



Europass Curriculum Vitae

Personal information

First name(s) / Surname(s) **SILVIA CELLINI**

Address(es)

Telephone(s)

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Nationality ITALIAN

Date of birth 6th February 1978

Fiscal Code CLLSLV78B46D548Q

Gender Female

Desired employment / Occupational field

Project Manager (CPM)

Work experience

Dates	1 st Sep 2009 – up to now
Occupation or position held	Clinical Project Manager
Main activities and responsibilities	1st April 2013 – till now: PM of ATPCI Study (Servier) “the efficacy and safety of trimetazidine in patients with angina pectoris having been treated by percutaneous coronary intervention” -"phase III – 4 years. Responsible of study start-up, feasibility, activation and follow-up in Greece. 6 sites.
	1st February 2013 – till now: PM of Signify Study (CL3-16257-083) (Servier) “ Study assessing the morbidity-mortality benefits of the IF inhibitor Ivabradine in patients with coronary artery disease” Phase III – 3 years Direct responsible of Mexico management including CRAs activities management, regulatory activities follow-up, site’s contacts, site’s payments, medical reviewer activities management, for 33 sites and 584 patients.
	1st September 2012 – 31st March 2013: Central PM of ATPCI Study (Servier) “the efficacy and safety of trimetazidine in patients with angina pectoris having been treated by percutaneous coronary intervention” -"phase III – 4 years. Responsible of study feasibility in 20 countries: Argentina, Brazil, Perù, the Netherlands, Switzerland, Spain, Italy, Slovenia, Serbia, Croatia, Bosnia, Montenegro, Greece, turkey, Russia, Kazakhstan, Georgia, Belarus, Armenia and China.
	15th October 2010 – till now: Central PM of Signify Study (CL3-16257-083) (Servier) “ Study assessing the morbidity-mortality benefits of the IF inhibitor Ivabradine in patients with coronary artery disease” Phase III – 3 years Responsible of 4 Latin American Countries: Mexico, Argentina, Brazil and Uruguay and 2 European (Spain) and not European (Turkey) Countries for a total of 5 CROs, around 200 sites and 1600 patients.
	1st Sep 2010 – till now: PM of Examination Study (Spanish Society of Cardiology) “A Clinical Evaluation of Everolimus Eluting Coronary Stents in the Treatment of Patients With ST-segment Elevation Myocardial Infarction” (NCT00828087)

Phase III – 5 years
Responsible of 1 country (Italy) with 2 sites and around 200 patients

1st Sep 2010 – till now: PM of Clarify Study (Servier Italia + IFB Stroder) "Prospective observational registry of patients with stable artery disease" Phase IV – 5 years
Responsible of 1 country (Italy) 58 sites with 2146 patients

1st Sep 2010 – 1st May 2011: PM of BRAVE DREAMS study (Azienda Ospedaliero Universitaria di Ferrara) "Studio randomizzato multicentrico per la valutazione dell'efficacia e sicurezza dell'intervento di disostruzione delle vene extracraniche nel trattamento della sclerosi multipla"
Responsible of the protocol finalization and feasibility process in Italy.

1st Sep 2009 – 31st Dec 2010: PM of SHIFT Study (CL3-16257-063) (Servier) "Effects of ivabradine on cardiovascular events in patients with moderate to severe chronic heart failure and left ventricular systolic dysfunction. A three-year randomised double-blind placebo-controlled international multicentre study."

Responsible of 7 European and not European Countries: Greece, Italy, Spain, Portugal, Slovenia, Russia and Turkey with 1128 patients.

