

ESMO Public Policy Webinar:
Clinical Trials Regulation

Rationalising the bureaucratic burden in clinical trials

ESMO Clinical Research Observatory – ESMO Public Policy Group



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European Society for Medical Oncology

October 28th 2021

Rationalising the bureaucratic burden in clinical trials

- Excessive burden of bureaucracy
 - Overinterpretation of regulations
 - Complex procedures
- Patient welfare: Clinical interference
- Conclusions

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Overinterpretation of regulations: Superfluous documents

Guideline for good clinical practice E6(R2)

Step 5



1.28. Informed consent

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

... Yet , investigators are constantly required to duplicate the documentation process in the medical records (which are not signed by the patient)

Overinterpretation of regulations: Superfluous documents (II)

Request from a study monitor regarding documentation of informed consent in the medical records:

- *“Please (...) **add to the medical records** of patient # 3106002 an addendum to the visit of November 25:*
 - *the version of the informed consent signed by the patient (in our case, **version 8.1** of August 30, 2016).*
 - *That he read it and signed it before performing any procedure of the corresponding visit.*
 - *That he was given enough time to read with confidence the information contained in the patient information sheet*
 - *That he was given the opportunity to ask and all the doubts that had arisen were resolved (or that the patient did not raise any questions or questions, as the case may be).*
 - *That he decided to sign the consent freely and voluntarily.*
 - *That he was given a copy of it.”*

Overinterpretation of regulations: Complex documents templates and procedures

Guideline for good clinical practice E6(R2)












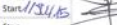
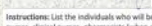
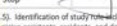
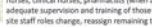
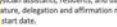
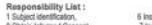



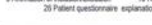



Step 5



4.1.5.

The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

Standard delegation log for a single study

Name (N) and Rule (R)	Full Signature	Initials	Authorized Responsibilities, Write Numbers (see list)	Date of Study Involvement	PI Signature to Authenticate Description and Identification of Identity of Individual	Date of Signature	PI Signature for End of Study or End of Rule	Date of Signature
PRINT CLEARLY								
		JALF		Start 26 Oct 14		26 Oct 14		
		CRBF		Stop				
		JPF		Start 4 Dec 14		17 Dec		
		HSH		Stop		20 Dec		
		JALF		Start 11 Jan 15		1 Apr 15		
		JALF		Stop				
		JALF		Start 11 Jun 16		31 Jul		
		JALF		Stop		1 Jul		
		JALF		Start 11 Jul 15		21 Jul		
		JALF		Stop		1 Jul		
		JALF		Start 11 Jul 15		21 Jul		
		JALF		Stop				
Instructions: List the individuals who will be delegate nurses, clinical nurses, pharmacists (when appropriate) adequate supervision and training of these to whom is site staff roles change, ressign (remaining tasks to a)				5). Identification of study rules includes but is not limited to: physician assistants, residents, and data recorders). The principal nature, delegation and affirmation must occur prior to individual start date.				
Responsibility List :				CRF Completion/REC Entry				
1 Subject Identification				16 Shipping Biological				
2 Obtain Informed Consent				17 Filing and Archiving				
3 Physical Examination				18 Data Query Complete				
4 Medical History				19 Obtain lab samples				
5 Affirmation of inclusion/exclusion				20 Data Query Signature				
20 Patient questionnaire explanation								

Printed Name	Signature	Title	Date	Signature	Date	Signature	Date
Role #1		Principal Investigator					
PRINT CLEARLY							
	MJR	1, 2, 14, 16 8, 11		[Signature]	1 JUL 2017		
	YSR						
	SEA	5, 16, 19, 21	FECU CON				
	MEG	8, 17, 20	AUGUSTO				
	LRC	24, 8, 17					

Instructions: List the individuals who will be delegated study-related tasks (e.g., nurses, clinical nurses, pharmacists [when appropriate], technicians, nurse practitioners, physician assistants, residents, and data recorders). The principal investigator is responsible for providing adequate supervision and training of those to whom tasks are delegated. Investigator signature, delegation and affirmation must occur prior to individual conducting any duties on the clinical trial site. Staff roles change; maintain remaining tasks to a single staff member and include the new start date.

