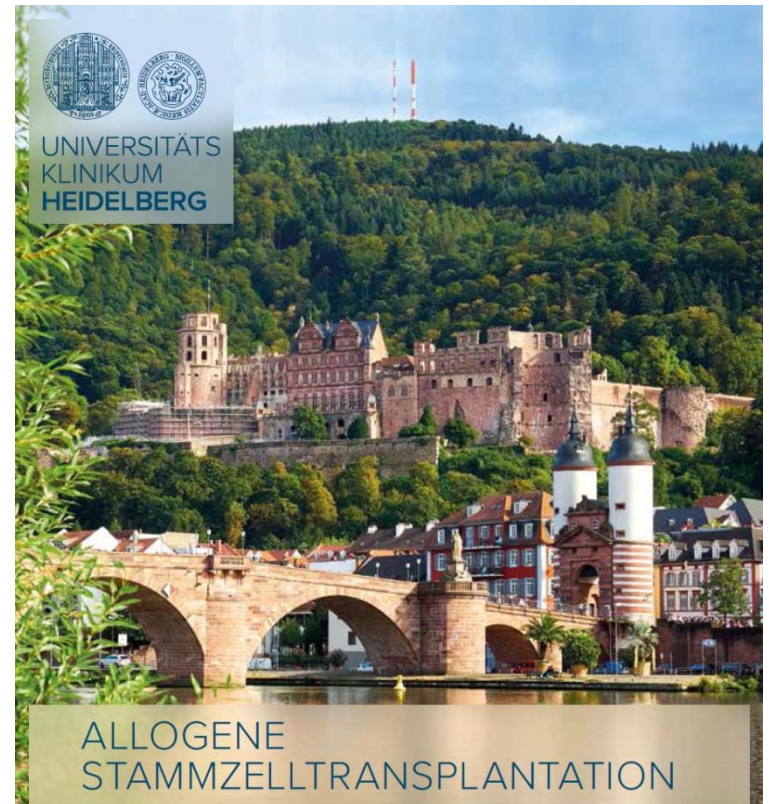




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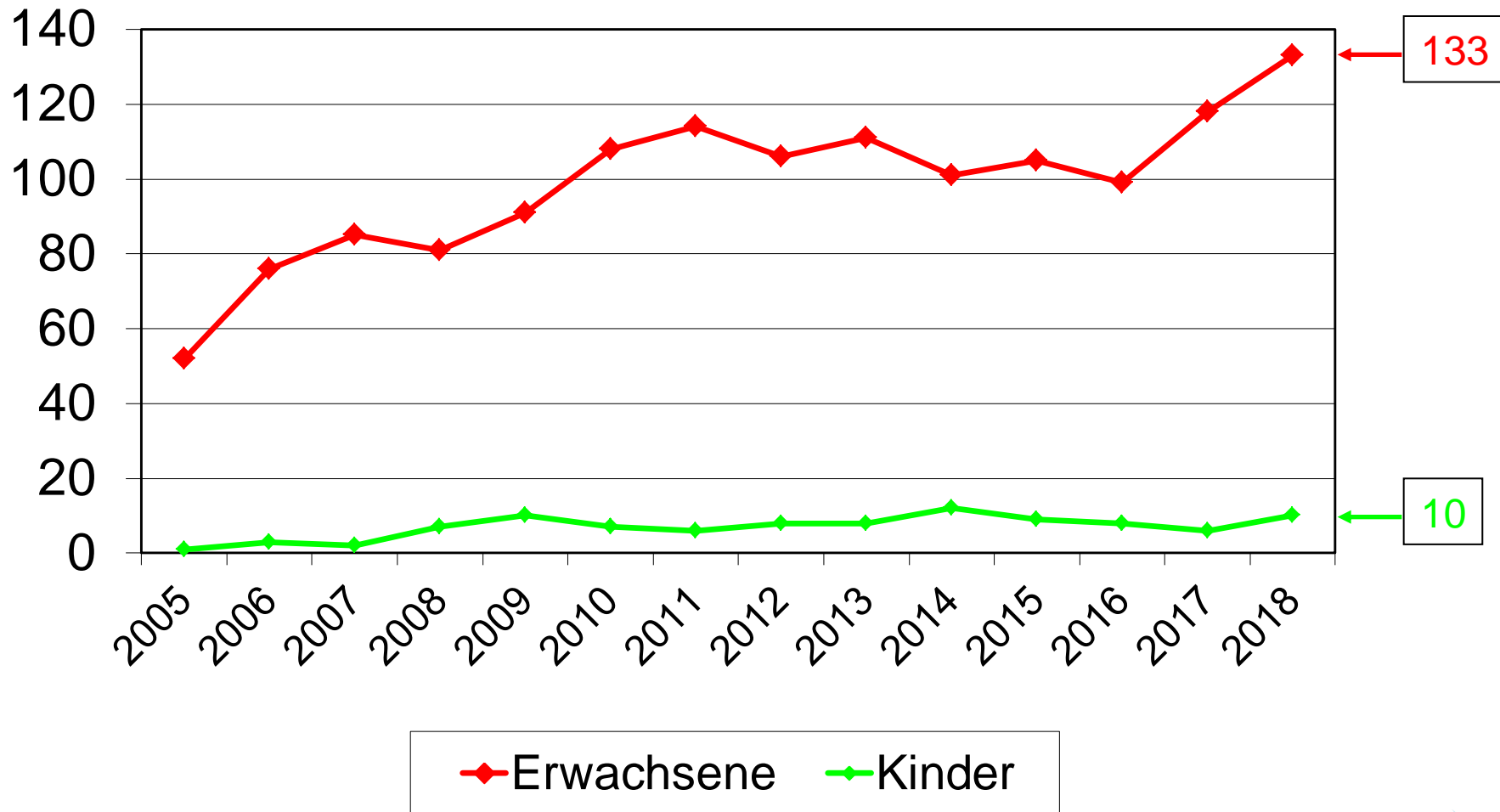
Sektion Stammzelltransplantation: Jahresbericht 2018

