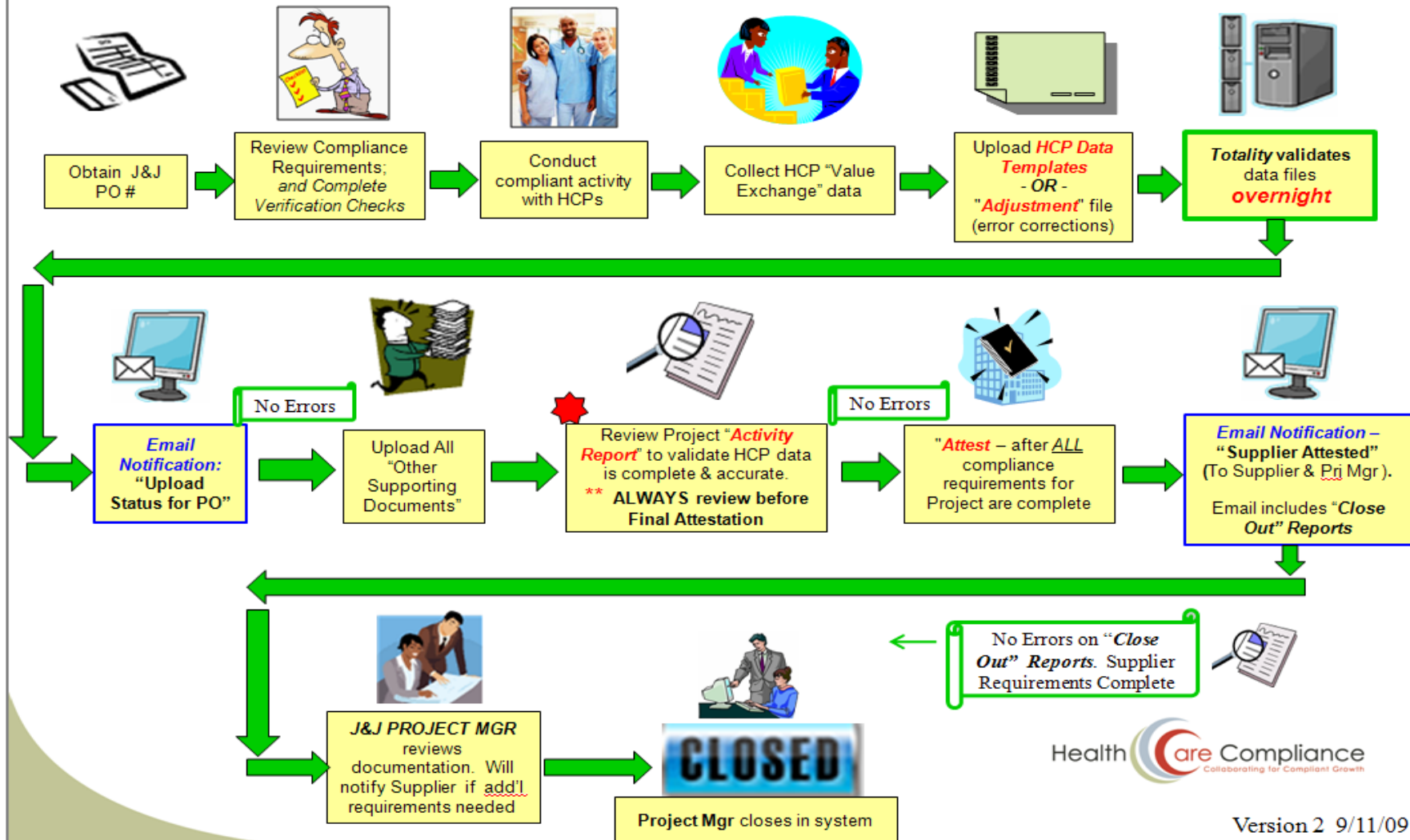
- ✓ Currently available on the Totality Extranet Login Page under the “**Training Materials**” link
- ✓ Future – Reference and training tools will be available via the “**Training and Resource**” link on the Extranet.



