

16.1.4.1 List of investigators

Site number	Investigator	Site type	Site address	Site status	Deputy investigator(s) at the site
276-01	(Coordinating investigator & Principal investigator Mannheim) Dr. Dr. med. Armin Schultz	Clinical CRO site	CRS Clinical Research Services Mannheim GmbH Grenadier Str. 1 68167 Mannheim Germany	Open	Dr. med. Friedeborg Seitz
276-02	(Principal investigator Berlin) Dr. med. Sybille Baumann	Clinical CRO site	CRS Clinical Research Services Berlin GmbH Seller Str. 31 13353 Berlin Germany	Open	Dr. med. Matthias Berse, Manuela Casjens MD

CRO = contract research organization.

090177e194f36bf2\Approved\Approved On: 18-Sep-2020 07:17 (GMT)

CURRICULUM VITAE

Personal Data

Name: Dr Sybille Katharina Baumann, MD

Date and Place of Birth: (b) (6)

Nationality: (b) (6)

School Education

1979 Graduation: General Qualification for University Entrance

Career

1979 - 1981 Nursing School
Municipal Hospital
Frankenthal

1981 - 1987 Studying Human Medicine
University of Heidelberg

12.05.1987 Physician Exam

05.06.1987 License to practice Medicine
Regional Administrative Authority Stuttgart

12.05.1987 Doctorate
Institute for Anaesthesia and Resuscitation
Clinic Mannheim

10/1987 - 01/1988 Assistant Physician
Anaesthesia Department
Protestant Hospital "Hochstift"
Worms

02/1988 - 03/1991 Assistant Physician
Anaesthesia Department
District Hospital "Bergstrasse"
Heppenheim

04/1991 - 01/1997 Assistant Physician at the Clinic for Anaesthesia and
Intensive Care Medicine
University Clinics "Saarland"
Homburg/Saar

28.01.1993 Recognition as Doctor for Anaesthesia

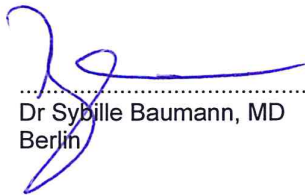
08/1993	Appointment as Functional Head Physician of the University Clinics "Saarland" Homburg/Saar
1995 - 1997	Practice Substitute for Dr. M. Penninger Neustadt/Weinstraße
	Practice Substitute for Dr. A. Penninger Ludwigshafen
07/1997 - 07/1999	Group Practice together with Physicians Dr. Penninger and Dr. Kohler Ludwigshafen
08/1999 – 12/2003	Physician Department Clinical Studies Phase I-II Institut für Klinische Pharmakologie Bobenheim Prof. Dr. Lücker GmbH, (IKP GmbH) Grünstadt
since 01/2004	Qualification as Principal Investigator of Clinical Trials acc. to § 40 German Drug Law
01/2004 – 01/2007	Head Clinical Investigator Department Clinical Studies Phase I-II Institut für Klinische Pharmakologie Bobenheim Prof. Dr. Lücker GmbH As of January 01, 2007 operating as: CRS Clinical Research Services Mannheim GmbH Mannheim
02/2007 – 03/2007	Clinical Investigator Phase I Abbott GmbH Ludwigshafen
04/2007 – 04/2008	Clinical Investigator Department Clinical Studies Phase I-II CRS Clinical Research Services Mannheim GmbH Mannheim
04/2008 – 12/2015	Deputy Medical Director Clinical Pharmacology Unit CRS Clinical Research Services Mannheim GmbH Mannheim
02/2015	Recognition as Specialist in Clinical Pharmacology District Medical Association, Karlsruhe


as of 01/2016

Medical Director
Clinical Pharmacology Unit
CRS Clinical Research Services Berlin GmbH
Berlin

Language Skills

German, native speaker
English, fluent in writing and speaking


.....
Dr Sybille Baumann, MD
Berlin


.....
Date

090177e194f36bec\Approved\Approved On: 18-Sep-2020 07:17 (GMT)

CURRICULUM VITAE

Personal Data

Name: Dr Matthias Berse, MD, M.Sc.
Date and Place of Birth: (b) (6) [REDACTED]
Nationality: (b) (6) [REDACTED]

School Education

1996 Graduation: General Qualification for University Entrance

Career

1997 - 2004 Studies of Human Medicine
Free University of Berlin and
Charité University Medicine
Berlin

12/2004 License to practice Medicine
Regional Authorities for Health and Social Affairs
Berlin

07/2005 – 12/2005 Assistant Physician
Department of Neurology
German Red Cross Clinics
Berlin-Köpenick