Prof. Dr. Peter Dreger
Klinik Innere Medizin V
Universitätsklinikum Heidelberg

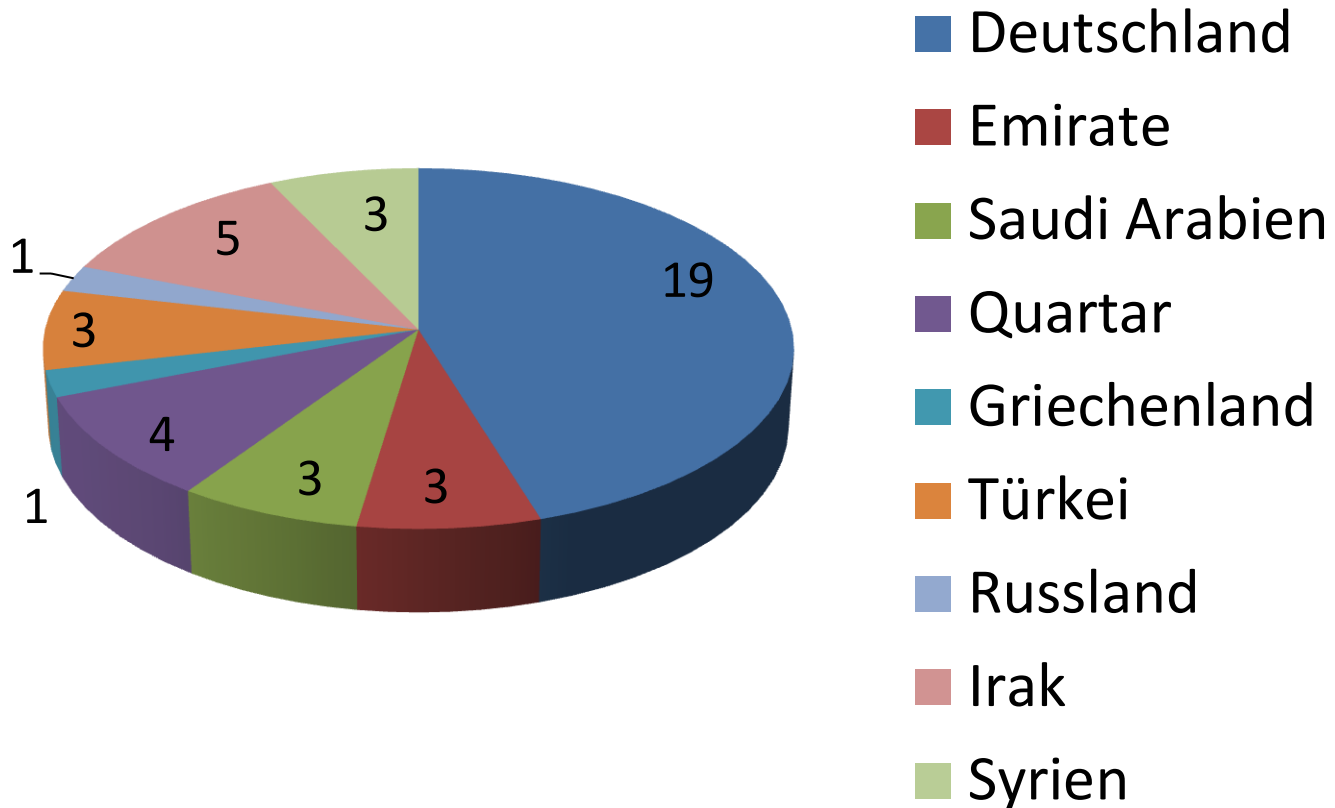


Patienten

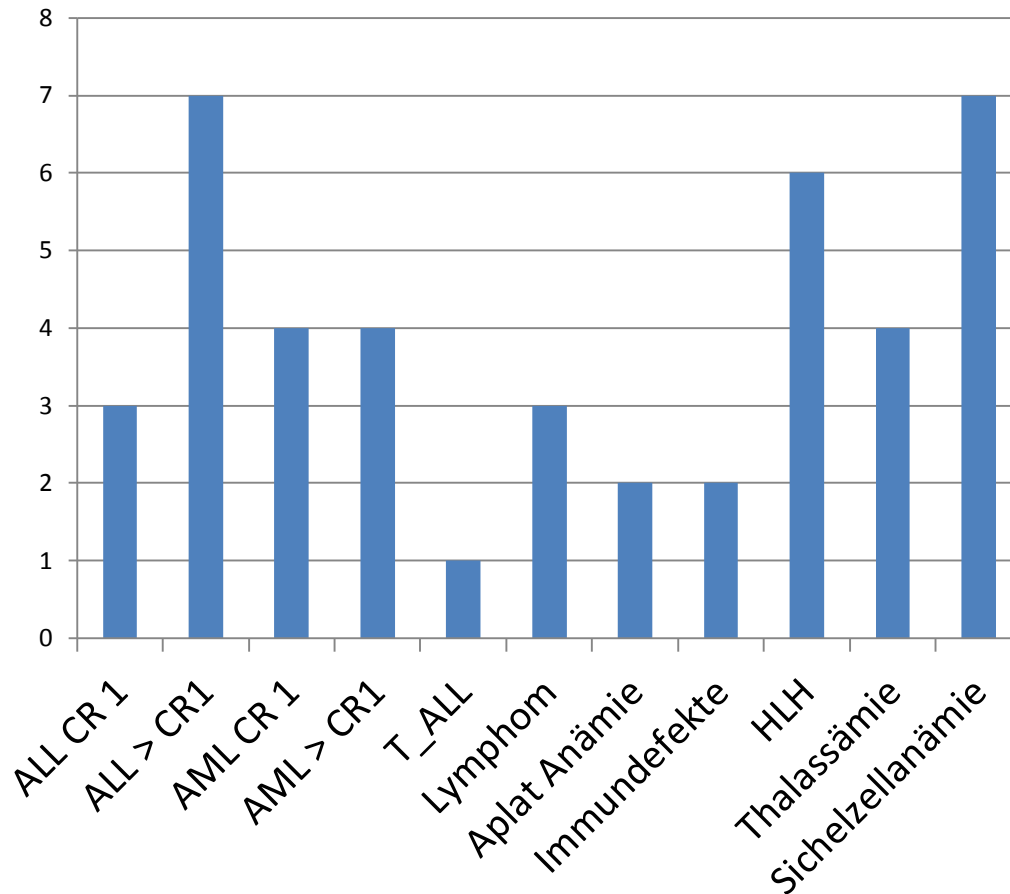
Allogene Transplantationen



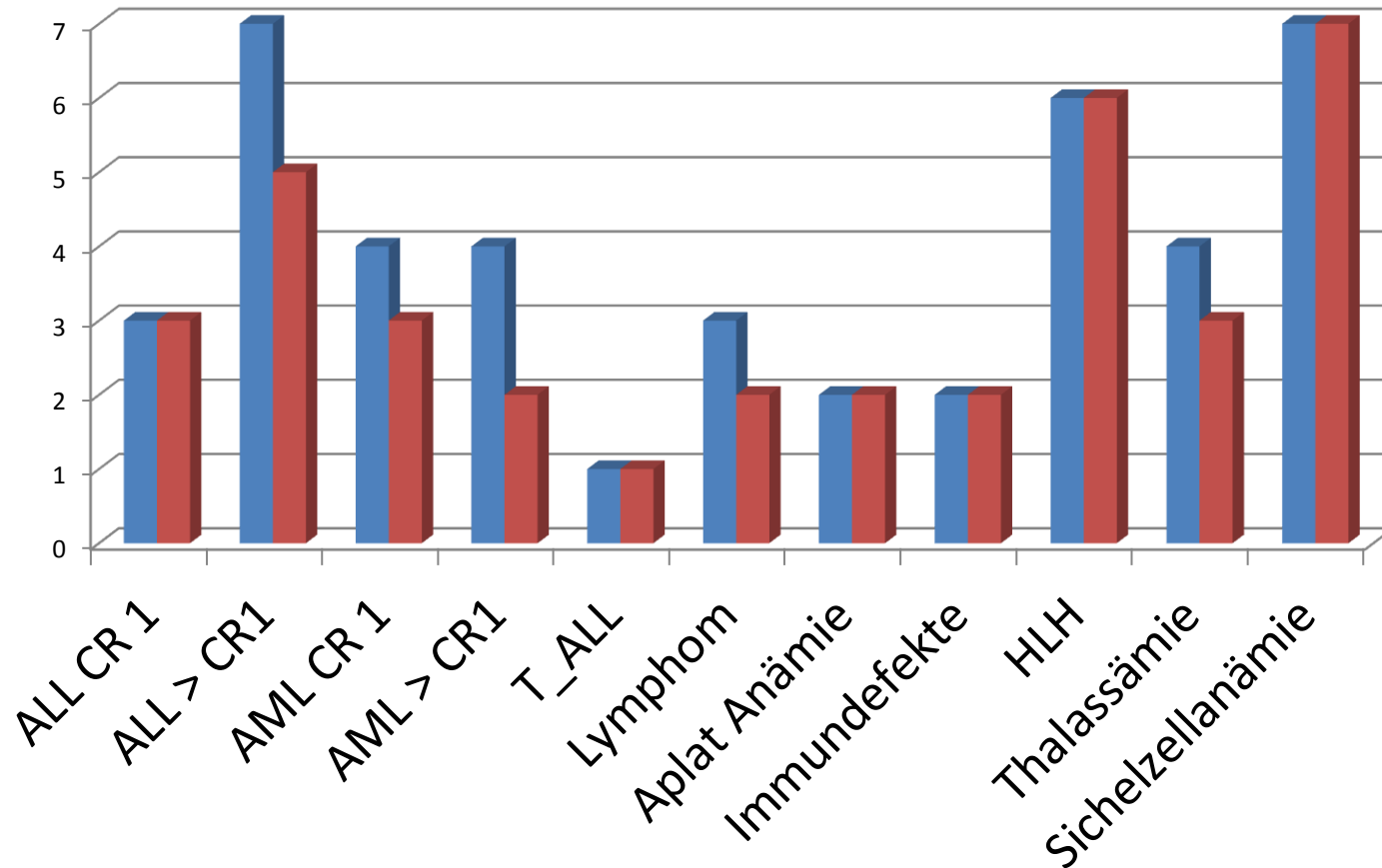
Kinder 2014-2018 (n=42): Herkunftsländer



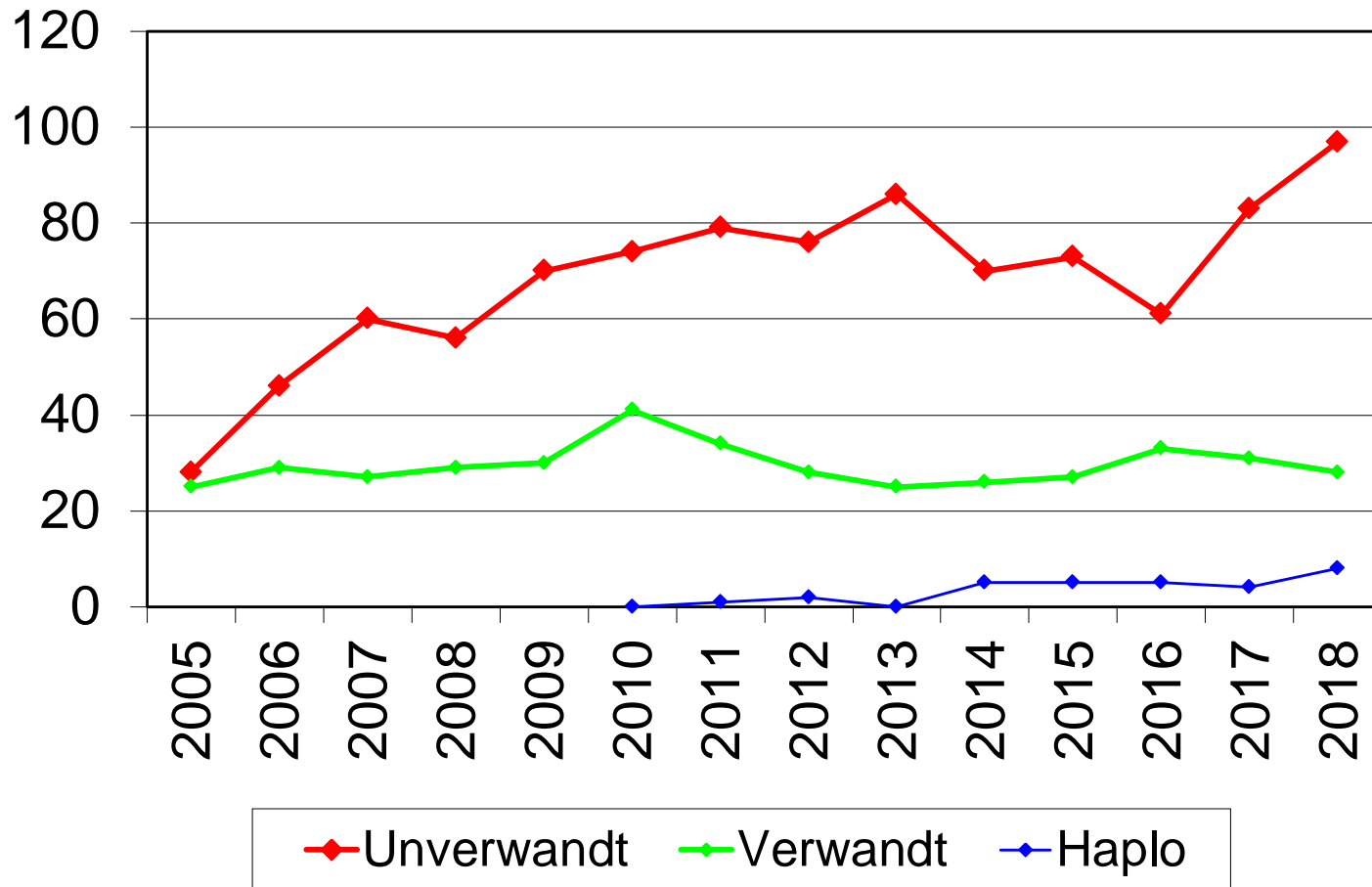
Kinder 2014-2018 (n=42): Diagnosen



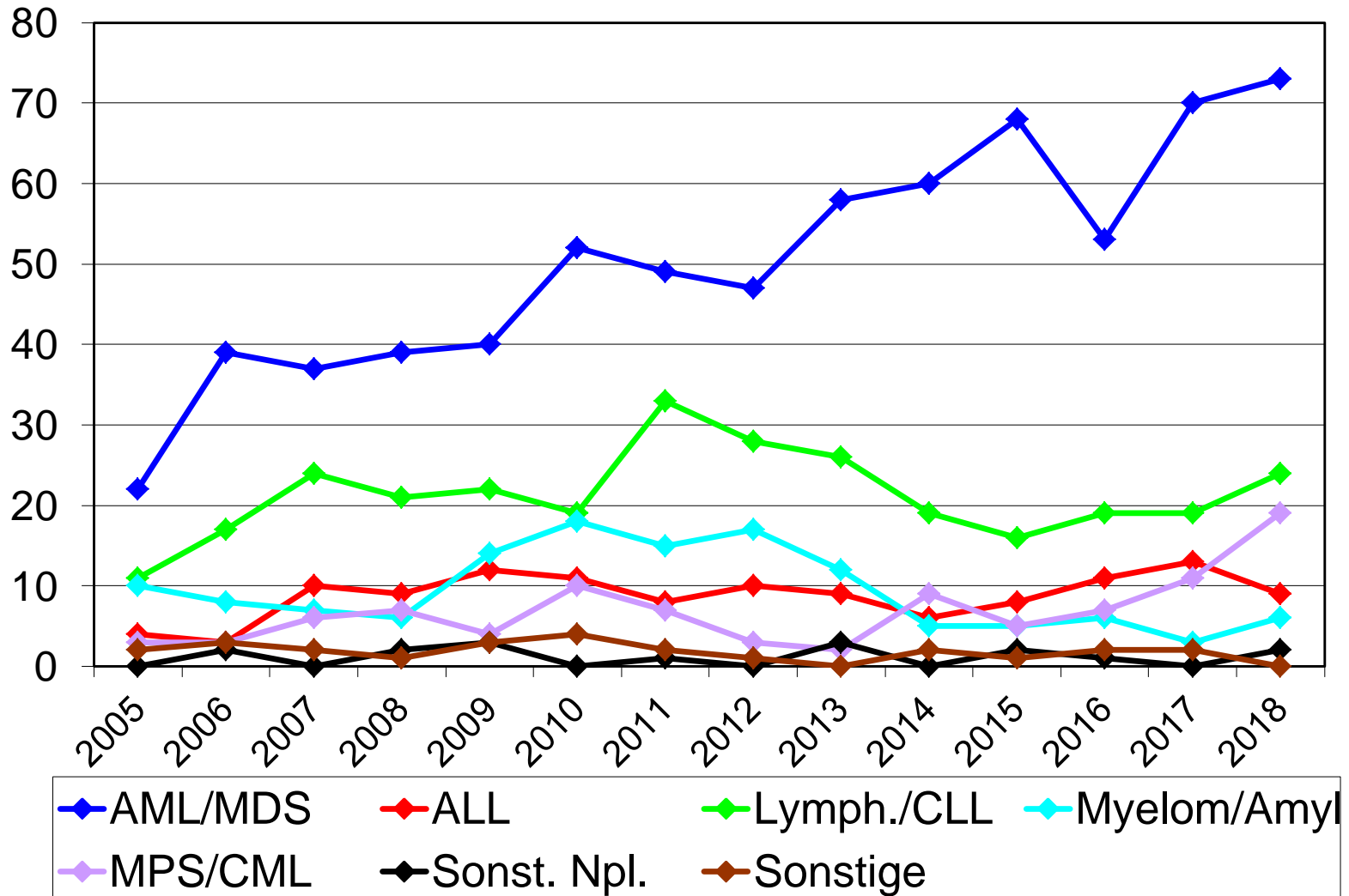
Kinder 2014-2018 (n=42): Overall survival nach Diagnosen



