




DEMO eCRF V1 - 1. Visit 1

Trial:	DEMO eCRF	Proband:	PAT_01	DoB:	
eCRF:	Visit 1	Group:		Visit:	V1
Status:	complete - signed	User:	Leonard McCoy	Print:	9. June 2018 18:06
Title:	<i>screening visit</i>				
Description:	<i>demographics, medical history, concomitant medication, inclusion/exclusion criteria, randomization</i>				

 Successful signature validation!
eCRF DEMO eCRF V1 - 1. Visit 1 database records content for subject 546477 from 08.06.2018 08:32, signed by phoenix (Leonard McCoy) is evidentially untampered.
Signature: qmGYB5fNx1cK4RZlwBu7uAPctXo14BDcQsg2z9G/bV0rlyeUw8WHsJFtk/rrb...
Time of verification: 09.06.2018 18:02

01 - demographics

1. subject id:*	<input type="text" value="001"/>
<small>Leonard McCoy (6. May 2018 19:05)</small>	

2. date of birth:*	<input type="text" value="2013/05/01"/>
<small>Leonard McCoy (8. June 2018 08:06)</small>	

<small>failed validation check closed:</small>	<i>closing demonstrative failed validation check...</i>
<small>Leonard McCoy (8. June 2018 08:06)</small>	

<small>new failed validation check:</small>	<i>01 - demographics - [demo] date of birth: subject is younger than 5 years</i>
<small>Leonard McCoy (10. May 2018 20:05)</small>	

Saved (version 0):	2018/05/04
<small>Leonard McCoy (6. May 2018 19:05)</small>	

3. ethnicity:*	<input type="radio"/> hispanic or latino
	<input checked="" type="radio"/> not hispanic or latino
<small>https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126396.pdf</small>	
<small>Leonard McCoy (6. May 2018 19:05)</small>	

02 - medical history

02 - medical history: index 0

1. diagnosis/procedure*	<input checked="" type="radio"/> diagnosis
	<input type="radio"/> medical procedure
<small>Leonard McCoy (7. May 2018 04:05)</small>	

2. diagnosis/procedure name*	<input type="text" value="Hypertension"/>
<small><i>please select from suggested ICD10 diagnoses/OPS procedures.</i></small>	
<small>Leonard McCoy (7. May 2018 04:05)</small>	

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3. diagnosis/procedure code: **I10.90**

the primary ICD-10 or OPS code.

Leonard McCoy (7. May 2018 04:05)

4. diagnosis date of onset/procedure (start) date:*

NK-NK-2009

enter dates like "12-MAY-2017". use "NK"/"NA"/"ND" for missing date parts.

Leonard McCoy (7. May 2018 04:05)

5. ongoing:*



Leonard McCoy (7. May 2018 04:05)

6. stop date:

enter dates like "12-MAY-2017". use "NK"/"NA"/"ND" for missing date parts.

Leonard McCoy (7. May 2018 04:05)

02 - medical history: index 1

1. diagnosis/procedure*

diagnosis

medical procedure

Leonard McCoy (7. May 2018 05:05)

2. diagnosis/procedure name*

Appendektomie

please select from suggested ICD10 diagnoses/OPS procedures.

Leonard McCoy (4. June 2018 02:06)

query - corrected:

Leonard McCoy (4. June 2018 03:06)

query resolution:

Entered "Appendektomie" as on paper source.

Leonard McCoy (4. June 2018 02:06)

query update:

Please enter what was written on the source paper, even if it does not match any suggestion.

Leonard McCoy (4. June 2018 02:06)

Saved (version 0):

appendektomie-mi

Leonard McCoy (7. May 2018 05:05)

new query:

the system suggests various types of appendectomy surgeries. what exact procedure should be entered to have a ICPM/OPS code?

Leonard McCoy (7. May 2018 05:05)

3. diagnosis/procedure code:

the primary ICD-10 or OPS code.

Leonard McCoy (7. May 2018 05:05)

4. diagnosis date of onset/procedure (start) date:*

NK-JUN-1999

enter dates like "12-MAY-2017". use "NK"/"NA"/"ND" for missing date parts.

Leonard McCoy (7. May 2018 05:05)

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5. ongoing:*

Leonard McCoy (7. May 2018 05:05)

6. stop date:

enter dates like "12-MAY-2017". use "NK"/"NA"/"ND" for missing date parts.