Questions regarding project requirements or HCC policy should be directed back to the applicable J&J affiliate Project Manager

Exhibit A – Part I

Supplier Totality Process Flow – No Errors



Version 2 9/11/09

Exhibit A – Part II

Supplier Totality Process Flow – Upload Errors

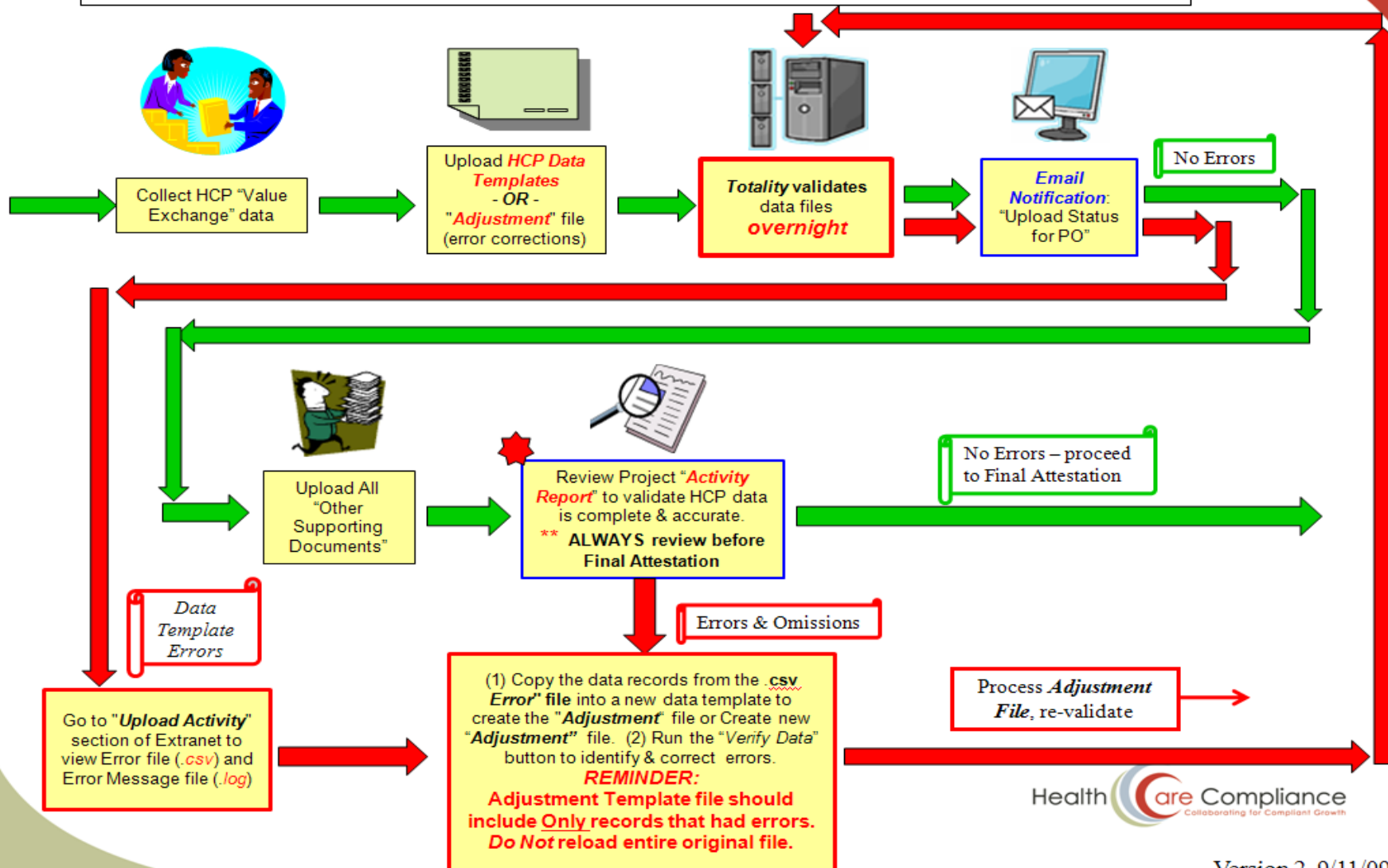



Exhibit B

Supplier Compliance Deliverables Matrix – by Activity Type

CLOSE-OUT DELIVERABLES	Event						Consultant (Not Supplier Checks)					
	Data Template (Value Exchange occurs)	Agenda	Sign-in Sheet	Approved Presentation Materials ***	Project Deliverable	Attest Deliverables Complete	Executed HCP (Individual/ Institution) Contract	OIG Exclusion *	EPLS Exclusion *	FDA Debarment Verification **	License Verification (if applicable) **	Govt. Release or Permission Slip (if gov't employee)
Consulting Arrangements - Company Sponsored Research												
Clinical Studies Company Sponsored Research	H and I				X	X	X	X	X	X	X	X
Clinical Advisory Board/Data Safety Monitoring Board	A	X	X	Approved Deck	X	X	X	X	X	X	X	X
Research Related Services	May Vary				X (Milestone)	X	X	X	X	X	X	X
General Consulting - Clinical	A				X	X	X	X	X	X	X	X
Investigator Meeting	A, B, C	X	X	Presentation		X	X	X	X	X	X	X
Consulting Arrangements - Other Consulting												
Advisory Board	A	X	X	Approved Deck	Final Report	X	X	X	X	X	X	X
General Consulting - Sales & Marketing	A				Final Report	X	X	X	X	X	X	X
Marketing and Advertising Promotion	A				Final Report	X	X	X	X	X	X	X
Speaker Training	A		X	Approved Deck		X	X	X	X	X	X	X
Speaker Bureau	D, E, F, G		X	Approved Deck		X	X	X	X	X	X	X
Development of Educational Materials	A		X		Ed Materials	X	X	X	X	X	X	X
Patient & Educ Items; Conventions/Receptions; Premium - Sales Supply	B or C											
International Symposium	A	X		Presentations		X	X	X	X	X	X	X
Market Research	Secondary market research constructed by OPcO are "blind" do not have close-out deliverables											
Market Research (Primary)	A	X	X	Approved Deck	Final Report	X	X	X	X	X	X	X
IIS												
Preceptorship	A	X				X	X	X	X	X	X	X
Publications	A				Publication	X	X	X	X	X	X	X
Clinical and Pre Clinical Research	May Vary				X (Milestone)	X	X	X	X	X	X	X
Independent Educational Grants												
Royalties												