Spender

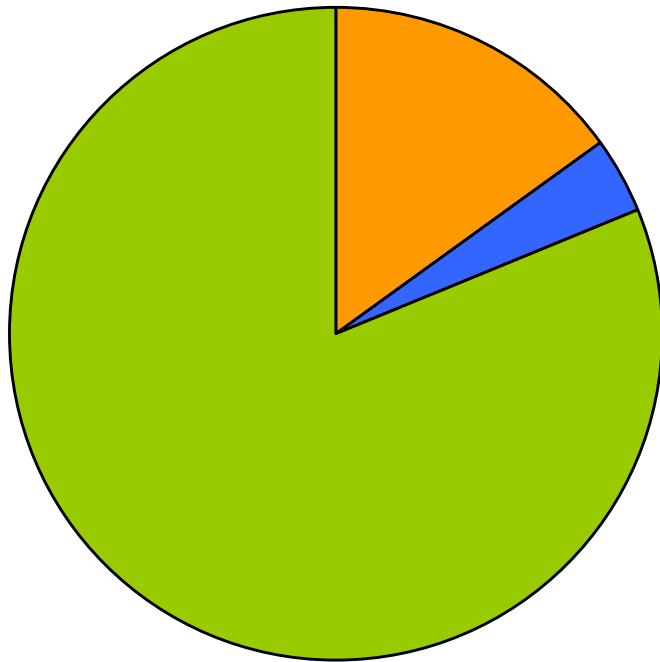


Indikationen



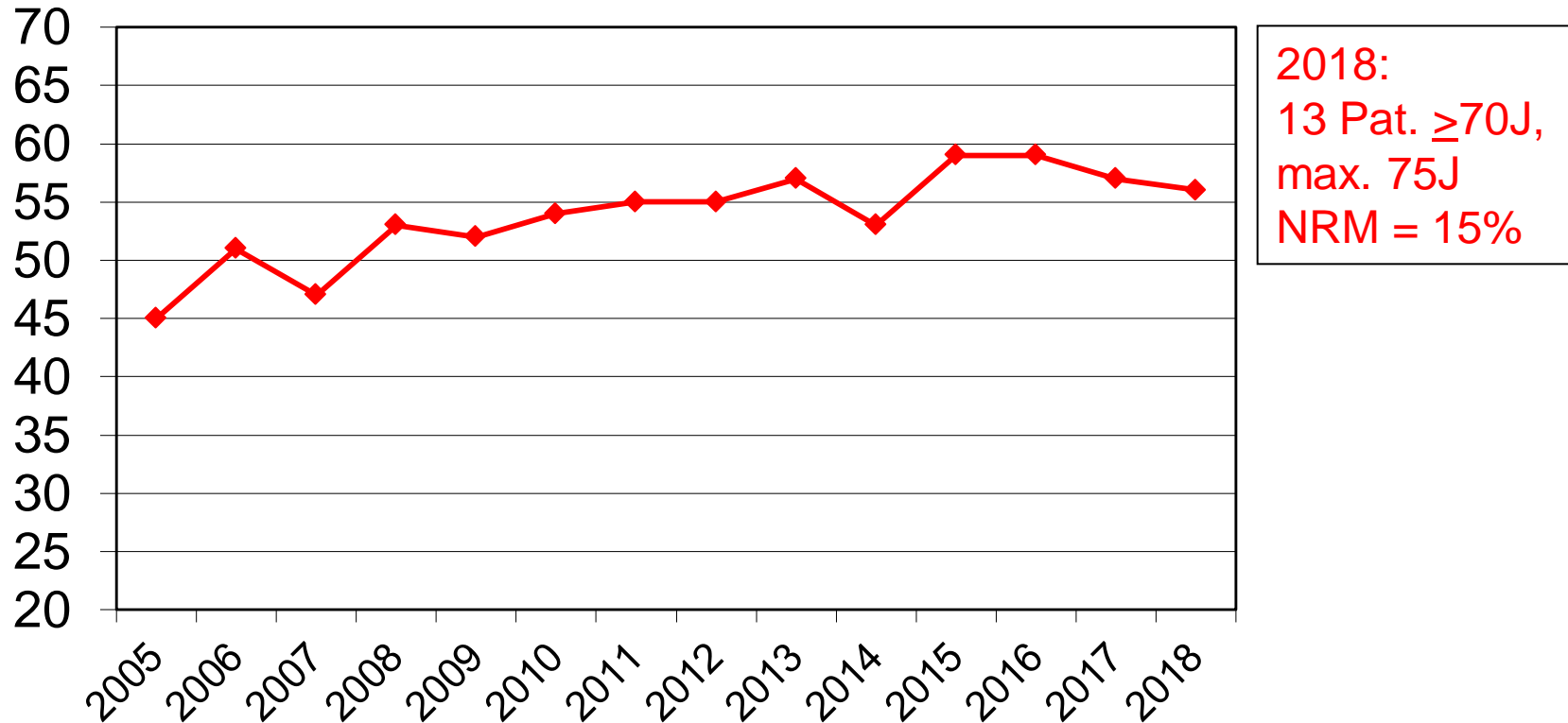
Zuweiser 2018

Insgesamt

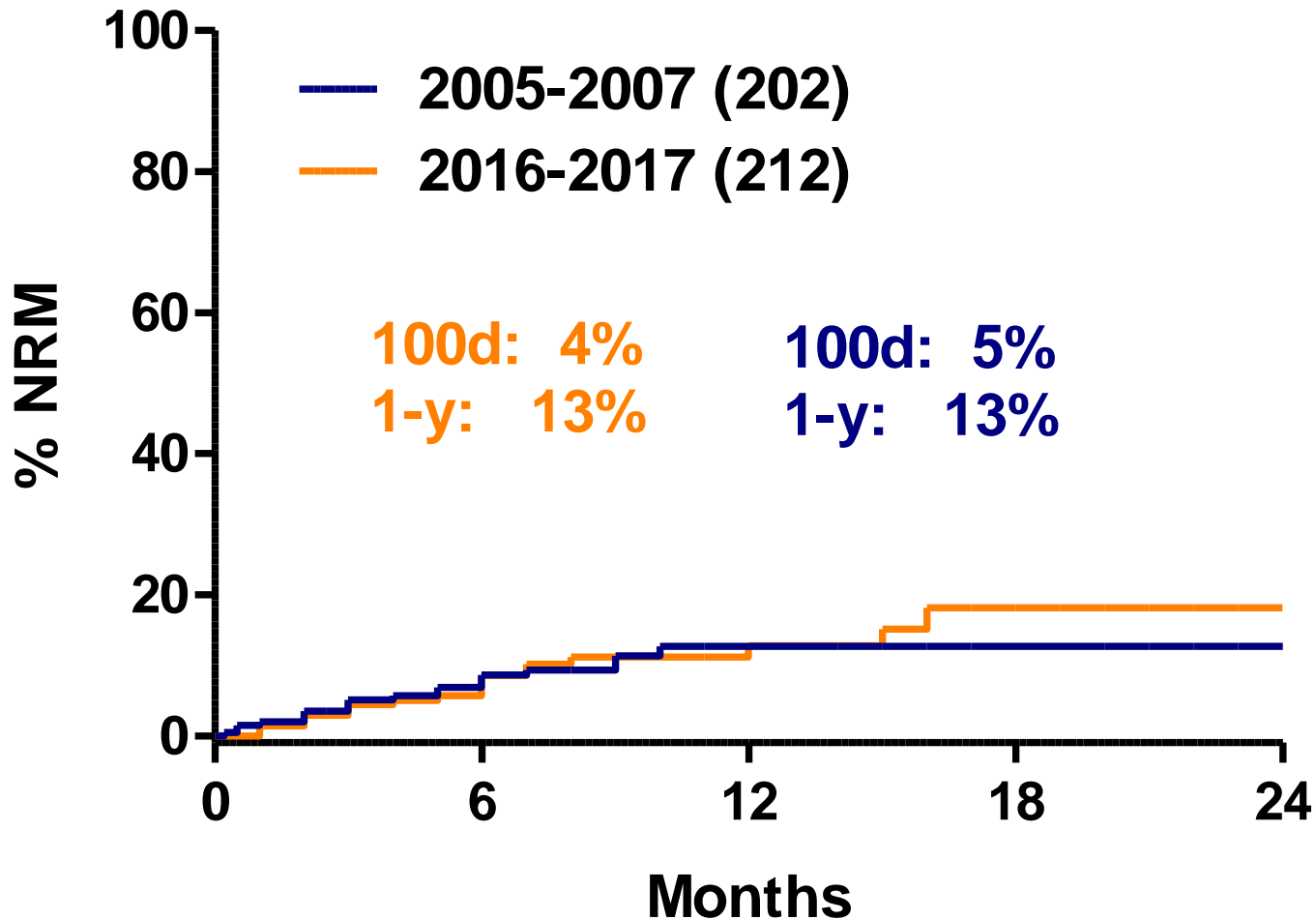


■ National ■ International ■ Regional

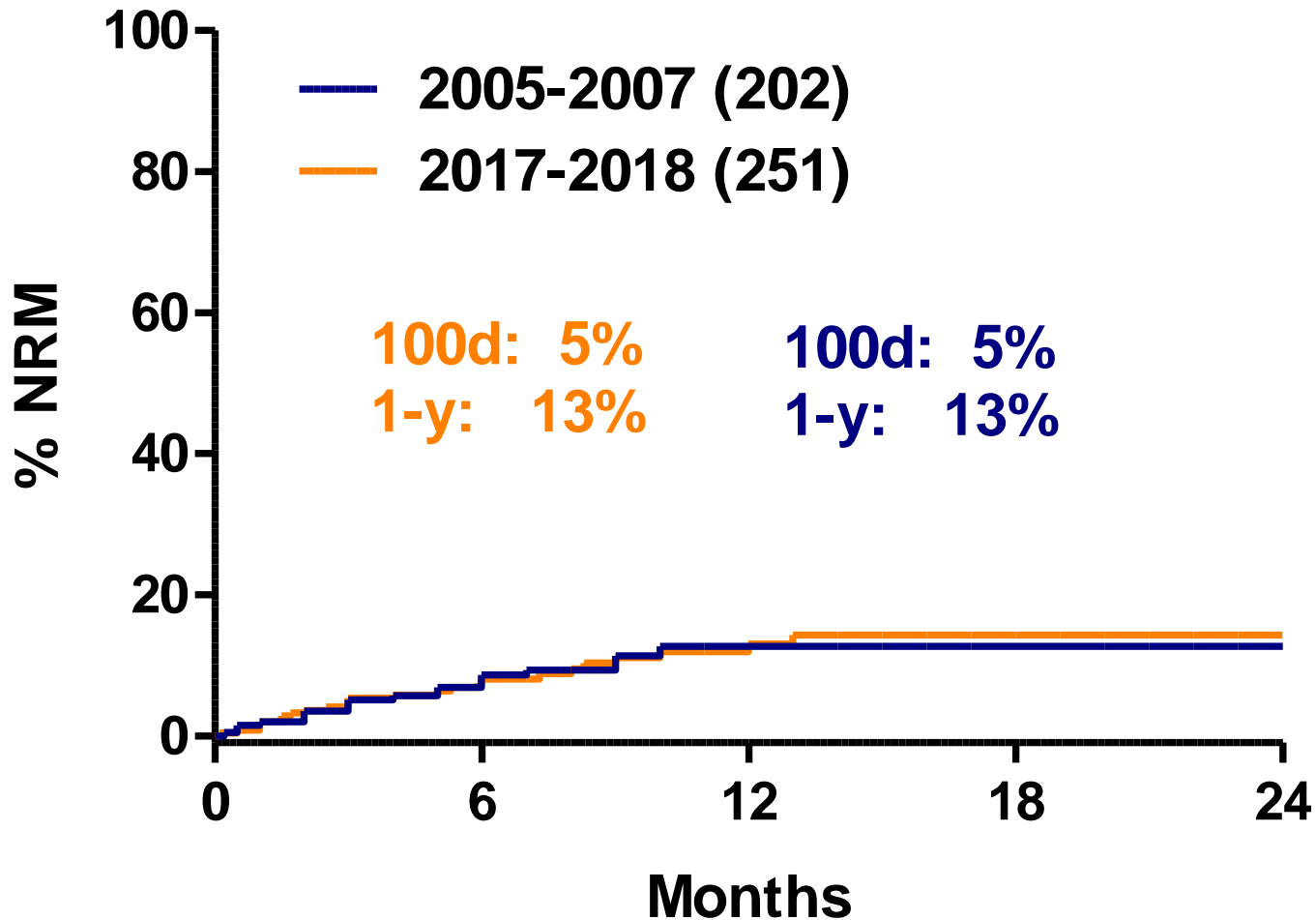
Medianes Patientenalter



Non-relapse mortality by period

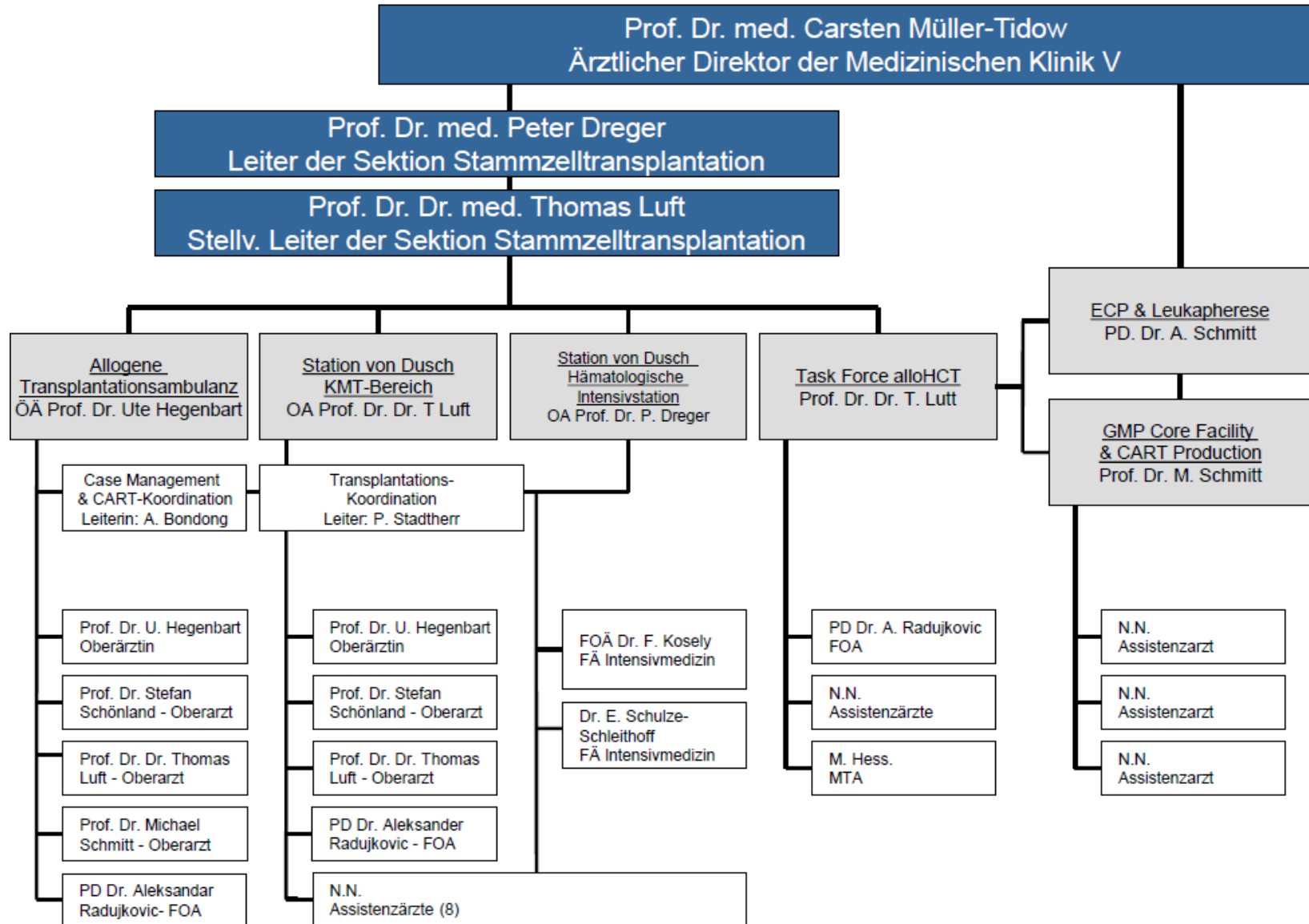


Non-relapse mortality by period



Innovationen

Organigramm Sektion SZT





EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 November 2017
EMA/CHMP/737340/2017
Committee for Medicinal Products for Human Use (CHMP)

Prevymis
letermovir

Summary of opinion¹ (initial authorisation)

The full indication is: "Prevymis is indicated for prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic haematopoietic stem cell transplant (HSCT)."

- EU-Verfügbarkeit ab 15.02.2018

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

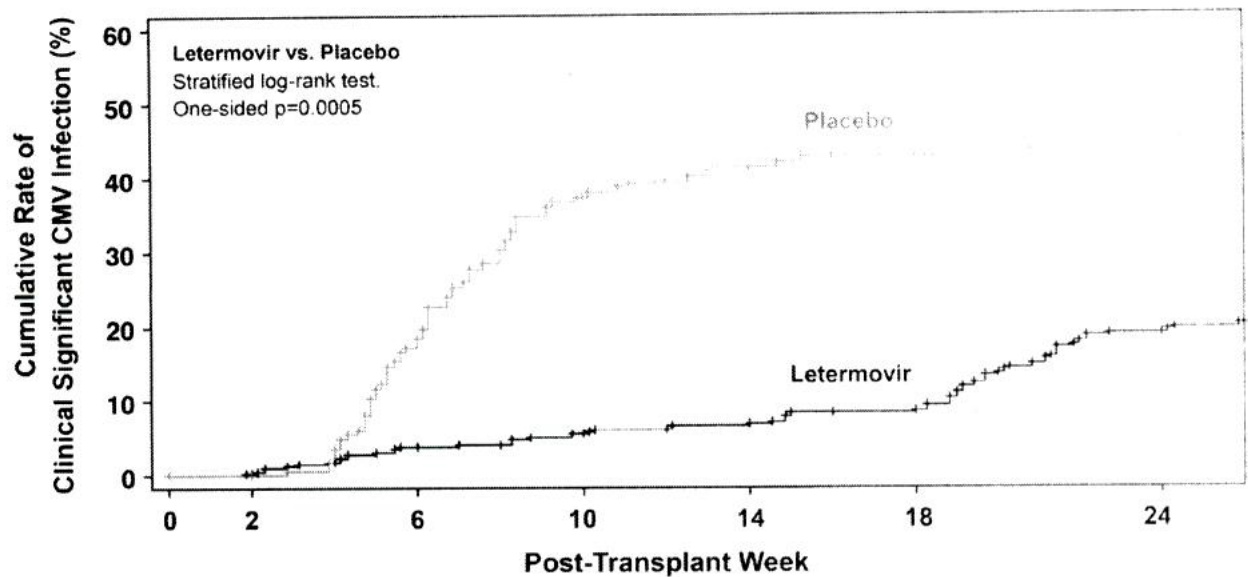
MAY 8, 2014

VOL. 370 NO. 19

Letermovir for Cytomegalovirus Prophylaxis in Hematopoietic-Cell Transplantation