Leonard McCoy (8. May 2018 14:05)

02 - medical history: index 2

1. diagnosis/procedure* diagnosis
 medical procedure

Leonard McCoy (8. May 2018 04:05)

2. diagnosis/procedure name* **Grippe [Grippaler Infekt]**

please select from suggested ICD10 diagnoses/OPS procedures.

Leonard McCoy (8. May 2018 04:05)

3. diagnosis/procedure code: **J06.9**

the primary ICD-10 or OPS code.

Leonard McCoy (8. May 2018 04:05)

4. diagnosis date of onset/procedure (start) date:* **03-APR-2017**

enter dates like "12-MAY-2017". use "NK"/"NA"/"ND" for missing date parts.

Leonard McCoy (8. May 2018 04:05)

5. ongoing:*

Leonard McCoy (8. May 2018 04:05)

6. stop date: **07-APR-2017**

enter dates like "12-MAY-2017". use "NK"/"NA"/"ND" for missing date parts.

Leonard McCoy (8. May 2018 04:05)

03 - concomitant medication

03 - concomitant medication: index 0

1. trade name:* **Beloc 50 mg - Tabletten**

please select from suggested drug products.

Leonard McCoy (9. May 2018 10:05)

2. ATC code: **C07AB02**

the drug's ATC code.

Leonard McCoy (9. May 2018 10:05)

DEMO eCRF

eCRF: Visit 1



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eCRF:	Visit 1	Group:		Visit:	V1
Status:	complete - signed	User:	Leonard McCoy	Print:	9. June 2018 18:06

3. dose: **50mg**
specify the drug product's base dose per contained substance, eg. "2.5g" or "150mg/30µg".
 Leonard McCoy (9. May 2018 10:05)

4. frequency: **1-0-1**
please specify medication intake over day like "1-0-0-1" (morning-noon-evening-night), "1-0-1" etc. or "3x1". specifiers like "/week", "3x/month" or "every second day" can be appended.
 Leonard McCoy (9. May 2018 10:05)

5. total daily dose: **100mg**
specify the drug product's base dose per contained substance, eg. "2.5g" or "150mg/30µg".
 Leonard McCoy (9. May 2018 10:05)

6. medical history reference: **0**
 Leonard McCoy (9. May 2018 10:05)

03 - concomitant medication: index 1

1. trade name:* **Piperacillin/Tazobactam Kabi 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung**
please select from suggested drug products.
 Leonard McCoy (9. May 2018 10:05)

2. ATC code: **J01CR05**
the drug's ATC code.
 Leonard McCoy (9. May 2018 10:05)

3. dose: **4g/0.5g**
specify the drug product's base dose per contained substance, eg. "2.5g" or "150mg/30µg".
 Leonard McCoy (9. May 2018 10:05)

4. frequency: **1-1-1-1**
please specify medication intake over day like "1-0-0-1" (morning-noon-evening-night), "1-0-1" etc. or "3x1". specifiers like "/week", "3x/month" or "every second day" can be appended.
 Leonard McCoy (9. May 2018 10:05)

5. total daily dose: **16g/2g**
specify the drug product's base dose per contained substance, eg. "2.5g" or "150mg/30µg".
 Leonard McCoy (9. May 2018 10:05)

6. medical history reference: **1**
 Leonard McCoy (9. May 2018 10:05)

03 - concomitant medication: index 2

1. trade name:* **Novalgin Tropfen**
please select from suggested drug products.
 Leonard McCoy (10. May 2018 10:05)

DEMO eCRF

eCRF: Visit 1



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Status:	complete - signed	User:	Leonard McCoy	Print:	9. June 2018 18:06

2. ATC code: <i>the drug's ATC code.</i> Leonard McCoy (10. May 2018 10:05)	N02BB02
3. dose: <i>specify the drug product's base dose per contained substance, eg. "2.5g" or "150mg/30µg".</i> Leonard McCoy (10. May 2018 10:05)	1 drops
4. frequency: <i>please specify medication intake over day like "1-0-0-1" (morning-noon-evening-night), "1-0-1" etc. or "3x1". specifiers like "/week", "3x/month" or " every second day" can be appended.</i> Leonard McCoy (10. May 2018 10:05)	3x30
5. total daily dose: <i>specify the drug product's base dose per contained substance, eg. "2.5g" or "150mg/30µg".</i> Leonard McCoy (10. May 2018 10:05)	90 drops
6. medical history reference: Leonard McCoy (10. May 2018 10:05)	1