With the following main activities:

- Maintaining primary contact with the Sponsor
- managing the project team members
- Coordinating and planning the operational aspects of the project(s).
- Regularly reporting project status to Sponsor.
- Managing the external services providers.
- tracking and managing the budget allocated to the project.
- Evaluating the training needs and overseeing relevant training of the MTA project team and the external project teams.
- Analyzing potential issues and risks that affect the projects, particularly those that affect operational area.
- Reviewing and developing solutions, action plans, contingency plans for the projects as appropriate
- Reviewing, adapting and/or developing project specific documents
- Reviewing the timelines and resources (internal and external) for the project(s) necessary for project implementation
- Ensuring full compliance with applicable regulation, ICH-GCP and SOPs
- Ensuring learning and knowledge transfer during and at the completion of the projects
- Updating periodically GPL and GM on the study project status.
- Participate to meetings with GPL and GM regarding general or study /project specific management aspects.

Name and address of employer Medical Trials Analysis Italy S.r.l.
Via Ariosto, 28
44121 Ferrara

Type of business or sector Clinical Trials of phase III and IV

Dates 1st January 2009 – 31st December 2009

Occupation or position held Senior Clinical Research Associate (CRA)

Main activities and responsibilities CRA for SHIFT Study in 10 Italian sites with the following main activities.
Preparation of clinical report and accessory documents
Contact with the Sponsor
Support of Project Manager
Monitoring of the Italian centres
Management of the safety and contact with the Medical Reviewer

Name and address of employer Medical Trials Analysis Italy S.r.l.
Via Ariosto, 28
44121 Ferrara

Type of business or sector Clinical Trials of phase III

Dates 1st November 2007 – 31st December 2008

Occupation or position held Junior Clinical Research Associate (CRA)

Main activities and responsibilities CRA for SHIFT Study in around 10 Italian sites with the following main activities.

Preparation of clinical report and accessory documents
Contact with the Sponsor
Support of Project Manager
Monitoring of the Italian centres
Management of the safety and contact with the Medical Reviewer

Name and address of employer Medical Trials Analysis Italy S.r.l.
Via Ariosto, 28
44121 Ferrara

Type of business or sector Clinical Trials of phase III

Dates 28th May 2007 – 31st October 2007

Occupation or position held Training period for the Master "Clinical and Epidemiologic Research"

Main activities and responsibilities Contact with the Ethic Committee
Management of the Trial Master File

Name and address of employer Medical Trials Analysis Italy S.r.l.
Via Ariosto, 28
44121 Ferrara

Type of business or sector Clinical Trials

Dates 1st January 2007 – 31st August 2007

Occupation or position held Researcher in University Research Laboratory

Main activities and responsibilities Plan and execution of experimentation on animal model (mouse: C57BL/6 and Balb/c) to evaluate the immune response induced by different combination of vaccination with protein or DNA.
Management of the laboratory equipment and bureaucracy.

Name and address of employer Prof. Riccardo Gavioli
Università degli Studi di Ferrara
via Luigi Borsari, 46
44121 Ferrara, Italy

Type of business or sector Preclinical Research

Dates 1st June 2003 – 31st December 2003

Occupation or position held Training in Pharmacy

Main activities and responsibilities Knowledge of the Pharmacist activity. In particular, reading the prescription, galenic formulation, ect.

Name and address of employer Farmacia Salus
piazza Bruno Buozzi, 22
44123 Ferrara, Italy

Type of business or sector Pharmacist

Dates 1st April 2003 – 31st December 2003

Occupation or position held Researcher in University Research Laboratory

Main activities and responsibilities Fundamental research to evaluate the modulation of the human memory immune response, in particular the T cell response.

Name and address of employer Prof. Riccardo Gavioli
Università degli Studi di Ferrara
via Luigi Borsari, 46
44121 Ferrara, Italy

Type of business or sector Basic Research

Education and training

Dates 2007 - 2008

Title of qualification awarded Master of II Level in "School of the Clinic and Epidemiologic Research"

Principal subjects/occupational skills covered To plan and manage a clinical trial or epidemiologic study.
To know the characteristics and the typologies of the different clinical studies.
GCP training
Basic notion of statistic for a correct valuation of the champion of study, the methods for the data

analysis, etc.