Responsibility List:

1 Subject Identification,	6 Inclusion on Investigational Product Administration	11 CRF Completion/EDC Entry	16 Shipping Biological Samples – IATA trained	21 Drug accountability
2 Obtain Informed Consent	7 Investigational Product Dispensing	12 CRF Signature	17 Filing and Archiving of Data	22 IRIS/WARS Access
3 Physical Examination	8 Trial measurements (e.g., BP, HR)	13 Training Staff	18 Data Query Completion	23 Unblinding IRIS
4 Medical History	9 Review, Assessment of AEGAE Criteria	14 Tumor Assessment	19 Obtain lab samples	24 Drug receipt
5 Affirmation of inclusion/exclusion	10 Reporting of Serious Adverse Events	15 Interpretation of Lab Data	20 Data Query Signature	25 Other: _____

26 Patient questionnaire explanation

Name (N) and Role (R)	Initials	Authorized Responsibilities, Write Numbers (see list)	Dates of Study Involvement	PI Signature to Authorize Delegation and Affirmation of Identity of Individual	Date of Signature	PI Signature for End of Study or End of Role	Date of Signature
PRINT CLEARLY							
N: <i>NIOSH DATA</i>	<i>[Signature]</i>	CUN 1, 7, 24	Start 12/14/16 Stop	<i>[Signature]</i>	12/14/16	<i>[Signature]</i>	FILED FEB 17
R: <i>NIOSH DATA</i>	<i>[Signature]</i>	MBS 1, 2, 3, 4, 5, 6, 9, 10 4, 15	Start 4-14-16 Stop	<i>[Signature]</i>	4-14-16	<i>[Signature]</i>	30/sep/2016 CUN 6/16/16
N:			Start				
R:			Stop				
N:			Start				
R:			Stop				
N:			Start				
R:			Stop				

Instructions: List the individuals who will be delegated study-related tasks (per ICH G4 1.5). Identification of study role includes but is not limited to sub-investigator, study coordinators, study nurses, clinical nurses, pharmacists (when appropriate), technicians, nurse practitioners, physician assistants, residents, and data recorders. The principal investigator is responsible for providing adequate supervision and training of those to whom tasks are delegated. Investigator signature, delegation and affirmation must occur prior to individual conducting any duties on the clinical trial. If site staff roles change, assign remaining tasks to a site staff member and include the new start date.

Responsibility List:

1 Subject Identification	6 Instruction on Investigational Product Administration	11 CRF Completion/EDC Entry	16 Shipping Biological Samples – IATA trained	21 Drug accountability
2 Obtain Informed Consent	7 Investigational Product Dispensing	12 CRF Signature	17 Filing and Archiving of Data	22 IRIS/NIRS Access
3 Physical Examination	8 Trial measurements (e.g., BP, HR)	13 Training Staff	18 Data Query Completion	23 Unblinding IRIS
4 Medical History	9 Review, Assessment of AEs/SAEs/Critere	14 Urine Assessment	19 Obtain lab samples	24 Drug receipt
5 Affirmation of Individualization	10 Reporting of Serious Adverse Events	15 Interpretation of Lab Data	20 Data Query Signature	25 Other _____
6 Patient questionnaire explanation				

Name (N) and Role (R)	Full Signature	Initials	Authorized Responsibilities, White Numbers (see N/A)	Date of Study Involvement	PI Signature to Authorize Delegation and Affirmation of Identity of Individual	Date of Signature	PI Signature for Date of Study or Date of Role	Date of Signature
POINT CLARITY								
Dr. David S. GARDY		DCR	14	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	14	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		AGA	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	4, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 18, 19	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David S. GARDY		JAR	1, 2, 3, 4, 5, 6, 9, 10, 13, 14, 15	Start 2/27/2014		25.04.2		
Dr. David S. GARDY				Stop		25.04.2		
Dr. David								