04 - eligibility

1. does the subject meet the inclusion criteria below?*	<input type="radio"/> no <input checked="" type="radio"/> yes
<i>"The subject signed the informed consent."</i> Leonard McCoy (10. May 2018 19:05)	
2. does the subject meet the inclusion criteria below?*	<input type="radio"/> no <input checked="" type="radio"/> yes
<i>"The subject is older than 5 years."</i> Leonard McCoy (10. May 2018 19:05)	
3. does the subject meet the exclusion criteria below?*	<input checked="" type="radio"/> no <input type="radio"/> yes
<i>"The subject is participating another trial."</i> Leonard McCoy (10. May 2018 19:05)	
4. screening result:*	<input type="radio"/> screening failure <input checked="" type="radio"/> screening ok
Leonard McCoy (8. June 2018 07:06)	
failed validation check closed: Leonard McCoy (8. June 2018 07:06)	<i>closing demonstrative failed validation check...</i>

DEMO eCRF

eCRF: Visit 1



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eCRF:	Visit 1	Group:		Visit:	V1
Status:	complete - signed	User:	Leonard McCoy	Print:	9. June 2018 18:06

new failed validation check: *04 - eligibility - [demo] screening result expected: screening ok*
Leonard McCoy (10. May 2018 20:05)

Saved (version 0): **screening failure**
Leonard McCoy (10. May 2018 19:05)

05 - randomization

1. randomized proband group: **G1**
Leonard McCoy (10. May 2018 20:05)



DEMO eCRF G1:V2 - 2. Visit 2

Trial:	DEMO eCRF	Proband:	PAT_01	DoB:	
eCRF:	Visit 2	Group:	G1	Visit:	V2
Status:	complete - review	User:	Leonard McCoy	Print:	9. June 2018 18:06
Title:	<i>first intervention visit</i>				
Description:	<i>body mass index, heart rate, blood pressure</i>				

01 - body mass index

1. body height (m):	<input type="text" value="1.89"/>
<small>Leonard McCoy (11. May 2018 11:05)</small>	

2. body weight (kg):	<input type="text" value="85"/>
<small>Leonard McCoy (11. May 2018 11:05)</small>	

3. body mass index (kg/m ²):	<input type="text" value="23"/>
<small>Leonard McCoy (11. May 2018 11:05)</small>	

new failed validation check: 01 - body mass index - [demo] body mass index expected: 23.8
Leonard McCoy (11. May 2018 12:05)

02 - heart rate

1. heart rate (bpm):*	<input type="text" value="62"/>
<small>Leonard McCoy (11. May 2018 11:05)</small>	

03 - blood pressure

1. blood pressure (mmHg):	<input type="text" value="105/59"/>
<small>Leonard McCoy (11. May 2018 11:05)</small>	

new failed validation check: 03 - blood pressure - [demo] blood pressure: diastolic blood pressure exceeds normal range (60mmHg - 100mmHg)
Leonard McCoy (11. May 2018 12:05)



DEMO eCRF G1:V3 - 3. Visit 3

Trial:	DEMO eCRF	Proband:	PAT_01	DoB:	
eCRF:	Visit 3	Group:	G1	Visit:	V3
Status:	complete - review	User:	Leonard McCoy	Print:	9. June 2018 18:06
Title:	<i>second intervention visit</i>				
Description:	<i>body mass index, heart rate, blood pressure</i>				

01 - body mass index

1. body height (m):	<input type="text" value="1.89"/>
<small>Leonard McCoy (11. May 2018 12:05)</small>	
2. body weight (kg):	<input type="text" value="86"/>
<small>Leonard McCoy (11. May 2018 12:05)</small>	
3. body mass index (kg/m ²):	<input type="text" value="24.08"/>
<small>Leonard McCoy (11. May 2018 12:05)</small>	

02 - heart rate

1. heart rate (bpm):*	<input type="text" value="65"/>
<small>Leonard McCoy (11. May 2018 12:05)</small>	

03 - blood pressure

1. blood pressure (mmHg):	<input type="text" value="110/70"/>
<small>Leonard McCoy (11. May 2018 12:05)</small>	