03/2006 Doctorate
Department of Surgery
Division of Molecular Biology
Charité
Berlin

2007 – 2008 Studies of Mathematics
Humboldt University
Berlin

2008 – 2011 Studies of Biostatistics
Graduation: Master (M.Sc.)
Ruprecht Karls University
Heidelberg

07/2008 – 10/2011 Investigator
Clinical Pharmacology Unit
Bayer Schering Pharma AG
Berlin

090177e194f36bed\Approved\Approved On: 18-Sep-2020 07:17 (GMT)



since 07/2010

Qualification as Principal Investigator of Clinical Trials acc. to § 40 German Drug Law

10/2011 – 06/2013
Bayer Pharma AG
Berlin

Head of Clinical Pharmacology Unit

as of 07/2013

Deputy Medical Director
Clinical Pharmacology Unit
CRS Clinical Research Services Berlin GmbH
Berlin

Language Skills

German, native speaker
English, fluent in writing and speaking

.....
Dr Matthias Berse, MD, M.Sc.
Berlin

.....
Date

090177e194f36bed\Approved\Approved On: 18-Sep-2020 07:17 (GMT)

CURRICULUM VITAE

Personal Data

Name: Manuela Casjens, M.D.
Date and Place of Birth: (b) (6)
Nationality: (b) (6)

School Education

1981 Graduation: General Qualification for University Entrance

Career

1982 Administration
Job Center III
Berlin

1983 – 1986 Vocational Training as registered Nurse
Spandau Hospital
Berlin-Spandau

1986 – 1988 Nurse
Surgical Intensive Care Unit
Spandau Hospital
Berlin-Spandau

1988 - 1994 Studies of Human Medicine
Free University
Berlin

1994 – 1996 Resident
Cardiological Department
Neukölln Hospital
Berlin

08.03.1996 License to practice Medicine
Senate Department for Social Affairs and Health
Berlin

1996 – 1997 Assistant Physician
Clinic "Am Roseneck"
Berlin

1998 – 1999 Further Education in Health Management
mibeg Institute
Berlin



2004 – 10/2011 Investigator
Clinical Pharmacology Unit
Bayer Schering Pharma AG
Berlin

since 10/2006 Qualification as Principal Investigator of Clinical Trials acc.
to § 40 German Drug Law

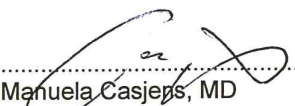
11/2011 – 06/2013 Investigator (via leasing company)
Clinical Pharmacology Unit
Bayer Schering Pharma AG
Berlin

07/2013 – 05/2015 Investigator (via leasing company)
Clinical Pharmacology Unit
CRS Clinical Research Services Berlin GmbH
Berlin

as of 06/2015 Investigator (Part-Time)
Clinical Pharmacology Unit
CRS Clinical Research Services Berlin GmbH
Berlin

Language Skills

German, native speaker
English, fluent in writing and speaking
French, good basic knowledge
Italian, basic knowledge


.....
Manuela Casjers, MD
Berlin

27 APR 2019
.....
Date

090177e194f36bee\Approved\Approved On: 18-Sep-2020 07:17 (GMT)

CURRICULUM VITAE

Personal Data

Name: Dr Dr Armin Schultz, MD

Date and Place of Birth: (b) (6)

Nationality: (b) (6)

School Education

1975 Graduation: General Qualification for University Entrance

Career

1977 - 1984 Studies of Biology
Ruprecht Karls University of Heidelberg

1985 –1986 Diploma Thesis
Institute for Immunology and Genetics
German Center for Cancer Research
Heidelberg

1987 – 1991 Scientific Assistant (PhD Thesis)
Institute for Immunology and Genetics
German Center for Cancer Research
Heidelberg

1991 – 1992 Scientific Employee
Laboratory for Oncologic Surgery
University Clinic for Surgery
Heidelberg

06/1992 Doctorate in Biology (PhD)
Ruprecht Karls University of Heidelberg

1992 – 1998 Studying Human Medicine
Ruprecht Karls University
Heidelberg

04/1998 – 05/1999 Practical Year
General Hospital Schwetzingen

08/1999 – 01/2001 Resident
Institute for Clinical Pharmacology, Faculty for
Clinical Medicine Mannheim of the
University of Heidelberg