Name (in full) and Role (in full)	Full Signature	Initials	Authorized Responsibilities, Write Names (see list)	Date of Study Involvement	PI Signature to Authenticate Delegation and Affirmation of Identity of Individual	Date of Signature	PI Signature for End of Study or End of Role	Date of Signature																									
PRINT CLEARLY																																	
N. J. ...	[Signature]	ENF	4, 6, 7, 8, 9, 10, 11, 13, 16, 17, 18, 19, 21, 22	Start 2/10/2014 Stop	[Signature]	25. 9.02 20.14																											
N. J. ...	[Signature]	JBL	11, 16, 17, 18, 19, 21, 22	Start 25.10.2014	[Signature]	25. 9.02 20.14																											
N. J. ...	[Signature]	1160	7, 22, 24		[Signature]	25. 9.02 20.14																											
N. J. ...	[Signature]	16.5	1, 2, 3, 4, 5 9, 10, 13, 14		[Signature]	25. 9.02 20.14																											
N. J. ...	[Signature]	100P	6, 7, 8, 9, 10, 11, 13, 18, 19, 21, 22	Stop	[Signature]	25. 9.02 20.14																											
<p>Instructions: List the individuals who will be delegated study-related tasks (per ICH GCP 4.1.5). Identification of study roles includes but is not limited to sub-investigators, study coordinators, study nurses, clinical nurses, pharmacists (when appropriate), technicians, nurse practitioners, physician assistants, residents, and data recorders. The principal investigator is responsible for providing adequate supervision and training of those to whom tasks are delegated. Investigator signature, delegation and affirmation must occur prior to the individual conducting any duties on the clinical trial. If site staff roles change, reassign remaining tasks to a site staff member and include the new start date.</p>																																	
<p>Responsibility List:</p> <table border="0"> <tr> <td>1 Subject Identification</td> <td>6 Instruction on Investigational Product Administration</td> <td>11 ORF Completion/EDC Entry</td> <td>18 Shipping Biological Samples - IATA trained</td> <td>21 Drug accountability</td> </tr> <tr> <td>2 Observational Consent</td> <td>7 Investigational Product Dispensing</td> <td>12 CDRF Signature</td> <td>17 Filing and Archiving of Data</td> <td>22 Unblinding Access</td> </tr> <tr> <td>3 Physical Examination</td> <td>8 Trial Measurements (e.g., BP, HR)</td> <td>13 Training Staff</td> <td>18 Data Query Completion</td> <td>23 Unblinding ORS</td> </tr> <tr> <td>4 Medical History</td> <td>9 Review, Assessment of Adverse Events</td> <td>14 Tumor Assessment</td> <td>19 Clinical lab samples</td> <td>24 Drug receipt, 25. 9.02</td> </tr> <tr> <td>5 Affirmation of Inclusion/Exclusion</td> <td>10 Reporting of Serious Adverse Events</td> <td>15 Interpretation of Lab Data</td> <td>20 Data Query Signature</td> <td>25 Other</td> </tr> </table>									1 Subject Identification	6 Instruction on Investigational Product Administration	11 ORF Completion/EDC Entry	18 Shipping Biological Samples - IATA trained	21 Drug accountability	2 Observational Consent	7 Investigational Product Dispensing	12 CDRF Signature	17 Filing and Archiving of Data	22 Unblinding Access	3 Physical Examination	8 Trial Measurements (e.g., BP, HR)	13 Training Staff	18 Data Query Completion	23 Unblinding ORS	4 Medical History	9 Review, Assessment of Adverse Events	14 Tumor Assessment	19 Clinical lab samples	24 Drug receipt, 25. 9.02	5 Affirmation of Inclusion/Exclusion	10 Reporting of Serious Adverse Events	15 Interpretation of Lab Data	20 Data Query Signature	25 Other
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Name (N) and Title (T) PRINT CLEARLY	Full Signature	Initials	Authorized Responsibilities, Write Numbers (see list)	Dates of Study Involvement	PI Signature to Authenticate Delegation and Affirmation of Identity of Individual	Date of Signature	PI Signature for End of Study or End of Role	Date of Signature
N: [Signature] T: [Signature]	[Signature]	SKT	4, 6, 7, 8, 9, 10, 11, 13, 16, 17, 18, 19, 21, 22	Start 2/10/2024 Stop [Signature]	[Signature]	25. 9.02 20.14		
N: [Signature] T: [Signature]	[Signature]	SBL	11, 16, 17	Start 9.10.2024	[Signature]	25. 9.02 20.14		
N: [Signature] T: [Signature]	[Signature]	11/04	7, 22, 24		[Signature]	25. 9.02 20.14		
N: [Signature] T: [Signature]	[Signature]	16.5	1, 2, 3, 4, 5, 9, 10, 13, 11		[Signature]	25. 9.02 20.14		
N: [Signature] T: [Signature]	[Signature]	40P	6, 7, 8, 9, 10, 16, 17, 19, 21, 22	Stop [Signature]	[Signature]	25. 9.02 20.14		