Name and type of organisation providing education and training Università degli Studi di Ferrara
Ufficio Post-Laurea
Via Scienze, 41/b
44121 FERRARA

Level in national or international classification Master of II level

Dates a.a. 2003-2004 – a.a. 2006-2007

Title of qualification awarded PhD

Principal subjects/occupational skills covered Preclinical Trial on the mouse model.
Study of the immune response in human and mouse model.
Title of the PhD thesis: "Immunomodulatory effect of the Tat protein of the HIV-1: development of the news vaccine combinations against HIV/AIDS"

Name and type of organisation providing education and training Università degli Studi di Ferrara – Facoltà di Medicina e Chirurgia
Via Luigi Borsari, 46
44121 Ferrara, Italy
www.unife.it

Level in national or international classification PhD, Dottore di Ricerca

Dates December 2006

Title of qualification awarded European Computer Driving Licence (ECDL)

Principal subjects/occupational skills covered The European Computer Driving Licence (ECDL) is the internationally recognized qualification which enables people to demonstrate their competence in computer skills, in particular:

- Basic concepts of Information Technology
- Using the computer and managing files
- Word processing
- Spreadsheets
- Database/Filing systems
- Presentation
- Information Network Services

Name and type of organisation providing education and training Università degli Studi di Ferrara
Polo Scientifico Tecnologico
Via Saragat, 1 Blocco F
44121 Ferrara

Level in national or international classification ECDL Core

Dates 25th May 2004

Title of qualification awarded Pharmacy License

Principal subjects/occupational skills covered Knowledge of the Pharmacist activity. In particular, reading the prescription, galenic preparation, ect.

Name and type of organisation providing education and training Università degli Studi di Ferrara – Facoltà di Medicina e Chirurgia
Via Luigi Borsari, 46
44121 Ferrara, Italy
www.unife.it

Level in national or international classification Pharmacist

Dates a.a. 1997-1998 – a.a. 2001-2002

Title of qualification awarded Degree in Pharmaceutical Chemistry and Technology

Principal subjects/occupational skills covered Biology
Immunology
Physiology
Pharmacology
Biotechnology

Title of the thesis: "**Effect of the Tat Protein of the HIV-1 on the T cell activation**"

Name and type of organisation providing education and training
Università degli Studi di Ferrara – Facoltà di Farmacia
via Luigi Borsari, 46
44121 Ferrara, Italy
www.unife.it/farmacia

Level in national or international classification
Master's Degree (old university system - 5 years)

Dates a.a. 1992-1993 – a.a. 1996-1997

Title of qualification awarded
Scientific Diploma

Principal subjects/occupational skills covered
Chemistry, Biology, Mathematic, Physic and Informatics

Name and type of organisation providing education and training
Liceo Classico "Ludovico Ariosto" – Liceo Sperimentale Indirizzo Scientifico
via Arianuova,17
44121 Ferrara, Italy

Level in national or international classification
Diploma of the Secondary School

Personal skills and competences

Mother tongue(s) **ITALIAN**

Other language(s)

Self-assessment

European level (*)

English

Spanish

Understanding

Listening

Reading

Speaking

Spoken interaction

Spoken production

Writing

B2 Independent User B2 Independent User B2 Independent User B2 Independent User B2 Independent User