Roy F. Chemaly, M.D., Andrew J. Ullmann, M.D., Susanne Stoelben, M.D., Marie Paule Richard, M.D.

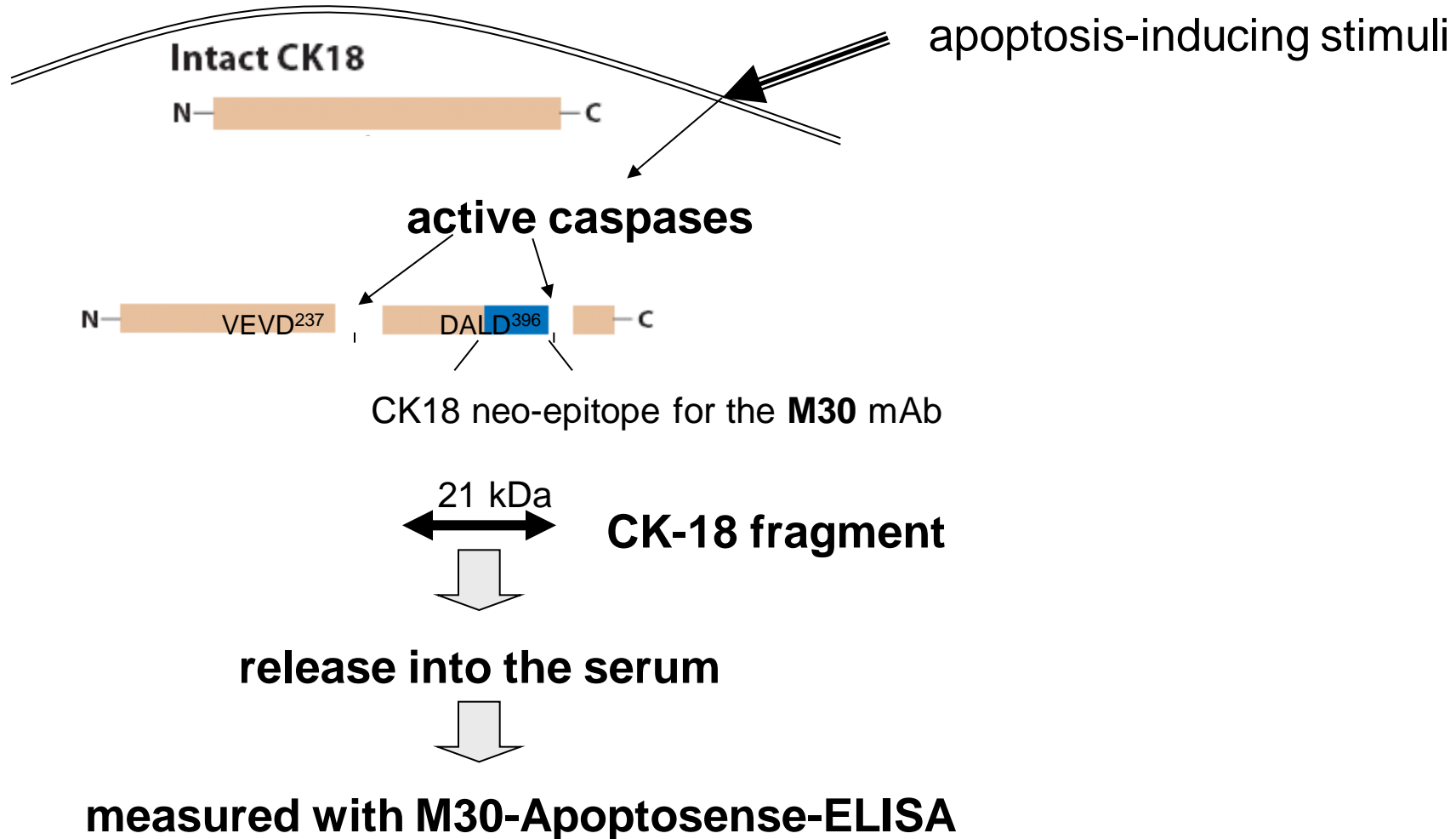
Figure 1. Time to Onset of Clinically Significant CMV Infection
Subjects with undetectable CMV DNA at Randomization



MK8228 Ph-III
RCT
(Marty et al,
ASBMT2017)

Serum cytokeratin-18 fragments as quantitative markers of epithelial apoptosis in liver and intestinal graft-versus-host disease

Thomas Luft, Michael Conzelmann, Axel Benner, Michael Rieger, Michael Hess, Ulrich Strohmaecker, Martin Görner, Ute Hegenbart, Anthony D. Ho and Peter Dreger



- Objectives:
 - CK18/CK18F diagnostic for HI aGVHD?
 - CK18/CK18F predictive for imminent HI aGVHD?
 - CK18/F predictive for refractory aGVHD?
- Eligible: adult patients undergoing alloHCT
- Prospective CK18/F measurement before conditioning and weekly thereafter
- Target: n=100

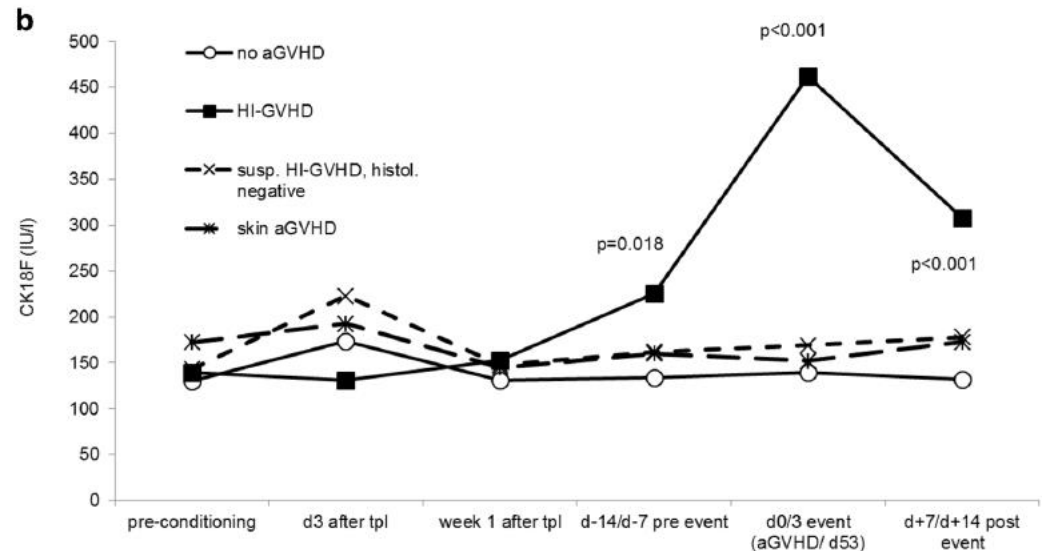
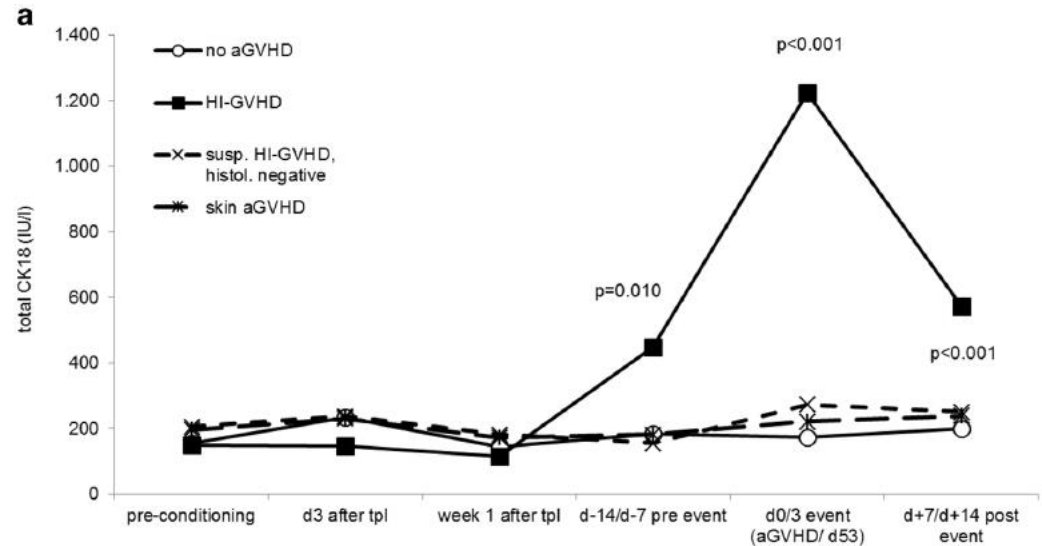
Leukemia