Instructions: List the individuals who will be delegated study-related tasks (per ICH GCP 4.3.5). Identification of study members includes but is not limited to sub-investigator, study coordinators, study nurses, clinicians, pharmacists (when appropriate), technicians, nurse practitioners, physician assistants, residents, and data recorder(s). The principal investigator is responsible for providing adequate supervision and training of those to whom tasks are delegated. Investigator signature, delegation and affirmation must occur prior to individual completing any duties on the clinical trial. If the staff role changes, reassess remaining tasks to a site staff member and include the new start date.

Responsibility List:				
1 Subject Identification	6 Instruction on Investigational Product Administration	11 CRF Completion/EDC Entry	16 Shipping Biological Samples - iATA trained	21 Drug accountability
2 Obtain Informed Consent	7 Investigational Product Dispensing	12 CRF Signature	17 Filing and Archiving of Data	22 IVRS/IRRS Access
3 Physical Examination	8 Trial measurements (e.g., BP, HR, Wt)	13 Training Staff	18 Data Query Completion	23 Unblinding 100%
4 Medical History	9 Review Assessment of AEs/SAE Events	14 Tutor Assessment	19 Obtain lab samples	24 Drug recovery (see 24.1)
5 Affirmation of Inclusion/Exclusion	10 Reporting of Serious Adverse Events	15 Interpretation of Lab Data	20 Data Query Signature	25 Other _____
6 Patient questionnaire completion				

Central lab reports for one single patient and visit

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INVESTIGATOR: (X53764)
Dr. Jose Luis Perez-Gracia
Department: Oncología-B Planta
Clínica Universitaria Navarra
Avenida Pio XII, 36
Pamplona, Navarra, Spain 31008

PROTOCOL: XL184-308
INVESTIGATOR NO.: 3426
SUBJECT ID: 3452
SUBJECT INITIALS: XXX
VISIT: V001

Week 5 Day 1
COLLECTION TIME: 08:46 DATE: 08-Jul-2014
DATE RECEIVED IN LABORATORY: 09-Jul-2014
DATE REPORTED BY LABORATORY: 09-Jul-2014
SEX: M BIRTHDATE: 01-Jan-1961 AGE: 53
Lates 94083-0511

SPONSOR REPORT TO:

HCL CS Comments		
TSN	0.50	0.34-5.40 uIU/L

NI = Not Clinically Significant
CI = Clinically Significant

Investigator's Signature

Date

4.8.214

NI/High or U/Lab/Values above or below Clinical reference range
T-Displayed P-Printed

XXXX

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Lates 94083-0511

SPONSOR REPORT TO:

HCL CS Comments		
PATIENT FASTING AT LEAST 8HRS?		
Fasting	Yes	
PK BLOOD COLLECTION DATE/TIME		
PK Date	08-Jul-2014	
PK Time	08:46	
PLASMA BIODISPONIBLE COLL. D/T		
Date Bio	08-Jul-2014	
Time Bio	08:46	

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SPONSOR REPORT TO:

HCL CS Comments		
CHEMISTRY PANEL		
Total Bilirubin	5	0-01 mmol/L
ALT (SGPT)	34	35-131 U/L
AST (SGOT)	37	4-43 U/L
GGT	110	11-36 U/L
ALP	110	10-41 U/L
CR	110	53-124 U/L
Urea	5.7	1.4-8.4 mmol/L
Creatinine	0.6	40-119 umol/L
Glucose	4.4	3.9-5.4 mmol/L
Phosphorus	0.94	0.71-1.45 mmol/L
Total Protein	72	61-84 g/L
Albumin	38	20-48 g/L
Triglyceride	1.54	0.40-2.44 mmol/L
Cholesterol	5.91	4.40-7.53 mmol/L
ELECTROLYTE PANEL		
Sodium	139	132-147 mmol/L
Potassium	4.7	3.4-5.4 mmol/L
Bicarb	29.3	17.0-30.6 mmol/L
Chloride	97	94-112 mmol/L
Magnesium	0.80	0.62-1.27 mmol/L
CORRECTED CALCIUM		
Corr Ca	2.44	2.07-2.64 mmol/L

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CI = Clinically Significant

Investigator's Signature

Date

4.8.214

NI/High or U/Lab/Values above or below Clinical reference range
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XXXX

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SPONSOR REPORT TO:

HCL CS Comments		
LIPASE		
Lipase	30	0-100 U/L
AMYLASE		
Amylase	104	20-120 U/L
HEMATOLOGY DIFFERENTIAL PANEL		
WBC	141	127-181 g/L
NEUT	0.45	0.39-0.54
RBC	5.4	4.5-6.4 T/L
HGB	16.9	15.0-19.0 g/L
HCT	4.74	3.80-5.70 g/L
Neutrophil	3.11	1.94-7.23 g/L
Lymphocyte	1.45	0.70-4.26 g/L
Monocyte	0.24	0.12-0.92 g/L
Eosinophil	0.12	0.00-0.57 g/L
Basophil	0.01	0.00-0.20 g/L
Neutrophil	43.0	40.5-75.0 %
Lymphocyte	29.5	15.4-48.3 %
Monocyte	4.8	2.6-10.1 %
Eosinophil	2.5	0.0-6.0 %
Basophil	0.3	0.0-2.0 %
Platelets	277	140-400 g/L

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Investigator's Signature

Date

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SUBJECT INITIALS: XXX
VISIT: V001

Week 5 Day 1
COLLECTION TIME: 08:46 DATE: 08-Jul-2014
DATE RECEIVED IN LABORATORY: 09-Jul-2014
DATE REPORTED BY LABORATORY: 09-Jul-2014
SEX: M BIRTHDATE: 01-Jan-1961 AGE: 53
Lates 94083-0511

SPONSOR REPORT TO:

HCL CS Comments		
CREATININE INCREASE		
Creat Incr	Toxicity Criteria Not Met	
HEMOGLOBIN INCREASE		
Hgb Incr	Toxicity Criteria Not Met	

NI = Not Clinically Significant
CI = Clinically Significant

Investigator's Signature

Date

4.8.214

NI/High or U/Lab/Values above or below Clinical reference range
T-Displayed P-Printed

XXXX

**** REPRINTED: 15-Jul-2014 ****
ACCESSION NO. J076728
Page 1 of 1

INVESTIGATOR: (X53764)
Dr. Jose Luis Perez-Gracia
Department: Oncología-B Planta
Clínica Universitaria Navarra
Avenida Pio XII, 36
Pamplona, Navarra, Spain 31008

PROTOCOL: XL184-308
INVESTIGATOR NO.: 3426
SUBJECT ID: 3452
SUBJECT INITIALS: XXX
VISIT: V001

Week 5 Day 1
COLLECTION TIME: 08:46 DATE: 08-Jul-2014
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DATE REPORTED BY LABORATORY: 09-Jul-2014
SEX: M BIRTHDATE: 01-Jan-1961 AGE: 53
Lates 94083-0511

SPONSOR REPORT TO:

HCL CS Comments		
URINE PROTEIN		
UrineProtein	22.4	ng/dL No Ref Rng
URINE PROTEIN/CREATININE RATIO		
UPro/Cr	22.38	ng/mmol Creatinine No Ref Rng
URINE CREATININE		
U Cr	10.01	mmol/L No Ref Rng

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SPONSOR REPORT TO:

HCL CS Comments		
RETICULOCYTE COUNT		
Abn Retic	0.043	T/L No Ref Rng
Retic FC	0.9	L 1.0-3.8 %
TOTAL ABS NEUTROPHIL COUNT		
Total ANC	3.11	1.96-7.23 g/L

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Lates 94083-0511

SPONSOR REPORT TO:

HCL CS Comments		
COAGULATION PANEL		
INR	1.0	0.8-1.2
APTT	32.7	22.0-35.3 sec
PT	11.0	9.7-12.3 sec

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XXXX



FIRECREST SITE PORTAL

FIRECREST

medidata

PAREXEL Safety Information System

ClinOne

PPD®
Interactive Web Response System

epharmasolutions



mystudies.roche.com



ORACLE® RDC Onsite

ORACLE

InForm™ GTM

Cumbersome online platforms: Instructions to reset a password

Dear xxxxxxxxxxxxxxxxxxxxxxxxx

The directions below will permit you to use your current CPAC/myLearning password to verify your identity and create a new password to access InForm.

1. Cut and paste the following URL in your Web browser to access the Password Management application for CPAC, myLearning and InForm: https://www.cpac.com/password_reset
2. Click on 'Site Users' link on Password Management Application menu page.
3. Enter your current CPAC/myLearning User ID and click the 'Continue' button.
4. At the next screen, select one of the three options to authenticate
 - a. Current CPAC/myLearning Password or Activation Code you were emailed by the Helpdesk analyst
 - b. Answer personal questions (use this option if you have forgotten your password)
 - c. Retrieve and Use Email PIN (Clicking on this option will trigger an email to you with a 4-digit PIN.)
5. Enter information in the authentication screen based on the selection you made and click 'Authenticate'.
6. You are now on Home screen with three options. Click on 'Change Password' option.
7. Select CPAC/myLearning or InForm (depending on which password you need to reset)
8. Enter a new password and confirm it following the on-screen instructions to set up a strong password. For security purposes, your InForm password cannot be the same as your CPAC/myLearning password.
9. Click the 'Change Password' button. When the confirmation page displays, you will see a list of the InForm trials to which this new password applies.
10. The next screen is a confirmation that your password was successfully changed. You will also receive an email letting you know that your password was successfully reset.
11. You can now access CPAC, myLearning or InForm via the URLs available on this final confirmation page.
12. As a reminder, when you logon to InForm, you must enter your USER NAME in UPPERCASE.

Your User ID for CPAC/myLearning and InForm trials remains the same. However, your password for InForm trials is different from your password for the CPAC/myLearning applications.

You can access InForm:


- a. By clicking on the hyperlink for the trial listed on the password change confirmation screen, or
- b. Via CPAC by clicking on the computer icon to the right of Site Name and Site#, or
- c. By clicking on or cutting and pasting the following URL in your web browser:

Your Case number is


24 e-mails in less than 24 hours to solve
the access to a signature page


<input type="checkbox"/>	<input type="star"/>	Recibidos	Dr. Pérez García. Movil por XXXXXXXX Acabo de ver que has firmado los pacientes!! Muchísimas gracias Jose Luis por tu ayu...	14 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Last steps before PI signature_URGENTE - Dr. Pérez García - I just called the helpdesk on your behalf. They confirmed they have...	14 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Dr. Pérez García. Movil por Mauro Filori - Perdona Jose Luis que te haya llamado al móvil. Me salta el contestador con lo que en...	14 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Last steps before PI signature_URGENTE - Dr. Pérez García - Buenos días Dr. Pérez Gracia, Siento que esté siendo todo tan com...	14 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Dr. Pérez García. Helpdesk en tu nombre - Perdona Jose Luis todo el tiempo que te están "robando" para poder gestionar lo que...	14 may.
<input type="checkbox"/>	<input type="star"/>		s before PI signature_URGENTE - Dr. Pérez García - It is impossible for me to call, I have a lot of patients to visit; and in the evenin...	14 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Last steps before PI signature_URGENTE - Dr. Pérez García - Dear Dr Gracia, First of all, I'm really sorry for my mistake on your n...	14 may.
<input type="checkbox"/>	<input type="star"/>		s before PI signature_URGENTE - Dr. Pérez García - Dear Ervelyne: I have just tried again and it still does not work. In addition, the...	14 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Last steps before PI signature_URGENTE - Dr. Pérez García - Dear Laura, Credentials have been res-sent to Dr. Perez García yest...	14 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	: Last steps before PI signature_URGENTE - Dr. Pérez Gracia - Dear Dr. Garcia, I apologize for the issues. I have c...	13 may.
<input type="checkbox"/>	<input type="star"/>		s before PI signature_URGENTE - Dr. Pérez Gracia - Dear team: I have received the new password and it still does not work. I have...	13 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Last steps before PI signature_URGENTE - Dr. Pérez García - Thanks Laura, Including Barb and Carolyn in copy to help resolutio...	13 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Last steps before PI signature_URGENTE - Dr. Pérez García - He is trying to login but system doesn't recognize his passwords a...	13 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Last steps before PI signature_URGENTE - Dr. Pérez García - Please keep Paco, Barb and Carolyn in copy to help resolution, Tha...	13 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Last steps before PI signature_URGENTE - Dr. Pérez García - Dear Ervelyne Dr. Perez García is trying to reset the password, sinc...	13 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Last steps before PI signature_URGENTE - Dr. Pérez García - Hi Leandro, What is the issue? Dr Perez Garcia didn't receive new p...	13 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Last steps before PI signature_URGENTE - Dr. Pérez García - Hi Everlyne Can you hep PI to reset the pssword? BR Leandro Barb...	13 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	ca: INCB54828-201: Last steps before PI signature_URGENTE - Dr. Pérez García - Dear sender, I will be out of office on Monday t...	13 may.
<input type="checkbox"/>	<input type="star"/>		s before PI signature_URGENTE - Dr. Pérez García - Estimada Laura: Muchas gracias por tu mensaje. He intentado firmar, pero el ...	13 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Last steps before PI signature_URGENTE - Dr. Pérez García - Estimado equipo investigador, Antes de nada, querría presentarme...	13 may.
<input type="checkbox"/>	<input type="star"/>	Recibidos	Last steps before PI signature_URGENTE - Muchas gracias Silvia, si nos podéis confirmar cuando el PI lo tenga firmado! Y lo in...	13 may.


Training courses


 **Courses to take** ← BACK


InForm 5.5 PI Data Entry and Signature

 **9**
ITEMS


 **0%**
COMPLETED

 **0**
ITEMS PAST DUE

 **0**
ATTACHMENTS

 **SEQUENCE NUMBER**

[Courses to take](#) > [InForm 5.5 PI Data Entry and Signature](#)

Module 1: Getting Started in InForm 

Module 2: Adding Subjects and Viewing Subject Data

Module 3: Entering Basic Data

Module 4: Working with Specialized Forms

Module 5: Modifying Data

Module 6: Working with Comments

Module 7: Monitoring Visits and End of Study

Module 8: Working with Signatures

Pharmacovigilance:

25 reports on same day ... from 15:45 to 16:01

REDACTAR	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017335780 Initial O	16:01
Recibidos (18.254)	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017328962 Initial O	16:01
Destacados	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017335780 Initial O	16:01
Enviados	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017328962 Initial O	16:00
Borradores (342)	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017316777 Initial O	15:49
[imap]Outbox	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017295287 Initial O	15:49
Correo antiguo	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017295072 Initial O	15:48
Imported Mail	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017316777 Initial O	15:48
Imported Mail Local	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017294658 Initial O	15:48
Inbox/notas movil (9)	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017295287 Initial O	15:48
Notes	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017073959 Initial O	15:48
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017295072 Initial O	15:48
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017290650 Initial O	15:48
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017294658 Initial O	15:48
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017279384 Initial O	15:47
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017073959 Initial O	15:47
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017290650 Initial O	15:47
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017279384 Initial O	15:47
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017267961 Initial O	15:47
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017186341 Initial O	15:46
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017159302 Initial O	15:46
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017267961 Initial O	15:46
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017186341 Initial O	15:46
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017075988 Initial O	15:46
	<input type="checkbox"/> ☆ ESP.SUSAR	PROD - Notification to Investigators on	: Individual Case Safety Report (ICSR)... - Report Details: Case Number : 2017159302 Initial O	15:46