A2 Basic User A2 Basic User A1 Basic User A1 Basic User A1 Basic User

(*) Common European Framework of Reference for Languages

Relevant Clinical Research Experience

1. **01 Aug 2007 – 30 Oct 2007**: 12 Co-monitoring visits with senior CRA as training
2. **01 Nov 2007- 31 Dec 2009 (14 months)**:
 - CRA for **SHIFT Study (CL3-16257-063)** :
 - 76 monitoring visits at the Italian sites.
 - 4 initiation visits at the Italian Sites
 - 4 Co-monitoring visits in Italy, Slovenia, and Spain.
 - 1 initiation visit in Greece.
3. **PM for SHIFT Study (CL3-16257-063)**
 - Organization of the International CRA meeting occurred on 12-13 January 2010 in Ferrara.
 - Visit to Spanish CRO as PM on 6-7-Oct-2009
4. **CRA/PM for Examination Study**:
 - 13 Site Monitoring Visits (2 MV in 2010 + 10 MV in 2011 + 1 MV in 2012)
5. **CRA/PM for Clarify Study**:
 - Presentation during the Investigator's Meeting on 19th November, Firenze
 - Sponsor meeting 22nd March 2011 (IFB Stroder – Firenze)
 - Web Investigator's Meeting 16th June 2011
 - Webinar meeting preparation and presentation- 13th June 2012
 - Webinar meeting preparation and presentation- 23rd January 2013
 - Webinar participation – 31st Jan 2013
 - 7 Site Monitoring Visits (5 in 2011 + 1 in 2012 + 1 in 2013)
 - 1 Site Closure visits (2011)

6. **PM for Signify Study (CL3-16257-083):**
 - Visit to Brazilian CRO from Oct 2010 to Dec 2011 every 2 months, from Jan 2012 till now every 6 months
 - Visit to Mexican CRO CRO from Oct 2010 to Dec 2011 every 2 months, from Jan 2012 till now every 6 months
 - Visit to Argentinian CRO CRO from Oct 2010 to Dec 2011 every 2 months, from Jan 2012 till now every 6 months
 - Pre-study visit on 21st Feb – Marillia – Sao Paulo – Brazil
 - Site Sponsor Audit preparation – Mexico – 25th-29th July 2011

Meeting Participation

1. **SHIFT Servier - meeting**
 - SHIFT - ESP-ITA-SVN Inv. Meeting Bologna on 26-27-Sep-2007
 - SHIFT - International CRA Meeting Paris on 19-21-feb-08
 - SHIFT - International Inv. Meeting Rome on 13-14-Oct-2008
 - SHIFT - CRA Meeting Rome on 15-16-Oct-2008
 - SHIFT - ESP INV Meeting Madrid on 29-Oct-2008
 - SHIFT – International CRA meeting Paris 1-2 Apr 2009
2. **SHIFT Servier – PM meeting**
 - SHIFT - PM meeting Paris on 12-13-May-2009
 - SHIFT - PM meeting Paris on 16-17-Sep-2009
 - SHIFT - PM meeting Paris on 2-3-Dec-2009
 - SHIFT - PM meeting Paris on 8-9-Mar-2010
3. **Participation to ESC Meeting (European Society of Cardiology) in Stockholm on 26-27 August 2010.**
Presentation of SHIFT results
4. **Participation to ESC Meeting (European Society of Cardiology) in Paris on 30th August 2011.**
Presentation of SIGNIFY preliminary data presentation
5. **SIGNIFY Servier –Meeting and Training participation**
 - Signify – PM meeting Paris on 25th November 2010
 - Signify – PM meeting Paris on 13th January 2011
 - Signify – Meeting with Local Servier Brazil on 22nd Feb 2011
 - Signify – WebSETHI training – Italian ICTR on 17th Feb 2011 (ICTR Italy)
 - Signify – WebSETHI training – Argentinian ICTR on 4th March (ICTR Mexico)
 - Signify – International CRA&MRs Meeting – Paris – 31st March and 1st April 2011
 - Signify – PM meeting Paris on 19th May 2011
 - Signify – PM meeting Paris on 16th September 2011
 - Signify – PM meeting Paris on 9th January 2012
 - Signify – International CRA&MRs Meeting – Paris – 28-30 March 2012
 - Signify – PM meeting Paris on 10th May 2012
 - Signify – PM meeting Paris on 9th October 2012
 - Signify – PM meeting Paris on 30th January 2013
 - Signify – Training Pharmacovigilance – Italian ICTR on 6th February 2013
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6. **SIGNIFY Servier –Meeting preparation**
 - ARG Investigator Meeting, Buenos Aires, Argentina on 2nd Nov 2010
 - MEX Investigator Meeting, Cancun, Mexico on 3rd Nov 2010
 - BRA Investigator Meeting, S. Paulo, Brazil on 23rd May 2011
 - ARG Investigator Meeting, Buenos Aires, Argentina on 30th May 2011