32:2685 (2018)

A prospective study on serum Cytokeratin (CK)-18 and CK18 fragments as biomarkers of acute hepato-intestinal GVHD

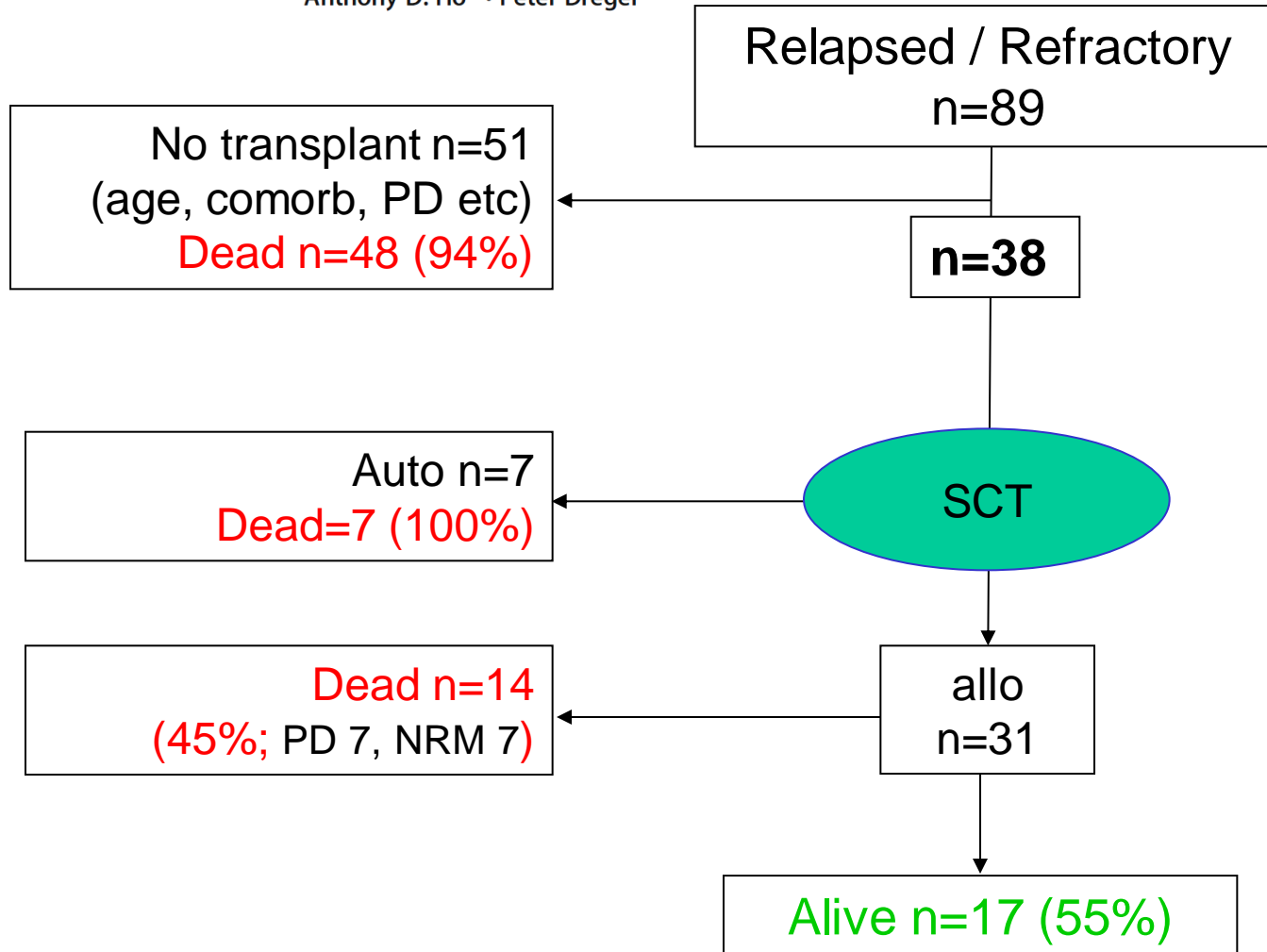
Sandra Sauer¹ · Johannes Hüsing² · Jacek Hajda² · Frank Neumann³ · Aleksandar Radujkovic¹ · Anthony D. Ho Peter Dreger¹ · Thomas Luft¹

- N = 109
- 2008-2009
- 33% developed HI-aGVHD
- CK18/F separated HI aGVHD from non-GVHD and skin GVHD
- CK18/F predicted HI aGVHD




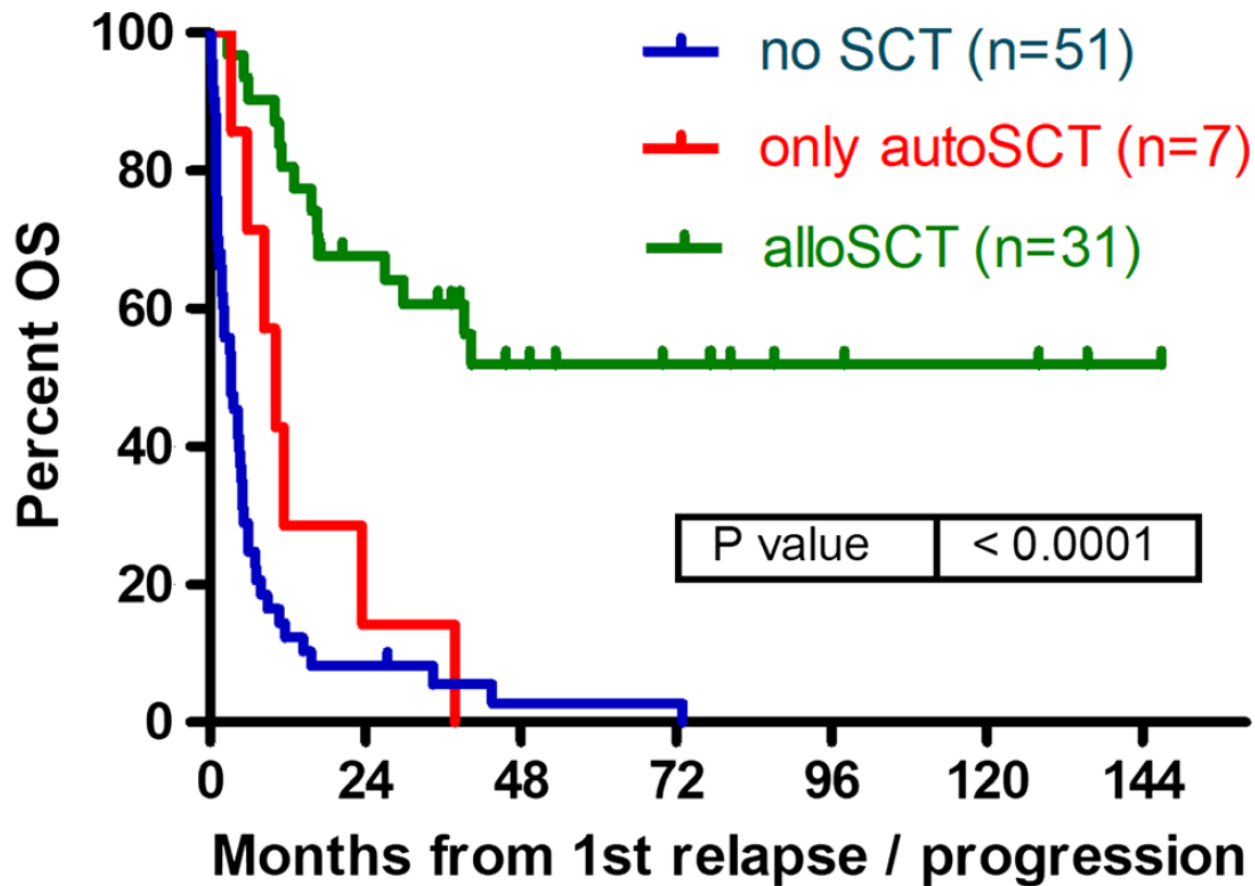
The impact of stem cell transplantation on the natural course of peripheral T-cell lymphoma: a real-world experience

Sarah Rohlfing^{1,2}  • Sascha Dietrich¹ • Mathias Witzens-Harig³ • Ute Hegenbart¹ • Stefan Schönland¹ • Thomas Luft¹ • Anthony D. Ho¹ • Peter Dreger¹



The impact of stem cell transplantation on the natural course of peripheral T-cell lymphoma: a real-world experience

Sarah Rohlfing^{1,2}  · Sascha Dietrich¹ · Mathias Witzens-Harig³ · Ute Hegenbart¹ · Stefan Schönland¹ · Thomas Luft¹ · Anthony D. Ho¹ · Peter Dreger¹



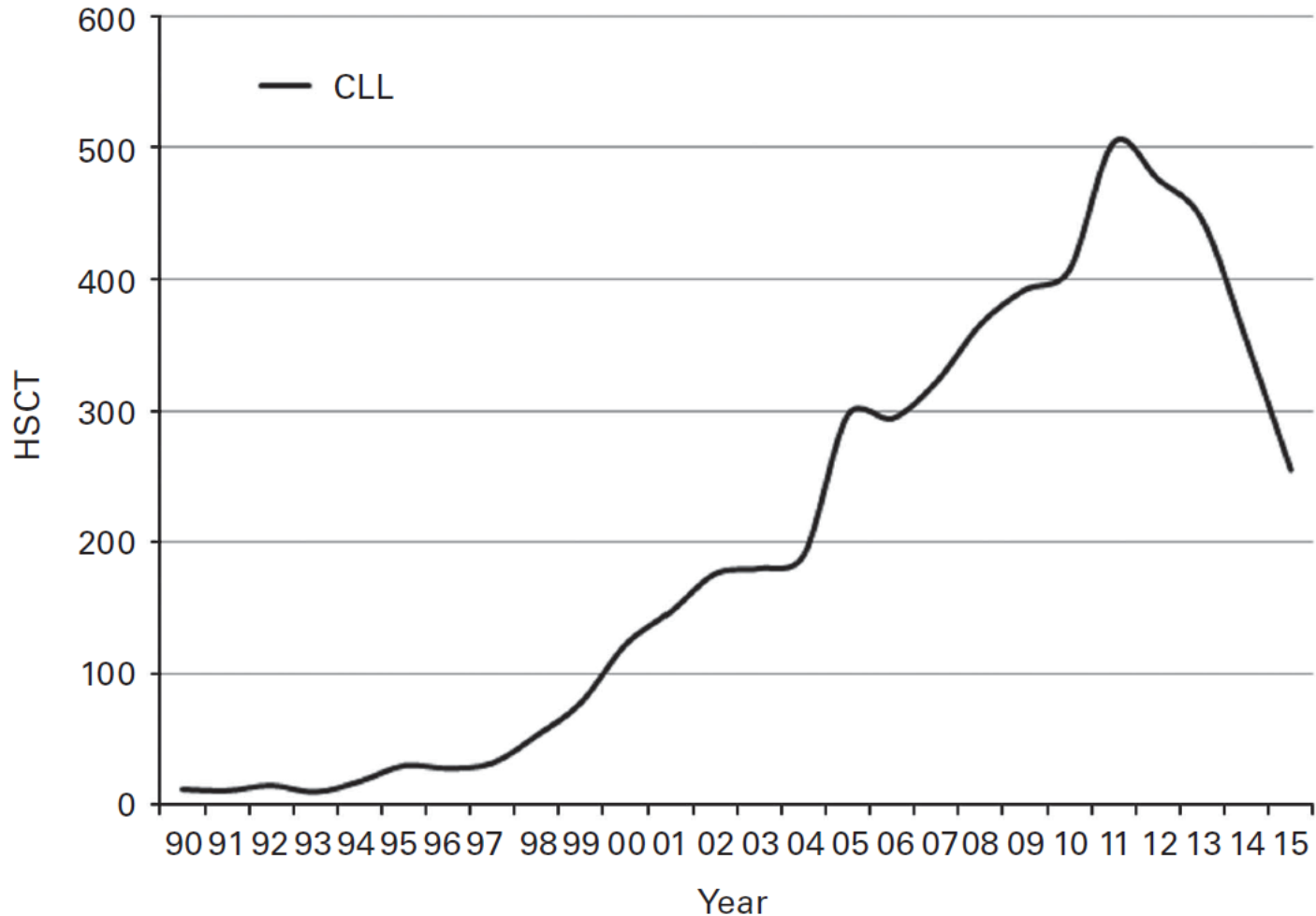


Figure 2. The rise and fall in absolute numbers of allogeneic HSCT for CLL in Europe 1990–2015.

