## Clinical characteristics and predictors of

 gangrene in patients with systemic sclerosis and digital ulcers in the Digital Ulcer Outcome Registry: a prospective, observational cohortDigital vasculopathy in systemic sclerosis (SSc) consists of a spectrum of Raynaud's phenomenon (RP), digital ulcers (DUs), critical digital ischaemia and escalation to gangrene. The complications of severe digital vasculopathy often require hospital-based management with intravenous therapies and surgery. ${ }^{1-3}$ Although gangrene is not infrequent in the clinic, data on the prevalence and implications of gangrene in patients with SSc are scarce. ${ }^{3-7}$ The DU Outcomes (DUO) Registry is a European, prospective,
multicentre, observational cohort of patients with SSc and past and/or current DUs at enrolment. ${ }^{8-10}$ The aims of the current study were (i) to describe the characteristics of an SSc -DU population according to the presence/history of gangrene and (ii) to identify the risk factors for the development of incident gangrene.

All patients in the participating centres with SSc and a history or presence of DUs are eligible for inclusion in the DUO Registry, irrespective of their treatment regimen. At enrolment, data were collected on demographic and clinical variables. Patients were categorised into three groups according to their past history of gangrene and current gangrene status at enrolment: 'never gangrene': no past and no current gangrene; 'ever gangrene': past and/or current gangrene; and 'current gangrene': gangrene reported at enrolment, irrespective of gangrene history (a subset of the 'ever gangrene' group).

Table 1 Enrolment characteristics and patient demographics according to gangrene status*

|  | Never ${ }^{\dagger}$ gangrene (n=3787) | Ever ${ }^{\ddagger}$ gangrene $(\mathrm{n}=855)$ | Current gangrene $(n=258)^{5}$ |
| :---: | :---: | :---: | :---: |
| Gender |  |  |  |
| Female, \% | 82.1 | 77.7 | 77.5 |
| Age at enrolment |  |  |  |
| Mean (95\% CI), years | 54.4 (53.9 to 54.8) | 54.8 (53.9 to 55.8) | 52.8 (50.9 to 54.7) |
| Smoking status |  |  |  |
| n | 3386 | 757 | 233 |
| Current, \% | 14.4 | 17.6 | 24.0 |
| Former, \% | 23.3 | 25.6 | 17.6 |
| Never, \% | 62.3 | 56.8 | 58.4 |
| Pack-years of smoking |  |  |  |
| n | 868 | 206 | 73 |
| Mean (95\% CI) | 37.8 (31.3 to 44.3) | 37.9 (27.5 to 48.4) | 44.9 (24.9 to 64.9) |
| Age at first RP |  |  |  |
| n | 3409 | 752 | 229 |
| Mean (95\% CI), years | 41.3 (40.8 to 41.8) | 40.7 (39.6 to 41.8) | 41.2 (39.0 to 43.3) |
| Age at first DU |  |  |  |
| n | 3000 | 700 | 218 |
| Mean (95\% CI), years | 47.6 (47.1 to 48.2) | 47.1 (45.9 to 48.2) | 48.3 (46.1 to 50.5) |
| SSc cutaneous subset |  |  |  |
| n | 3774 | 850 | 256 |
| Diffuse SSC, \% | 37.7 | 32.0 | 33.6 |
| Limited SSC, \% | 52.3 | 58.2 | 54.3 |
| Overlap, \% | 6.5 | 6.0 | 7.8 |
| Other, \% | 3.6 | 3.8 | 4.3 |
| Organ manifestations |  |  |  |
| n | 3787 | 855 | 258 |
| Gl tract, \% | 54.0 | 56.8 | 46.5 |
| Lung fibrosis, \% | 40.4 | 40.1 | 38.0 |
| PAH, \% | 12.1 | 15.2 | 13.2 |
| Heart, \% | 9.9 | 10.9 | 12.4 |
| Kidney, \% | 4.1 | 6.0 | 5.8 |
| Time from first RP to enrolment visit |  |  |  |
| n | 3409 | 752 | 229 |
| Mean (95\% CI), years | 13.1 (12.8 to 13.5) | 14.4 (13.6 to 15.3) | 11.9 (10.4 to 13.5) |
| Time from first DU to enrolment visit |  |  |  |
| n | 3000 | 700 | 218 |
| Mean (95\% CI), years | 5.9 (5.7 to 6.2) | 7.4 (6.8 to 8.0) | 4.6 (3.8 to 5.5) |

Continued

Table 1 Continued

|  |  | Never ${ }^{\dagger}$ gangrene <br> $(\mathbf{n}=3787)$ | Ever ${ }^{\ddagger}$ gangrene <br> (n=85) |
| :--- | :--- | :--- | :--- |
| (n=258) |  |  |  |

*Only patients who provided information on gangrene status ( $\mathrm{n}=4642 / 4944$ ) were categorised.
${ }^{\dagger}$ Patients with no past and no current gangrene.
${ }^{\ddagger}$ Patients with past and/or current gangrene.

