

**Table 5. PDUFA IV Meetings – Technical Discussions
with Regulated Industry IT/IM Subgroup**

Date Time Length	Subjects	Participants
03/29/06 2:00 p.m. 2 hours	<ul style="list-style-type: none"> • Kickoff Meeting • Preliminary list of IT sub-group issues for discussion 	Malcolm Bertoni, FDA Fred Farmer, FDA Mark Gray, FDA Len Wilson, FDA Margo Burnette, FDA Peter Beckerman, FDA Rachel Carle, Genzyme Joe Quinn, sanofi pasteur (BIO) Andrew Emmett, BIO Bob Birmingham, Johnson & Johnson PRD Edward Tripp, Abbott Laboratories Peter Loupos, sanofi aventis Bill Rosen, Pfizer Alison Lawton, Genzyme Steve Ward, Lilly
04/19/06 1:00 p.m. 2 hours	<ul style="list-style-type: none"> • Questions and Clarifications • PhRMA/BIO IT Data Request • Cross-cutting Issues (Safety & DDMAC) • PDUFA III - Follow-up on three areas identified in industry presentation (3/29) <ul style="list-style-type: none"> ○ eCTD ○ Electronic signatures ○ Secure email • Communication and technical interactions • Industry perspective • Informative presentation - FDA Governance Process 	Malcolm Bertoni, FDA Fred Farmer, FDA Mark Gray, FDA Len Wilson, FDA Margo Burnette, FDA Armando Oliva, FDA Allen Jones, GSK Joe Quinn, sanofi pasteur (BIO) Andrew Emmett, BIO Bob Birmingham, Johnson & Johnson PRD Bill Rosen, Pfizer Rachel Carle, Genzyme Peter Loupos, sanofi aventis Steve Ward, Lilly Edward Tripp, Abbott Laboratories
05/03/06 1:00 p.m. 2 hours	<ul style="list-style-type: none"> • Status of date on PDUFA IT spending during since PDUFA I • IT Standards and interoperability 	Malcolm Bertoni, FDA Fred Farmer, FDA Mark Gray, FDA Len Wilson, FDA Margo Burnette, FDA Peter Beckerman, FDA Peter Loupos, sanofi aventis Bill Rosen, Pfizer Andrew Emmett, BIO Joe Quinn, sanofi pasteur (BIO) Edward Tripp, Abbott Laboratories Alison Lawton, Genzyme Monica Mehta, Genzyme Steve Ward, Lilly Bob Birmingham, Johnson & Johnson

		PRD
05/05/06 1:30 p.m. 90 minutes	Discuss concept of shared information exchange	Malcolm Bertoni, FDA Fred Farmer, FDA Gary Gensinger, FDA Mark Gray, FDA Margo Burnette, FDA Peter Beckerman, FDA Ginger Leo, FDA Peter Loupos, sanofi aventis Bill Rosen, Pfizer Andrew Emmett, BIO Bob Birmingham, Johnson & Johnson PRD Edward Tripp, Abbott Laboratories Allen Jones, GSK Steve Ward, Lilly
05/17/06 1:00 p.m. 2 hours	FDA PDUFA IV cost estimate	Malcolm Bertoni, FDA Armando Oliva, FDA Mark Gray, FDA Len Wilson, FDA Margo Burnette, FDA Peter Loupos, sanofi aventis Bill Rosen, Pfizer Andrew Emmett, BIO Joe Quinn, sanofi pasteur (BIO) Edward Tripp, Abbott Laboratories Alan Goldhammer, PhRMA Steve Ward, Lilly Alison Lawton, Genzyme Rachel Carle, Genzyme Bob Birmingham, Johnson & Johnson PRD
05/24/06 8:30 a.m. 1 hour	Follow-up on FDA IT cost estimate	Malcolm Bertoni, FDA Mark Gray, FDA Margo Burnette, FDA Ginger Leo, FDA Tim Mahoney, FDA Andrew Emmett, BIO Joe Quinn, sanofi pasteur (BIO) Bob Birmingham, Johnson & Johnson PRD Steve Ward, Lilly Bill Rosen, Pfizer
05/31/06 1:00 p.m. 2 hours	<ul style="list-style-type: none"> • Discuss possible language for IT/IM "Communication and technical interactions" area. • Discuss PDUFA III IT performance goals • Follow-up on FDA IT cost estimate 	Malcolm Bertoni, FDA Fred Farmer, FDA Mark Gray, FDA Len Wilson, FDA Armando Oliva, FDA Andrew Emmett, BIO Edward Tripp, Abbott Laboratories Len Wilson, FDA Joe Quinn, sanofi pasteur (BIO) Bob Birmingham, Johnson & Johnson PRD Rachel Carle, Genzyme