When to use which cellular immunotherapy ?



blood[®]

2018 132: 892-902

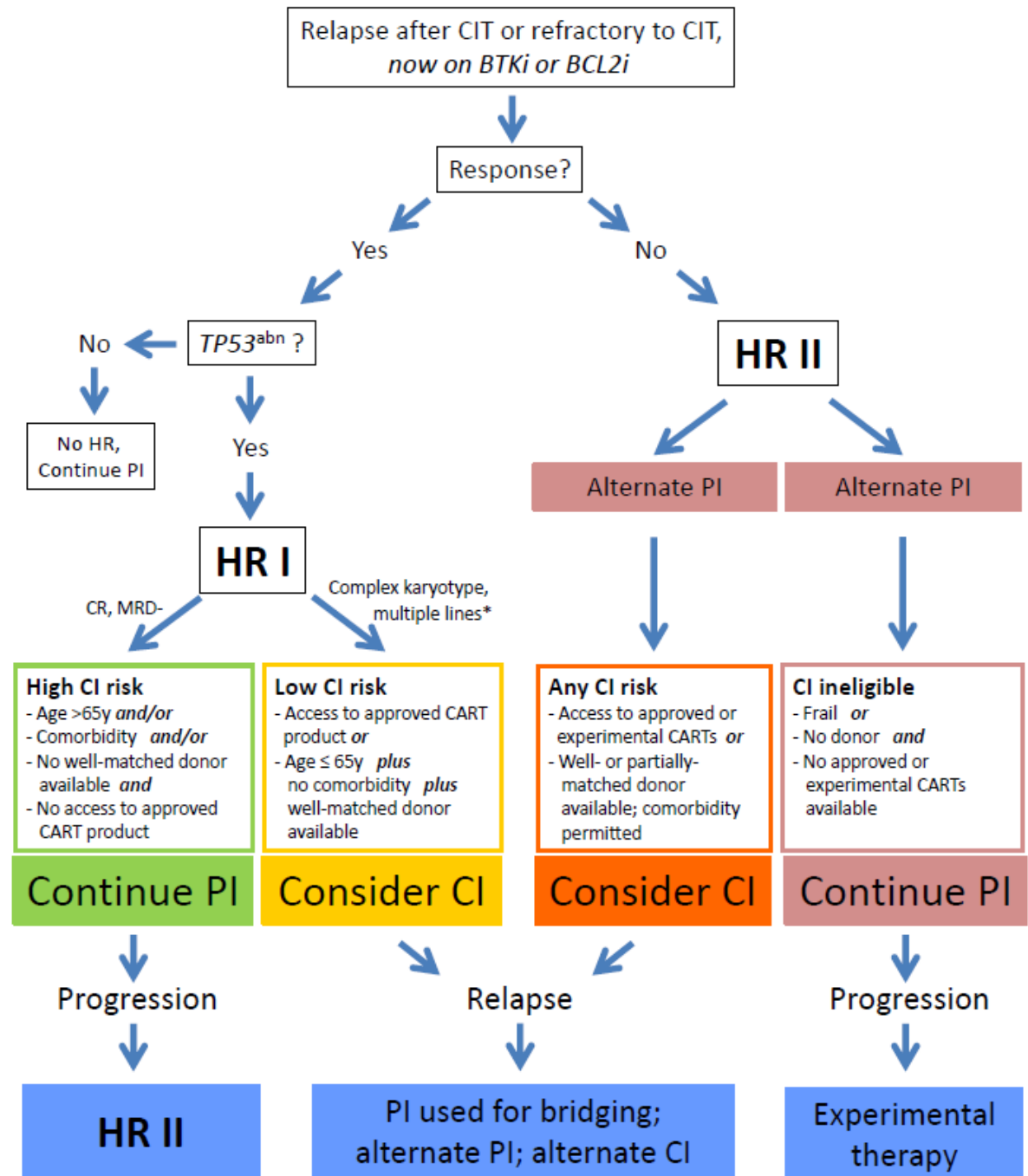
doi:10.1182/blood-2018-01-826008 originally published
online July 11, 2018

High-risk chronic lymphocytic leukemia in the era of pathway inhibitors: integrating molecular and cellular therapies

Peter Dreger, Paolo Ghia, Johannes Schetelig, Michel van Gelder, Eva Kimby, Mauricette Michallet, Carol Moreno, Tadeusz Robak, Stephan Stilgenbauer and Emili Montserrat

ERIC
European research initiative on CLL

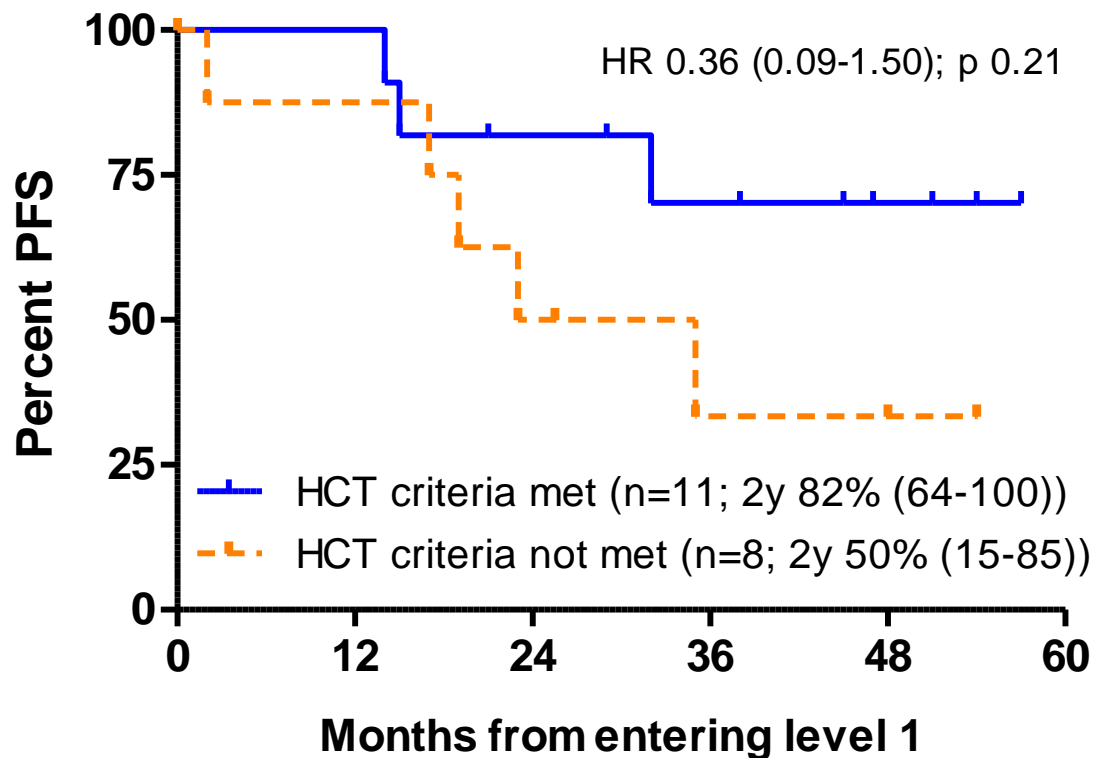




Allogeneic transplantation in high-risk chronic lymphocytic leukemia: a single-center intent-to-treat analysis

by Almuth Hoffmann, Sascha Dietrich, Susanne Hain, Michael Rieger, Ute Hegenbart, Leopold Sellner, Anthony Ho, Carsten Müller-Tidow, and Peter Dreger

Haematologica 2019 [Epub ahead of print]



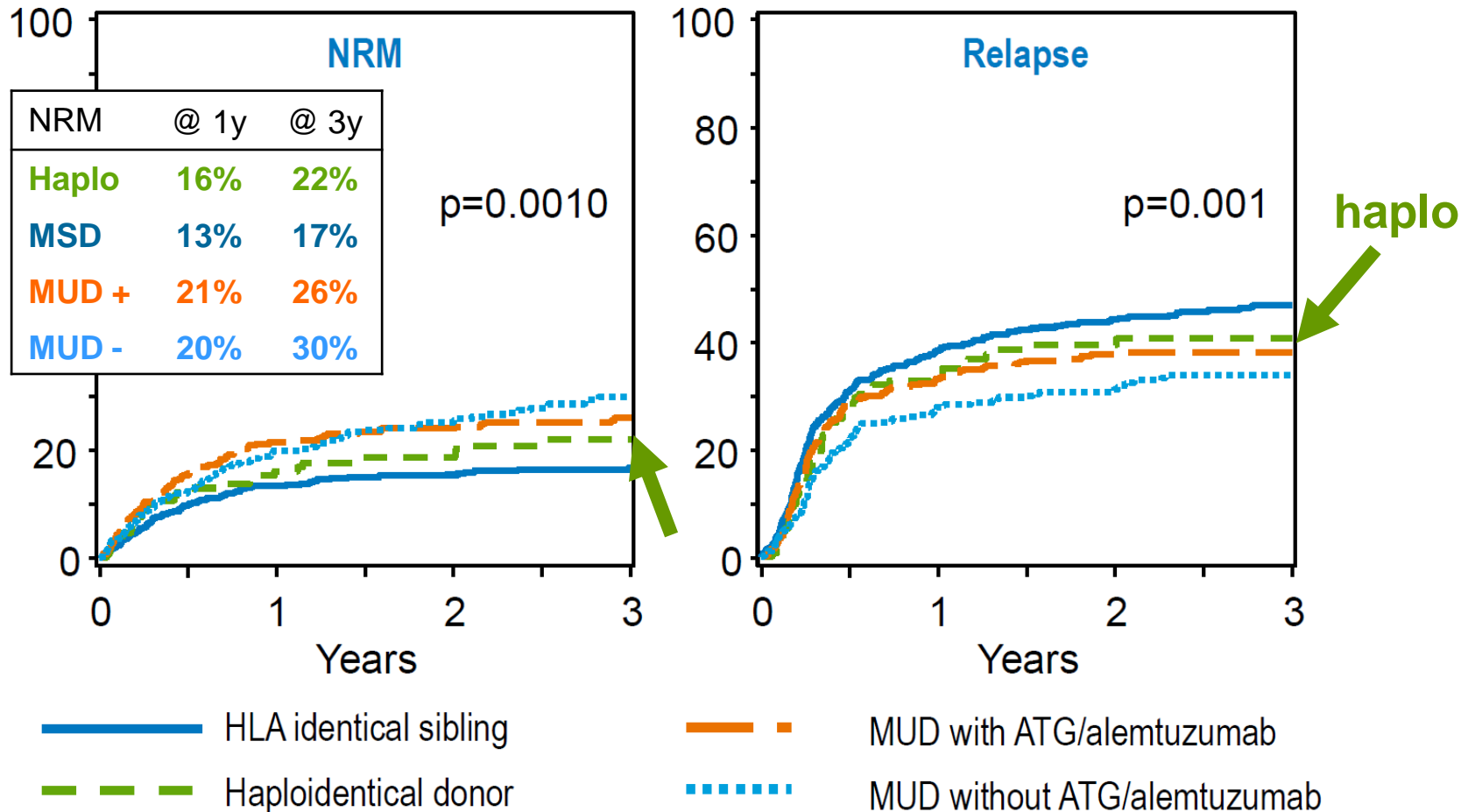
PTCy-based haploidentical vs matched related or unrelated donor reduced-intensity conditioning transplant for DLBCL

Peter Dreger,^{1,*} Anna Sureda,^{2,*} Kwang Woo Ahn,^{3,4} Mary Eapen,⁴ Carlos Litovich,⁴ Herve Finel,⁵ Ariane Boumendil,⁵ Ajay Gopal, Alex F. Herrera,⁷ Christoph Schmid,⁸ José Luis Diez-Martin,⁹ Ephraim Fuchs,¹⁰ Javier Bolaños-Meade,¹⁰ Mahasweta Gooptu,¹¹ Monzr M. Al Malki,⁷ Luca Castagna,¹² Stefan O. Ciurea,¹³ Alida Dominiotto,¹⁴ Didier Blaise,¹⁵ Fabio Ciceri,¹⁶ Johanna Tischer,¹⁷ Paolo Corradini,¹⁸ Silvia Montoto,^{5,19} Stephen Robinson,^{5,20} Zafer Gülbas,²¹ and Mehdi Hamadani⁴