02/2001	License to practice Medicine
as of 08/2001	Qualification as Principal Investigator of Clinical Trials acc. to § 40 German Drug Law
02/2001 – 01/2003	Assistant Physician Institute for Clinical Pharmacology, Faculty for Clinical Medicine Mannheim of the University of Heidelberg
02/2003 – 03/2007	Senior Physician Institute for Clinical Pharmacology, Faculty for Clinical Medicine Mannheim of the University of Heidelberg
06/2007	Doctorate in Medicine (MD) Medical Faculty Mannheim of the University of Heidelberg
2004 – 10/2005	Provisional Director of the Institute for Clinical Pharmacology, Medical Faculty Mannheim, University of Heidelberg
since 04/2007	Physician Department Clinical Studies Phase I-II CRS Clinical Research Services Mannheim GmbH Mannheim
04/2008 – 12/2015	Deputy Medical Director Clinical Pharmacology Unit CRS Clinical Research Services Mannheim GmbH Mannheim
as of 01/2016	Medical Director Clinical Pharmacology Unit CRS Clinical Research Services Mannheim GmbH Mannheim

Language Skills

German, native speaker
English fluent in speaking and writing

Armin Schultz
.....
Date 14 JAN 2020

Dr Dr Armin Schultz, MD
Mannheim

CURRICULUM VITAE

Personal Data

Name: Dr Friedeborg Seitz, MD, née Zielke

Date and Place of Birth: (b) (6)

Nationality: (b) (6)

School Education:

1985 Graduation: General Qualification for University Entrance

Career

1985 – 1993 Studies of Human Medicine
RWTH, Aachen
Ruprecht Karls University
Heidelberg

1993 – 1994 Assistant Doctor
Local Health Authority
Mannheim

1994-1996 Assistant Doctor
Doctor's Practice for General and Naturopathic Medicine
Dr. med. B. Mark
Mannheim

04/1994 Doctorate

1995 License to practice Medicine
Regional Administrative Authority Stuttgart

1996 –1999 Assistant Doctor
Doctor's Practice for General and Naturopathic Medicine
Dr. med. B. Mark, Mannheim

2001 – 2005 Practice Substitutions



01/2006 – 12/2010

own Practice
Mannheim

06/2006 – 12/2010

Part-time Physician
Department Clinical Studies Phase I - II
Institut für klinische Pharmakologie Bobenheim, Prof. Dr.
Lücker GmbH (IKP GmbH)
As of 01.01.2007 operating as:
CRS Clinical Research Services Mannheim GmbH
Mannheim

since 01/2011

Physician
Clinical Pharmacology Unit
CRS Clinical Research Services Mannheim GmbH
Mannheim

since 09/2012

Qualification as Principal Investigator of Clinical Trials acc.
to § 40 German Drug Law

Language Skills

German, native speaker
English, fluent in writing and speaking

.....
Dr Friedeborg Seitz, MD
Mannheim

13 JAN 2020
Date

090177e194f36bf0\Approved\Approved On: 18-Sep-2020 07:17 (GMT)

16.1.4.3 List of providers

Services provided	Name and address (including country)
Medical monitoring	Bexon Cincinal Consulting, LLC, P.O. Box 3143, Memorial Station, Upper Montclair, NJ 07043, USA
Trial conduct	CRS Clinical Research Services Andernach GmbH Rennweg 72, 56626 Andernach, Germany (no site, only main office)
Clinical Monitoring	Origio Clinical Monitoring GmbH An den Deichwiesen 21a, Hannover, 30659 Germany
Central laboratory analyses	MLM Medical Labs GmbH Dohrweg 63, D-41066 Moenchengladbach, Germany
Statistics	Staburo GmbH, Aschauer Str. 26b, 81549 München, Germany
Pharmacovigilance consultancy activities	SCRATCH Pharmacovigilance GmbH & Co. KG Schlossstrasse 25, D-35510 Butzbach, Germany
PV consultant activities	PHARMSOFT Dr. B. Rodust GmbH Königswall 22, 44137 Dortmund, Germany
Sample processing	Precision for Medicine / Epiontis GmbH Barbara-McClintock- Str. 6, 12489 Berlin, Germany
Specialty analysis	VisMederi, Strada del Petriccio e Belriguardo, 35, 53100 Siena, Italy
Specialty analysis	Pfizer Vaccine Research & Development 401 North Middletown Road, Pearl River, NY 10965, USA
Specialty analysis	Regeneron Pharmaceuticals 777 Old Saw Mill River Rd, Tarrytown, NY 10591, USA
Sample processing	BioNTech RNA Pharmaceuticals GmbH, An der Goldgrube 12, 55131 Mainz, Germany
Specialty analysis	BioNTech SE, An der Goldgrube 12, 55131 Mainz, Germany

090177e195a37561\Approved\Approved On: 28-Nov-2020 02:37 (GMT)