		Peter Loupos, sanofi Aventis Steve Ward, Lilly Bill Rosen, Pfizer
06/14/06 1:00 p.m. 2 hours	<ul style="list-style-type: none"> • Communication and technical interactions • Definition of "end-to-end electronic submissions" • Discuss commitment letter language 	Malcolm Bertoni, FDA Fred Farmer, FDA Mark Gray, FDA Len Wilson, FDA Armando Oliva, FDA Margo Burnette, FDA Bill Rosen, Pfizer Andrew Emmett, BIO Edward Tripp, Abbott Laboratories Joe Quinn, sanofi pasteur (BIO) Bob Birmingham, Johnson & Johnson PRD Rachel Carle, Genzyme Peter Loupos, sanofi Aventis Steve Ward, Lilly Alan Goldhammer, PhRMA Alison Lawton, Genzyme
06/28/06 9:00 a.m. 2 hours	<ul style="list-style-type: none"> • Commitment letter language on Communication and Technical Interactions • PDUFA IV IT Discussion Framework • Performance Goals • IT cost 	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Edward Tripp, Abbott Laboratories Andrew Emmett, BIO Steve Ward, Lilly Bob Birmingham, Johnson & Johnson PRD Rachel Carle, Genzyme
06/28/06 1:00 p.m. 2 hours	<ul style="list-style-type: none"> • Commitment letter language on Communication and Technical Interactions • PDUFA IV IT Discussion Framework • Performance Goals • IT cost 	Malcolm Bertoni, FDA Fred Farmer, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Edward Tripp, Abbott Laboratories Andrew Emmett, BIO Steve Ward, Lilly Bob Birmingham, Johnson & Johnson PRD Rachel Carle, Genzyme Bill Rosen, Pfizer Alan Goldhammer, PhRMA
07/12/06 9:00 a.m. 2 hours	<ul style="list-style-type: none"> • Discuss commitment letter language on Communication and Technical Interactions • Industry perspective <ul style="list-style-type: none"> ○ Their priorities ○ Standards and technical plans • Metrics and Measures 	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Peter Loupos, sanofi aventis Andrew Emmett, BIO Bill Rosen, Pfizer Rachel Carle, Genzyme Allen Jones, GSK

		Joe Quinn, sanofi pasteur (BIO) Edward Tripp, Abbott Laboratories Bob Birmingham, Johnson & Johnson PRD
07/12/06 1:00 p.m. 2 hours	<ul style="list-style-type: none"> • Discuss commitment letter language on Communication and Technical Interactions • Industry perspective <ul style="list-style-type: none"> ○ Their priorities ○ Standards and technical plans • Metrics and Measures 	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Peter Loupos, sanofi aventis Andrew Emmett, BIO Bill Rosen, Pfizer Rachel Carle, Genzyme Allen Jones, GSK Joe Quinn, sanofi pasteur (BIO) Edward Tripp, Abbott Laboratories Bob Birmingham, Johnson & Johnson PRD
07/19/06 1:30 p.m. 2 hours	<ul style="list-style-type: none"> • Discuss commitment letter language <ul style="list-style-type: none"> ○ Communications and Technical Interactions ○ Metrics and Measures ○ Standards and Technical plans 	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Peter Loupos, sanofi aventis Andrew Emmett, BIO Bill Rosen, Pfizer Rachel Carle, Genzyme Allen Jones, GSK Bob Birmingham, Johnson & Johnson PRD
07/26/06 9:00 a.m. 2 hours	<ul style="list-style-type: none"> • Goals <ul style="list-style-type: none"> ○ End-to-end review environment ○ Industry recommended commitment letter wording • Metrics and Measures • Discuss commitment letter wording <ul style="list-style-type: none"> ○ Communications and Technical Interactions ○ Standards and Technical plans 	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Bill Rosen, Pfizer Andrew Emmett, BIO Steve Ward, Lilly Rachel Carle, Genzyme Bob Birmingham, Johnson & Johnson PRD Joe Quinn, sanofi pasteur (BIO) Alan Goldhammer, PhRMA
07/26/06 1:00 p.m. 2 hours	<ul style="list-style-type: none"> • Goals <ul style="list-style-type: none"> ○ End-to-end review environment ○ Industry recommended commitment letter wording • Metrics and Measures • Discuss commitment letter 	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Bill Rosen, Pfizer Andrew Emmett, BIO Steve Ward, Lilly Rachel Carle, Genzyme