Variable	Haplo	MSD	MUD TCD+	MUD TCD-	p
N (patients)	132	525	403	378	
Age (years)	58 (20-75)	55 (19-73)	55 (19-75)	56 (23-73)	<0.001
Male gender	65%	62%	64%	58%	ns
Time dx_HCT (months)	22 (1-173)	26 (2-386)	24 (4-340)	28 (2-299)	ns
Previous autoHCT	42%	55%	59%	61%	0.002
Disease status at HCT					ns
CR	48%	41%	44%	45%	
PR	34%	34%	33%	35%	
<PR	18%	25%	23%	20%	
TBI in conditioning	86%	21%	7%	32%	<0.001
Graft source BM	76%	2%	7%	5%	<0.001

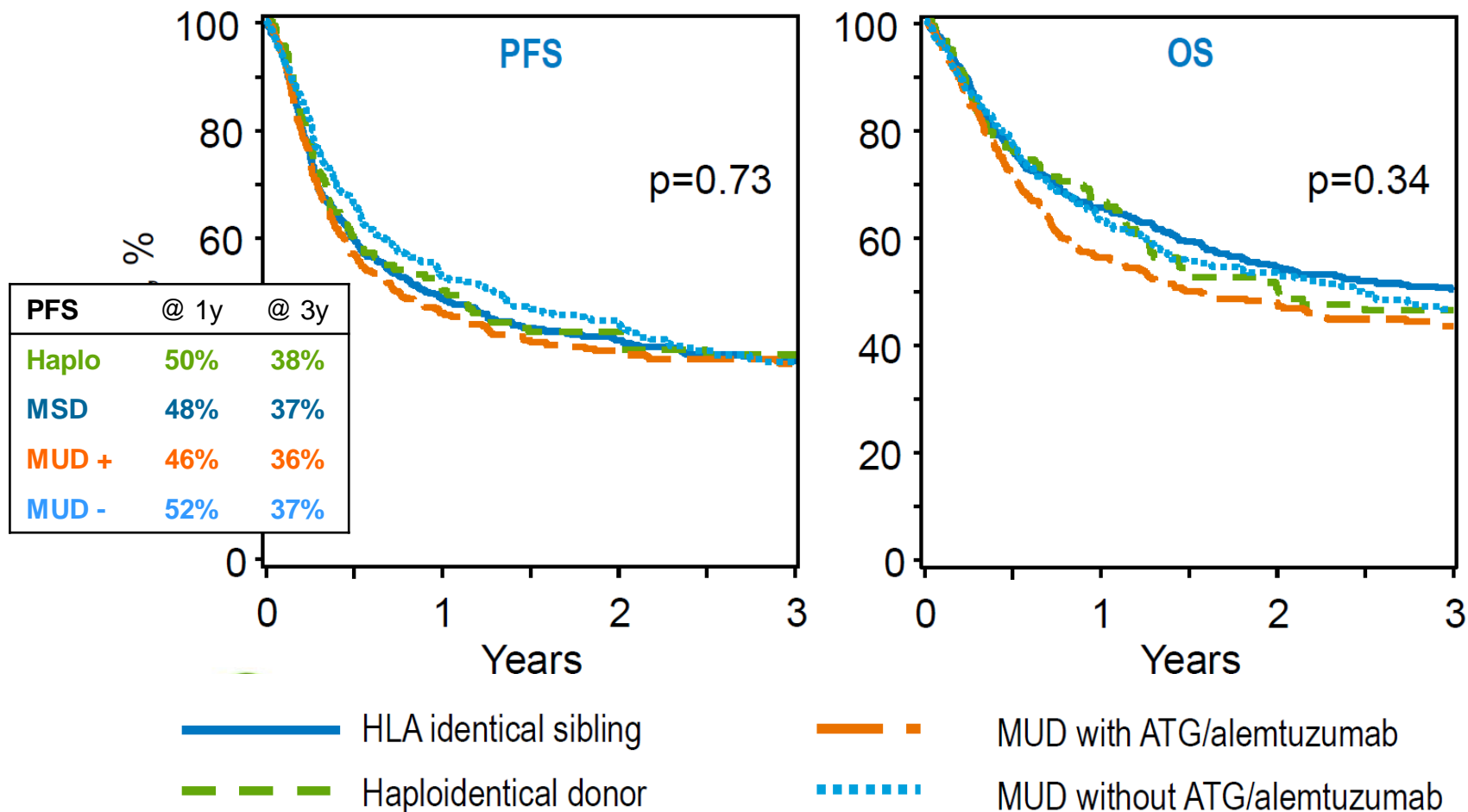
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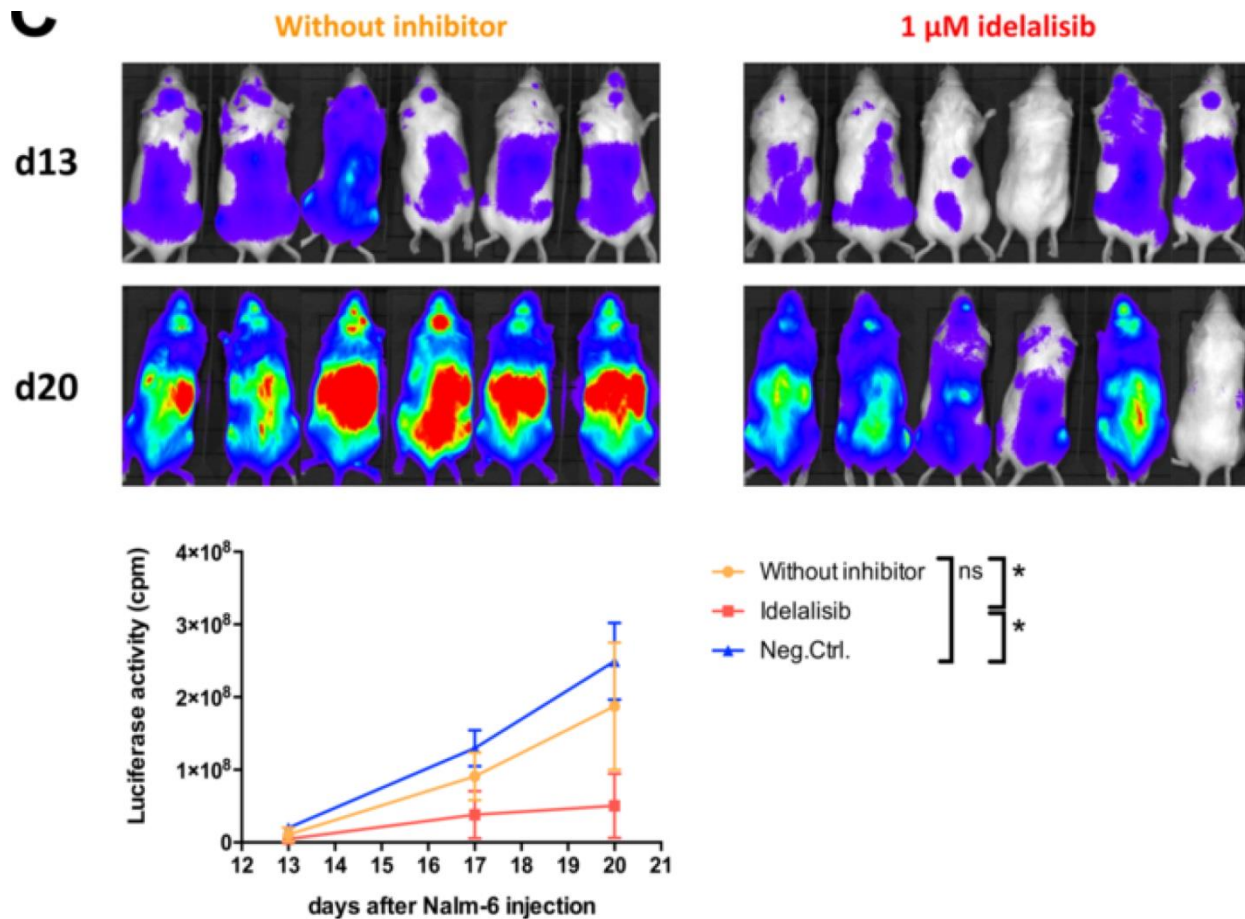
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Idelalisib for optimized CD19-specific chimeric antigen receptor T cells in chronic lymphocytic leukemia patients

Sophia Stock¹, Rudolf Übelhart^{2,3}, Maria-Luisa Schubert¹, Fuli Fan¹, Bailin He¹, Jean-Marc Hoffmann¹, Lei Wang¹, Sanmei Wang¹, Wenjie Gong¹, Brigitte Neuber¹, Angela Hüchelhoven-Krauss¹, Ulrike Gern¹, Christiane Christ², Monika Hexel², Anita Schmitt¹, Patrick Schmidt^{2,4}, Jürgen Krauss^{2,4}, Dirk Jäger^{2,4}, Carsten Müller-Tidow^{1,4}, Peter Dreger^{1,4}, Michael Schmitt^{1,4} and Leopold Sellner^{1,4}



Auch neu:
CAR-T-Zellen

CAR-HD-01

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut



Paul-Ehrlich-Institut Postfach 63207 Langen

Universitätsklinik Heidelberg

Herr Prof. Dr. Michael Schmitt
Im Neuenheimer Feld 410
69120 Heidelberg

EudraCT-Nr. 2016-004808-60

Vorlage-Nr.: 3148/01

Dr. H. Krafft

Referatsleiter klin. Prüfungen/Ref. S5

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E-Mail ct@pei.de

03.09.2018



Genehmigung der klinischen Prüfung gem. § 42 Abs. 2 AMG mit Nebenbestimmungen

Kurz-Titel: 3G-CART therapy for CD19+ lymphoid disease

Prüfsubstanz: CD19.CAR T cells

Ihr Antrag vom 14.07.2017

Bescheiddatum vom: 12.04.2018

Ihre Nachreichung von Unterlagen zur Erfüllung der Nebenbestimmungen vom 21.08.2018

Sehr geehrte Damen und Herren,

mit Schreiben vom 21.08.2018 haben Sie Unterlagen zur Erfüllung der Nebenbestimmungen, die Ihnen mit Bescheid vom 12.04.2018 auferlegt wurden, beim Paul-Ehrlich-Institut vorgelegt. Die vorgelegten Unterlagen wurden überprüft und zur Erfüllung der Nebenbestimmungen als ausreichend erachtet. Da nunmehr alle gesetzlichen Voraussetzungen des §§ 40, 42 AMG erfüllt sind, kann ab sofort mit der klinischen Prüfung begonnen werden.



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NATIONALES CENTRUM
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HEIDELBERG

getragen von:
Deutsches Krebsforschungszentrum
Universitätsklinikum Heidelberg
Thoraxklinik-Heidelberg
Deutsche Krebshilfe

**Treatment of patients with relapsed or refractory
CD19+ lymphoid disease
with T lymphocytes transduced by
RV-SFG.CD19.CD28.4-1BB ζ retroviral vector
- A unicenter Phase I/II clinical trial
CAR-HD-01
(Eudra-CT No. 2016-004808-60)**

Michael Schmitt, PI

Peter Dreger, Co-PI

Andreas Kulozik, Co-PI (pediatrics)

Protocol synopsis

Indications

Relapsed or refractory CD19⁺ lymphoid disease:

- **Stratum I:** Acute lymphoblastic leukemia (**ALL**)
- **Stratum II:** Pediatric ALL
- **Stratum III: NHL**

■ **CLL**

- Diffuse large (DLBCL)
- Follicular lymphoma
- Mantle cell lymphoma

- (1) Early relapse (within 2 years) after end of chemoimmunotherapy or chemoimmunotherapy refractoriness plus failure or intolerance of both BTK and BCL2 inhibitors OR
- (2) Relapse after alloSCT, ineligible for or refractory to standard interventions (donor lymphocyte infusions, CD20 antibodies, chemoimmunotherapy)