ESMO Clinical Research Observatory (ECRO): improving the efficiency of clinical research through rationalisation of bureaucracy

ECRO SURVEY

Table 2 Results of the ESMO survey on the administrative and bureaucratic burden in clinical research

Statement	Mean score (0=strongly disagree, 10=strongly agree)	
	Overall score (n=940)	Research experience >5 years (n=690)
The current burden of administrative tasks in clinical research is excessive.	8.3	8.6
Current administrative and bureaucratic procedures in clinical research could be reduced without affecting the safety and rights of the patients and the quality of the data.	8.2	8.5
Current administrative and bureaucratic procedures represent an obstacle for the development of clinical research.	8.1	8.4
It is necessary to incorporate the feedback from physicians about the procedures related with clinical research.	8.6	8.8

ESMO Clinical Research Observatory (ECRO): improving the efficiency of clinical research through rationalisation of bureaucracy

- **Negative impact of the increased administrative burden:**
 - poor use of the limited time physicians have available
 - frustration, loss of motivation and complaints from experienced investigators
 - decreases the interest of young physicians towards developing a clinical research career
 - significantly increases economic costs and contribute to delays in trial implementation
 - Negative impact on drug development and patient access to new drugs
 - Particularly relevant in the setting of independent academic clinical research
 - No evidence that this increased complexity leads to improved patient safety and quality of the data

Rationalising the bureaucratic burden in clinical trials

- Excessive burden of bureaucracy
 - Overinterpretation of regulations
 - Complex procedures
- Patient welfare: Clinical interference
- Conclusions

“Clinical Interference”

- Situations in which the protocol -or its interpretation by the sponsor/ CRO- impose a decision about patient management which is discordant with the best medical judgement, according to the clinical investigator.
- This may result in harm to the patient, in clear contrast with the main goals of the Declaration of Helsinki and the GCP guidelines.
- Examples:
 - Prohibition of relevant treatments
 - Unilateral decisions to discontinue study treatment
 - Unacceptably prolonged screening periods

“Clinical Interference”

- Example
 - 42 yr-old male NSCLC responding to therapy.
 - We request radiosurgery for a single new CNS lesion, maintaining therapy
- Response:

The patient can continue on **XXXXX** treatment as long as he is clinically stable.

However, patient can not get surgery or radiation therapy for the brain lesion while he is participating in the study.

Please understand that this is to test the efficacy of **XXXXX** objectively.

Thanks,

Treatment discontinuation mandated based on independent CT review

Dear Dr. XXXXXXXXXXXXX

Attached is the report from Bioclinica on your subject 3106-003 from the Week 80 scans performed on 11-Apr-2016. Bioclinica has confirmed metastasis to left para-aortic lymph nodes.

Based on the development of metastasis, the subject should have an end of treatment (EOT) visit (...) The patient should continue to be followed every 4 months for survival.

Please feel free to contact us if you have any questions.

Rationalising the bureaucratic burden in clinical trials

- Excessive burden of bureaucracy
 - Overinterpretation of regulations
 - Complex procedures
- Patient welfare: Clinical interference
- Conclusions

1. Urgent need to rationalize the bureaucratic burden associated with clinical research:

- strict adherence to current legal regulations: **not less ... but not more**
- respect to the time and expertise of investigators, who should be focused on clinical and research issues.
- Specific suggestions:
 - a. Limiting the administrative documents to those required by GCP and legal regulations
 - b. Using simplified document templates
 - c. Avoid redundant documentation
 - d. Avoid complex electronic resources

2. *Avoid Clinical Interference* of protocols with best medical practice:

- Include this concept in GCP
- Involve IRBs in detecting and preventing it

3. Review and improve Pharmacovigilance procedures.

Regulatory agencies must be aware of these problems and should actively address them

*“The only thing that saves us from bureaucracy
is its inefficiency.”*

Eugene McCarthy (1916-2005)



European Society for Medical Oncology

Thanks for your time!
jlgracia@unav.es