- MEX Investigator Meeting, Mexico City - Guadalajara, Mexico on 12-13 October 2012
- BRA Investigator Meeting, Salvador, Brazil on 19-20 October 2012

7. Brave Dreams –

- Presentation during Investigator's meeting on 25th March – Hotel Astra – Ferrara – Italy

8. ATPCI Study

- ATPCI 1st Kick-off meeting – Paris – Servier – 13-02-2013
- ATPCI MTA Kick-off meeting – Paris – Servier – 05-03-2013
- ATPCI 2nd Kick-off meeting – Paris – Servier – 06-03-2013

Social skills and competences

I'm an extrovert person, I like the job in team, I have good organizational and coordinate capacities. I am coherent and helpful to the dialogue / comparison. I am stimulated to learn new things. I'm able to face new problem with analytical and critical spirit. The experience matured in a laboratory of search has developed my attitude to work in team. The formative training in the pharmacy, has allowed instead me to improve the approach with different interlocutors, with different cultural backgrounds.

Organisational skills and competences

I am very fussy in the organization of the job, both of my personal project and of the project that concerns whole team. I organized the periodic and extraordinary maintenance of the scientific instrumentation.

Technical skills and competences

As Clinical Project manager:

- Maintaining primary contact with the Sponsor
- Selecting the contractors and managing the agreement
- Selecting and managing the project team members
- Coordinating and planning the operational aspects of the project(s).
- Regularly reporting project status to Sponsor.
- Managing the external services providers.
- Developing, tracking and managing the budget allocated to the project.
- Reviewing and developing solutions, action plans, contingency plans for the projects as appropriate
- Reviewing, adapting and/or developing project specific documents
- Reviewing the timelines and resources (internal and external) for the project(s) necessary for project implementation
- Ensuring full compliance with applicable regulation, ICH-GCP and SOPs
- Ensuring learning and knowledge transfer during and at the completion of the projects

As basic researcher:

Cellular Culture: division of different cellular population from the peripheral blood through Ficoll stratification; in vitro culture of cells in particular T lymphocytes and cancer cells lines, as carcinomas; generation of cellular lines immortalized by EBV virus; induction of primary and memory T cell responses; cloning of CTLs; cytotoxicity assay with release of 51chromium; Elispot assay; proliferation assay; isolation of cellular subpopulation; immunofluorescence and FACS analysis (flowcytometry). Molecular biology techniques: SDS-page, western blotting, protein and enzyme purification, evaluation of enzymatic activity. In vivo studies on laboratory animals: immunization and evaluation of the immune responses in laboratory mice; tweak of vaccination protocol based on DNA or protein administration. I know the roles to work in laboratory with security level P3 and to manage infected blood with HIV or HCV.

Bureaucratic aspects of the management of the laboratory: evasion of the orders, accountability management, maintained the contacts with the representatives and the company, opening of contracts of job, demand for a authorization for animal experimentation and use of the animal rooms.

Computer skills and competences

Operative System: Window 7, Windows Vista, XP, 2000 and previous versions and MacOS X, IX and previous versions.

ECDL core (European Computer Driving License):

Good knowledge of Word, Excel , Powerpoint and Webmail

moderate knowledge of Access

Web Design: good knowledge of Photoshop 7.0 to manage the images and photos.

Good capacity to use Internet with different browsers: Explorer, Netscape e FireFox (Mozilla).

Artistic skills and competences My hobbies are the reading (3-4 books for year), the cinema and comic theatre, the computer. I like a lot the swimming even if the job allows me not to practise it in constant way. I love travelling and I would like to be able to often make it more time.

I'm a voluntary of the Protezione Civile (Civil Defence) di Occhiobello (Rovigo province) since 2007 with logistic mansions and I'm kitchen responsible (HACCP Licence) .