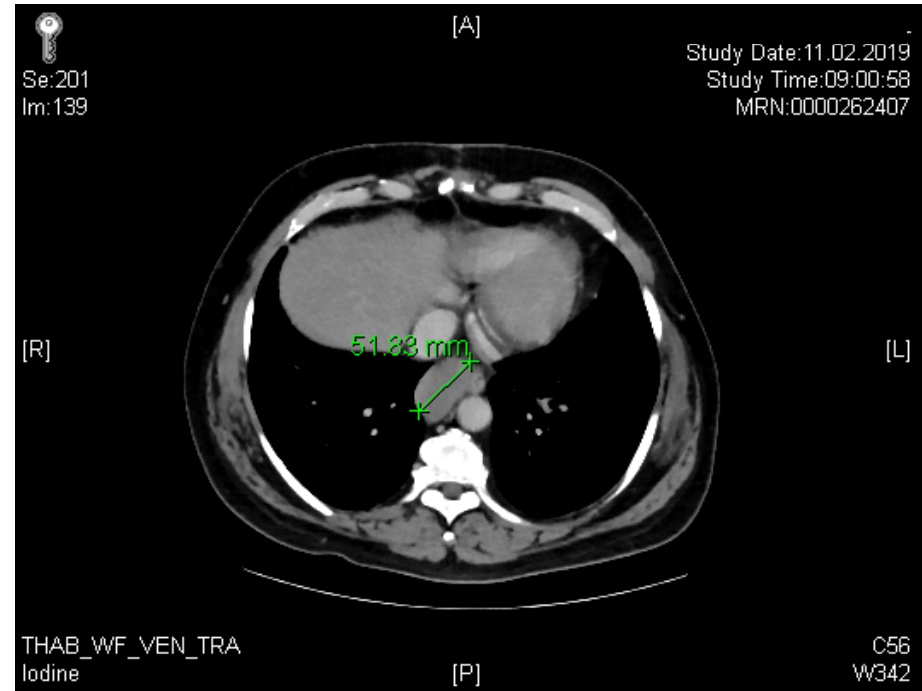
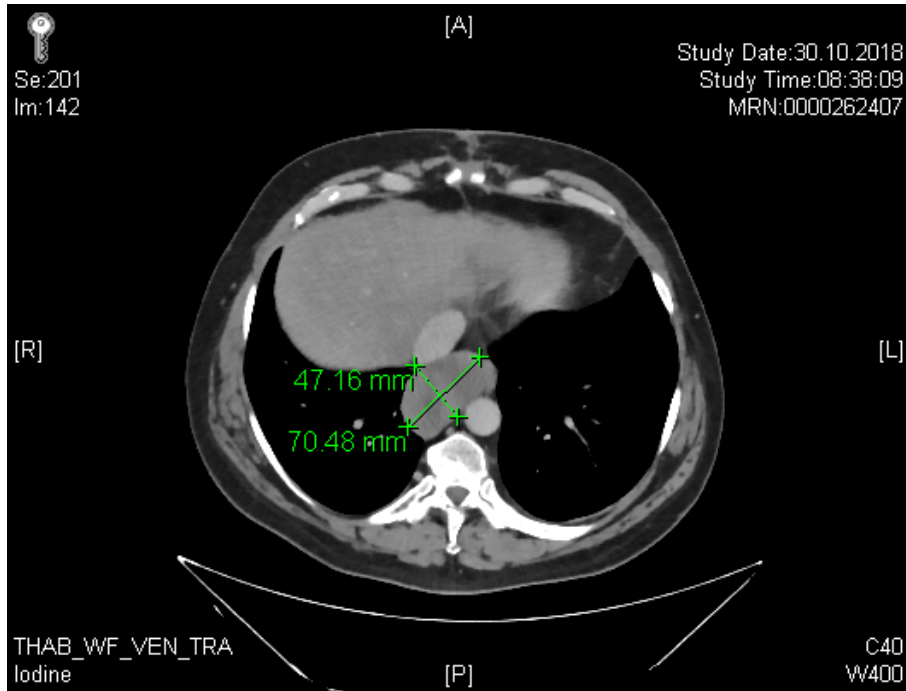
Sample size

- Phase I/II dose-escalation trial to evaluate safety of escalating doses of CAR T cells expressing CARs targeting the CD19 molecule (CD19.CAR)
- Three dose levels:
 - 1×10^6 transduced cells/m²
 - 5×10^6 transduced cells/m²

RV-SFG.CD19.CD28.4-1BB ζ : Ansprechen bei refraktärer chronischer lymphatischer Leukämie

Tag -14

Tag +90



Kite Accreditation

Dreger, Peter

Von: Torben Zachmann <Torben.Zachmann@gilead.com>
Gesendet: Donnerstag, 18. Oktober 2018 12:46
An: Dreger, Peter; Schmitt, Michael; Thalheimer, Markus
Cc: Gerold Stellmacher; Mathias Wundram; Alexander Stolskij; Daniela Van Eickels; Frederike Schmid; Denise Paltian
Betreff: Uniklinik Heidelberg - Qualifizierung & Aktivierung für die Bestellung von Yescarta
Wichtigkeit: Hoch

Sehr geehrter Herr Prof Dreger, sehr geehrter Prof Schmitt, sehr geehrter Dr Thalheimer,

Ich freue mich sehr, Ihnen nun offiziell mitteilen zu können, dass das Universitätsklinikum Heidelberg den Yescarta Qualifizierungsprozess erfolgreich durchlaufen hat und nun entsprechend der Zulassungsbedingungen autorisiert ist, Yescarta zu bestellen und anzuwenden.

Unser herzlicher Dank geht an Sie und Ihre Teams für die intensive partnerschaftliche Zusammenarbeit der letzten Monate.

Wir freuen uns auf die weitere Zusammenarbeit und stehen für evtl. Rückfragen jederzeit zur Verfügung.

Mit freundlichen Grüßen,
Torben Zachmann

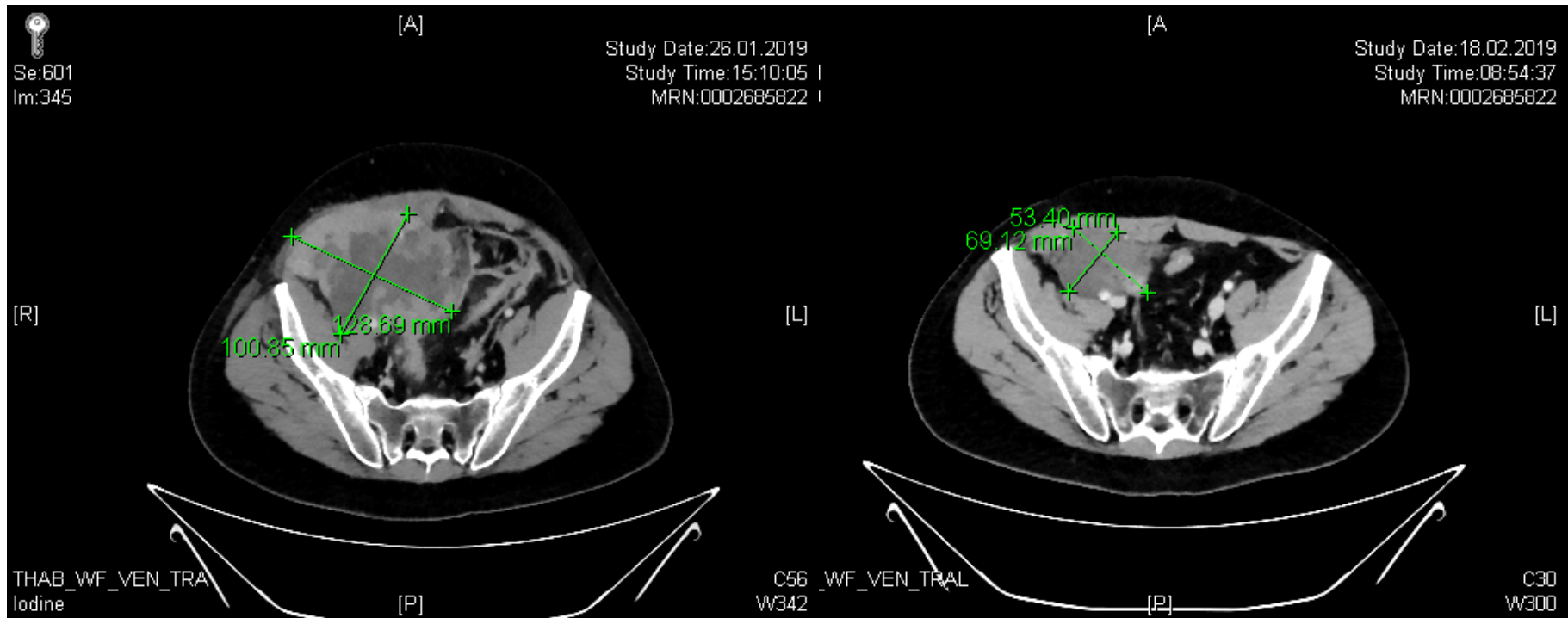
Torben Zachmann
Business Unit Director Cell Therapy



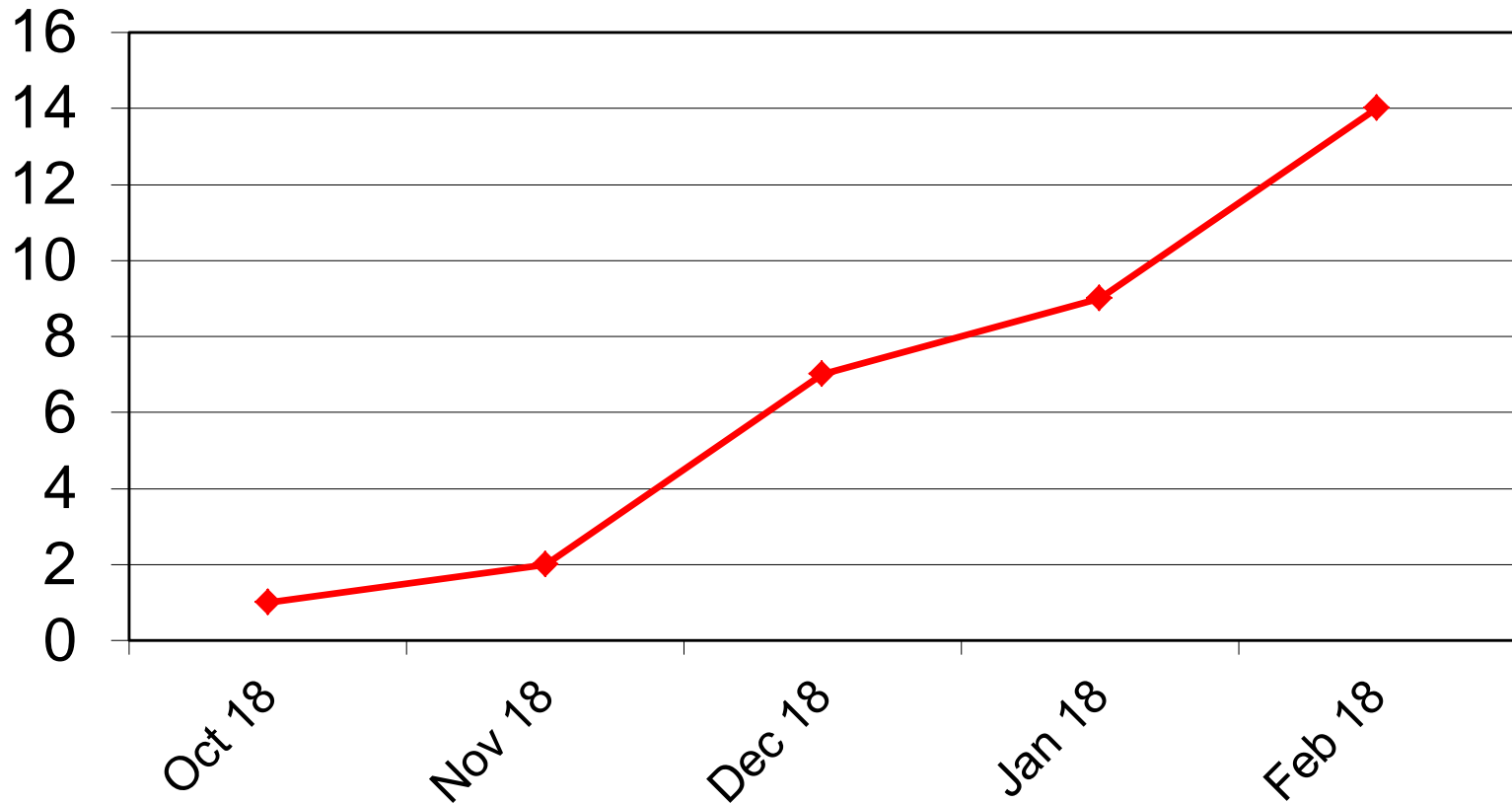
CD19-CART bei DLBCL: Ansprechen nach 4 Wochen

Tag +5

Tag +28



CART activity Heidelberg Feb 25, 2019 (cumulative)



“Allo” sind...



“Allo” sind...

„von Dusch“

M Lommatzsch

A Dugimont

...und das Team!

Station

F Kosely

AE Schulze-Schleithoff

M Bärtsch

M Blank

R Lutz

D Kaudewitz

B Köhler

N Magios

M Seiz

M von Deimling

A Martin

Sport

R Kühl

J Wiskemann

& Team

Koordination

P Stadtherr

I Opitz

Ambulanz

U Hegenbart

S Schönland

A Radujkovic

C Kimmich

C Pabst

S Raffel

J Tate

L Grammel

CART

M Schmitt

A Schmitt

& Team

ECP

A Schmitt

R Alexi

& Team

Case Manager

A Bondong

M Wegner

Labor

T Luft

S Dietrich

M Hess

A Radujkovic

A Hof

R Schulz

S Kräker

Psychologie

D Tönnessen

Sucheinheit

H Tran

K Nerbel

& Team

Sozialdienst

A Bergner

G Daiß

S Sontowski

Studienzentrale

J Klemmer

& Team

I.O. und andere

Affairs

M Geiss

JW Schmier

Anleitung

T Luft

P Dreger

...und natürlich auch

K Jordan

C Müller-Tidow

...alle Mitarbeiter der MedV !