<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> <p>Data Templates Legend :</p> <p>A. Consulting (HCP Individual_Institution)</p> <p>B. Receptions_Conventions</p> <p>C. Patient Benefits & Educational Items</p> <p>D. Speaker Bureau (Programs Details)</p> <p>E. Speaker Bureau (Speaker Projections)</p> <p>F. Speaker Bureau Completed Programs (Speaker)</p> <p>G. Speaker Bureau Completed Programs (Attendee)</p> <p>H. Clinical Sites Expenses (Site)</p> <p>I. Clinical Sites Visit Expenses (Investigator)</p> <p>J. Consultant Attendee_ Indirect Expenses (MD&D)</p> </div> <div style="width: 35%;"> <p>Examples:</p> <p>Individual - Speaker Training, General Consulting, Advisory Boards, etc</p> <p>Institution - General consulting or speaker engagements where HCP is an INSTITUTION</p> <p>Meal/Item of value provided to HCP attendees at company sponsored Receptions, Conventions</p> <p>Textbook programs; Subscriptions</p> <p>Speaker Bureau Programs - Costs associated with the SB PROGRAM</p> <p>Speaker Bureau Programs - Full year projects by Speakers for Future Confirmed Events & Current Completed programs</p> <p>Speaker Bureau Programs - Speaker value exchange details (i.e., honoraria, meals, travel)</p> <p>Speaker Bureau Programs - Attendee value exchange details (i.e., meals)</p> <p>Clinical Trials/Company Sponsored Research - Payments to clinical sites, including research related equipment supplied to site and not returned</p> <p>Clinical Trials - Exp. Incurred when providing hospitality to HCP's during the course of visits to the investigative site.</p> <p>HCP Indirect Expenses; HCP expenses associated with 3rd party distributors or sales agents</p> </div> <div style="width: 30%;"> <p>FOOTNOTES</p> <p>* Uploaded Screen shots required</p> <p>** Document the date of verification</p> <p>*** If presentation materials include "sensitive" information, please contact project manger and affiliate HCC for guidance</p> </div> </div>												

Exhibit C

HCP DATA UPLOAD REQUIREMENTS 				
HCP Value Exchange Through:	March 31	June 30	September 30	December 31
Upload Data Templates By:	April 30	July 31	October 31	JANUARY 31
** <u>ALL Current Year HCP Activity</u> is required to be uploaded into Totality no later than <u>JANUARY 31st</u> of the following year **				