Driving licence Italian Driving Licence (Cat. A) since 16/06/2005
Italian Driving Licence (Cat. B) since 07/05/1996
Private car

Additional information


- Publications
1. Lattanzi L., Rozera C., Marescotti D., D'Agostino G., Santodonato L., **Cellini S.**, Belardelli F., Gavioli R., Ferrantini M. 2011. *IFN-alpha boots epitope cross-presentation by dendritic cells via modulation of proteasome activity*. Immunobiology 2011 [in process]
 2. **Cellini S.**, 2009. *Ruolo chiave del Monitor negli Studi Clinici*. Biologi Italiani, 2009, 2: 7-10
 3. **Cellini S.**, Fortini C, Gallerani E, Destro F, Cofano EB, Caputo A, Gavioli R. *Identification of new HIV-1 Gag-specific cytotoxic T lymphocyte responses in BALB/c mice*. Virol J. 2008 Jul 14;5:81.
 4. Gavioli R, **Cellini S.**, Castaldello A, Voltan R, Gallerani E, Gagliardoni F, Fortini C, Cofano EB, Triulzi C, Cafaro A, Srivastava I, Barnett S, Caputo A, Ensoli B. 2007. *The Tat protein broadens T cell responses directed to the HIV-1 antigens Gag and Env: Implications for the design of new vaccination strategies against AIDS*. Vaccine. 2007 Dec 4; [Epub ahead of print]
 5. Marastoni M, Baldisserotto A, **Cellini S.**, Gavioli R, Tomatis R. 2004. *Peptidyl vinyl ester derivatives: new class of selective inhibitors of proteasome trypsin-like activity*. J Med Chem. 2005 Jul 28;48(15):5038-42.
 - 6.

- Educational Activities
1. **28 March 2006**: seminary: "The protein TAT-HIV-1 as immunomodulator for the development of new combined vaccines against HIV/AIDS: preclinical studies" on the Department of Biochemistry and Molecular Biology – University of Ferrara
 2. **ay 2005-2006** – Lesson at the Degree course in Chemistry and Pharmaceutical Technology on BIOCHEMISTRY matter - (Teacher Prof. Riccardo GAVIOLI);
 3. **ay 2005-2006** – Lesson at the Degree course in Chemistry and Pharmaceutical Technology on Cellular and Molecular Therapies matter - (Teacher Prof. Riccardo GAVIOLI);
 4. **ay 2005-2006** – Didactic Laboratories at the Degree course in Chemistry and Pharmaceutical Technology on BIOCHEMISTRY matter
 5. **ay 2006-2007** – Lesson at the Degree course in Chemistry and Pharmaceutical Technology on BIOCHEMISTRY IMMUNOLOGY matter - (Teacher Prof. Riccardo GAVIOLI);
 6. **ay 2006-2007** – Lesson at the Degree course in Chemistry and Pharmaceutical Technology on Cellular and Molecular Therapies matter - (Teacher Prof. Riccardo GAVIOLI);
 7. **ay 2006-2007** – Didactic Laboratories at the Degree course in Chemistry and Pharmaceutical Technology on BIOCHEMISTRY matter
 8. **aa 2009-2010** – Lessons at Master of II level on School of Clinical Research and Epidemiology – the key role of the Monitor on the Clinical Trials (14/05/2009)
 9. **aa 2010-2011** – Lessons at Master of II level on School of Clinical Research and Epidemiology – the key role of the Monitor on the Clinical Trials (06/05/2010)
 10. **aa 2012-2013** – Lessons at Master of II level on School of Clinical Research and Epidemiology – (14/05/2012, 10-12-2012)
 11. **aa 2013-2014** – Lessons at Master of II level on School of Clinical Research and Epidemiology – (28-03-2013; 04-07-2013)
 - 12.

I authorize the treatment of my personal data in according to the Italian D.Lgs. 196/03.

Ferrara, 4 November 2013


Silvia Cellini


Date and Signature