	<p>wording</p> <ul style="list-style-type: none"> ○ Communications and Technical Interactions <p>Standards and Technical plans</p>	<p>Bob Birmingham, Johnson & Johnson PRD</p> <p>Joe Quinn, sanofi pasteur (BIO)</p> <p>Alan Goldhammer, PhRMA</p> <p>Peter Loupos, sanofi Aventis</p> <p>Allen Jones, GSK</p>
<p>08/02/06 9:00 a.m. 2 hours</p>	<p>Review Industry Goals and Objectives in relation to the Commitment Letter</p>	<p>Malcolm Bertoni, FDA</p> <p>Len Wilson, FDA</p> <p>Mark Gray, FDA</p> <p>Margo Burnette, FDA</p> <p>Armando Oliva, FDA</p> <p>Bill Rosen, Pfizer</p> <p>Andrew Emmett, BIO</p> <p>Steve Ward, Lilly</p> <p>Rachel Carle, Genzyme</p> <p>Bob Birmingham, Johnson & Johnson PRD</p> <p>Joe Quinn, sanofi pasteur (BIO)</p> <p>Alan Goldhammer, PhRMA</p> <p>Edward Tripp, Abbott Laboratories</p>
<p>08/09/06 9:00 a.m. 2 hours</p>	<ul style="list-style-type: none"> • Discuss IT/IM language for the commitment letter • FDA presentation on the Proposed Funding vs. Flat Funding 	<p>Malcolm Bertoni, FDA</p> <p>Len Wilson, FDA</p> <p>Mark Gray, FDA</p> <p>Armando Oliva, FDA</p> <p>Margo Burnette, FDA</p> <p>Bill Rosen, Pfizer</p> <p>Andrew Emmett, BIO</p> <p>Joe Quinn, sanofi pasteur (BIO)</p> <p>Edward Tripp, Abbott Laboratories</p> <p>Alan Goldhammer, PhRMA</p> <p>Allen Jones, GSK</p> <p>Steve Ward, Lilly</p> <p>Rachel Carle, Genzyme</p>
<p>08/09/06 1:00 p.m. 2 hours</p>	<ul style="list-style-type: none"> • Discuss IT/IM language for the commitment letter <p>FDA presentation on the Proposed Funding vs. Flat Funding</p>	<p>Malcolm Bertoni, FDA</p> <p>Len Wilson, FDA</p> <p>Mark Gray, FDA</p> <p>Armando Oliva, FDA</p> <p>Margo Burnette, FDA</p> <p>Bill Rosen, Pfizer</p> <p>Andrew Emmett, BIO</p> <p>Joe Quinn, sanofi pasteur (BIO)</p> <p>Edward Tripp, Abbott Laboratories</p> <p>Alan Goldhammer, PhRMA</p> <p>Allen Jones, GSK</p> <p>Steve Ward, Lilly</p> <p>Rachel Carle, Genzyme</p>
<p>08/16/06 9:00 a.m. 2 hours</p>	<ul style="list-style-type: none"> • Review of the IT/IM commitment letter language 	<p>Malcolm Bertoni, FDA</p> <p>Len Wilson, FDA</p> <p>Mark Gray, FDA</p> <p>Armando Oliva, FDA</p> <p>Margo Burnette, FDA</p> <p>Bill Rosen, Pfizer</p> <p>Andrew Emmett, BIO</p> <p>Joe Quinn, sanofi pasteur (BIO)</p> <p>Rachel Carle, Genzyme</p>

		Steve Ward, Lilly Bob Birmingham, Johnson & Johnson PRD Allen Jones, GSK
08/16/06 1:00 p.m. 2 hours	<ul style="list-style-type: none"> Review of the IT/IM commitment letter language 	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Bill Rosen, Pfizer Andrew Emmett, BIO Joe Quinn, sanofi pasteur (BIO) Rachel Carle, Genzyme Steve Ward, Lilly Bob Birmingham, Johnson & Johnson PRD Allen Jones, GSK Peter Loupos, sanofi aventis
08/30/06 9:00 a.m. 2 hours	Review of the IT/IM commitment letter language	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Peter Beckerman, FDA Bill Rosen, Pfizer Peter Loupos, sanofi aventis Steve Ward, Lilly Rachel Carle, Genzyme Bob Birmingham, Johnson & Johnson PRD Joe Quinn, sanofi pasteur (BIO) Alan Goldhammer, PhRMA Edward Tripp, Abbott Laboratories Allen Jones, GSK
09/06/06 11:00 a.m. 1 hour	Review presentation to the PDUFA Steering Committee	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Margo Burnette, FDA Bill Rosen, Pfizer Steve Ward, Lilly Rachel Carle, Genzyme Bob Birmingham, Johnson & Johnson PRD Joe Quinn, sanofi pasteur (BIO) Edward Tripp, Abbott Laboratories Andrew Emmett, BIO Allen Jones, GSK
09/07/06 11:30 a.m. 1 hour.	Review presentation to the PDUFA Steering Committee	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Margo Burnette, FDA Peter Loupos, sanofi aventis Bill Rosen, Pfizer Rachel Carle, Genzyme Edward Tripp, Abbott Laboratories

09/15/06 10:00 a.m. 1 hour	Review commitment letter language	Malcolm Bertoni, FDA Len Wilson, FDA Mark Gray, FDA Armando Oliva, FDA Margo Burnette, FDA Peter Loupos, sanofi aventis Bill Rosen, Pfizer Rachel Carle, Genzyme Edward Tripp, Abbott Laboratories
12/06/06 3:00 p.m 30 minutes	PDUFA IV proposal update/status	Malcolm Bertoni, FDA Mark Gray, FDA Margo Burnette, FDA Bill Rosen, Pfizer Steve Ward, Lilly Rachel Carle, Genzyme Joe Quinn, sanofi pasteur (BIO) Alan Goldhammer, PhRMA Edward Tripp, Abbott Laboratories Andrew Emmett, BIO Allen Jones, GSK