Data Template/HCP "Value Exchange" Activity - Data Upload Requirements			
Data Template Name	Type of Activity	Frequency	Upload Timing
A Consulting (HCP Individual_Institution)	<i>Individuals</i> - Advisory Board, Speaker Training, Investigator Meeting, General Consulting; <i>Institutions</i> - Preceptorships, Sponsorships for Boothspace	After Event	30 days after Project/Event completion
B Receptions Conventions	Receptions (Attendee meal at company sponsored event); Conventions (Item of value received as part of a conference)	Quarterly	30 days after calendar Quarter close
C Patient Benefits & Educational Items	Textbook programs, Subscriptions, e-Detail, eXtendRx Sales Optimization Program	Quarterly	30 days after calendar Quarter close
D Speaker Bureau (Program Details) *	Speaker Bureau Programs - Program Details (i.e., venue, # attendees, attendee cost/meal, etc)	Quarterly	30 days after calendar Quarter close
E Speaker Bureau (Speaker Projections) *	Speaker Bureau Programs - Full year projects by Speakers for Future Confirmed events and Current programs (Completed or Cancelled and paid)	Monthly	30 days after calendar Month close
F Speaker Bureau Completed Programs (Speaker)	Speaker Bureau Programs - Speaker expenses only (i.e., honoraria, meals, travel)	Monthly	30 days after calendar Month close
G Speaker Bureau Completed Programs (Attendee)	Speaker Bureau Programs - Attendee expenses only (i.e., meals provided)	Quarterly	30 days after calendar Quarter close
H Clinical Sites Expenses (Site)	Clinical trial Site payments (i.e., local IRB fees, hospitalization fees, advertising costs, etc). Also includes cost of equipment provided to a site & not required to be returned after a clinical trial (computer, PDA, refrigerator, etc.)	Quarterly	30 days after calendar Quarter close
I Clinical Sites Visit Expenses	Hospitality (e.g., meal, refreshments) provided to HCP & staff during site visits	Quarterly	30 days after calendar Quarter close
J Consultant Attendee_Indirect Expenses * *	HCP Indirect expenses; HCP expenses associated with 3rd party distributors or sales agents	Quarterly	30 days after calendar Quarter close

All current year HCP activity is required to be uploaded *Quarterly*, 30 days after the close of the quarter, unless designated earlier
*New for 2010 **
*MD&D Affiliates 2010 **

Exhibit D Other Supporting Documentation

Documentation Deliverable	Description / Example
Agenda Sign-in Sheet	Final meeting agenda or event program (e.g., Symposium;) (1) Original/hand written Attendee sign in sheet from the meeting/event (2) Electronic record/card scans (i.e., data in separate system): Upload (a) List of Attendees (b) Note for File documenting the process (3) Web based meetings (e.g., SB with no value exchange/meal): Upload List of Attendees for proof of speaker services performed
Approved Presentation Materials <u>Project Deliverables</u>	e.g. Final presentation deck; discussion guides; meeting handouts; Promotional Review Committee approval #/record locator Documentation to demonstrate "Proof of Services" . Based on Contract deliverables/milestones per "Type" of project. Example: * Ad Board/Investigator Meeting/Web Meetings : Final report; Meeting minutes/feedback notes; Survey results, etc. * General Consulting/Sales Training/Promotional Speaker : Final product; confirmation letter; program/agenda; survey; deck, etc * Speaker Training : Education/training materials * Clinical Studies/Research Related Services : Contract/project milestones or final deliverables (eg. Final report, manuscript, etc) * Publications : Copy of final publication or publication/manuscript citation; copy of poster, etc.
Attest Deliverables Complete	Supplier (& Project Manager) required to "Attest" at end of project "when all Compliance Deliverables have been met"
Executed HCP Contract (Individual/Institution)	Complete copy of all fully executed HCP agreements (dually signed/dated). Contracts should be executed prior to initiation of work. SB & Sp Training - combined contract : (a) Upload contract once, to SB PO. (2) Upload "Note for File" to Training PO for cross reference.
<u>Verification Checks:</u> OIG Exclusion Verification *	NOTE-Speaker Bureaus : Verification required on <u>Quarterly basis</u> . <u>Upload</u> documentation/screen shot - 1st Annual only Upload <u>dated print screen</u> for each contracted HCP (US only). Verification required prior to contract/event http://exclusions.oig.hhs.gov/
EPLS Exclusion Verification *	Upload <u>dated print screen</u> for each contracted HCP (US only). Verification required prior to contract/event https://www.epls.gov/epls/search.do
FDA Debarment Verification **	Complete & document date of verification check for each contracted HCP (US only), prior to contract/event. <u>NO screen shot upload required</u> ** http://www.fda.gov/ora/compliance_ref/debar/default.htm
US State Board License Verification **	Complete & document date of verification check for each contracted HCP (US only), prior to contract/event. <u>NO screen shot upload required</u> ** http://www.ama-assn.org/ama/pub/education-careers/becoming-physician/medical-licensure/state-medical-boards.shtml
Govt. Release/Permission Slip (gov't employee)	Documentation from government employer/ethics committee to allow HCP participation as independent contracted consultant Documentation required <u>prior</u> to participation in work/travel. Special privacy consideration for Non-US HCP's
Other (optional)	Individual Affiliates may require additional documentation (e.g., HCP CV's, etc). Please refer to the J&J Affiliate project manager for guidance