"Data include only patients who provided information on the given item.
**Out of ERA, PDE-5i and prostacyclins, only ERA is ticked.
ACA, anticentromere antibody; ANA, antinuclear antibody; CCB, calcium channel blocker; DU, digital ulcer; ERA, endothelin receptor antagonist; GI, gastrointestinal; $n^{1} / n^{2}, n$ patients tested positive/n patients who had the test done; PAH, pulmonary arterial hypertension; PDE-5i, phosphodiesterase-type 5 inhibitor; RNP, ribonucleic protein; RP, Raynaud's phenomenon; SSc, systemic sclerosis.

Categorical variables were analysed using descriptive statistics. Potential risk factors for the development of incident gangrene in patients with $\geq 1$ follow-up visit and no current gangrene at enrolment were analysed using univariable logistic regression (ULR) conducted on demographics, clinical variables and autoantibody measurements collected at enrolment. Multivariable logistic regression (MLR) using forward selection was conducted on patients with complete covariate information using those
variables with a $p$ value $<0.15$ and sample size $>3000$ from the ULR models, considering interdependency among similar factors.

Among the 4944 patients enrolled in the DUO Registry from April 2008 to November 2014, 4642 had information recorded on their gangrene status: $81.6 \%(\mathrm{n}=3787)$ were categorised as 'never gangrene', $18.4 \%(\mathrm{n}=855)$ as 'ever gangrene' and $5.6 \%$ ( $\mathrm{n}=258$ ) as 'current gangrene'. The three groups were generally

Table 2 Risk factors associated with the development of incident gangrene during the observation period

| Risk factor | Incident gangrene $\mathbf{n} / \mathrm{N}$ (\%) | No incident gangrene, $\mathrm{n} / \mathrm{N}$ (\%) | OR (95\% CI) | $p$ Value* |
| :---: | :---: | :---: | :---: | :---: |
| (A) ULR ( $N=3809)^{\dagger}$ | $N=243$ | $N=3566$ |  |  |
| Female gender | 189/243 (77.8) | 2938/3566 (82.4) | 0.73 (0.53 to 1.01) | 0.055 |
| Smoking status |  |  |  |  |
| Current | 45/205 (22.0) | 438/3102 (14.1) | 1.91 (1.32 to 2.76) | $<0.001$ |
| Former | 58/205 (28.3) | 728/3102 (23.5) | 1.46 (1.04 to 2.04) | 0.028 |
| Number of finger DUs at enrolment |  |  |  |  |
| 1-2 | 89/236 (37.7) | 1315/3546 (37.1) | 1.27 (0.93 to 1.72) | 0.132 |
| $3+$ | 58/236 (24.6) | 666/3546 (18.8) | 1.54 (1.09 to 2.17) | 0.015 |
| Anti-Scl 70 | 103/196 (52.6) | 1279/2872 (44.5) | 1.39 (1.04 to 1.87) | 0.027 |
| Previous gangrene | 96/229 (41.9) | 404/3378 (12.0) | 4.75 (3.57 to 6.34) | <0.0001 |
| Previous autoamputation | 32/231 (13.9) | 188/3386 (5.6) | 2.69 (1.78 to 4.04) | <0.0001 |
| Previous soft-tissue infection requiring systemic antibiotics | 94/222 (42.3) | 933/3253 (28.7) | 1.76 (1.33 to 2.32) | <0.0001 |
| Previous osteomyelitis | 19/232 (8.2) | 84/3367 (2.5) | 3.24 (1.19 to 5.47) | <0.0001 |
| Ongoing autoamputation | 6/242 (2.5) | 46/3552 (1.3) | 2.32 (0.97 to 5.57) | 0.059 |
| Ongoing osteomyelitis | 4/243 (1.6) | 24/3558 (0.7) | 2.36 (0.80 to 6.99) | 0.121 |
| Previous hospitalisation(s) for DUs (at least 1 day) | 144/231 (62.3) | 1290/3385 (38.1) | 2.49 (1.89 to 3.29) | <0.0001 |
| Previous upper limb sympathectomy | 20/228 (8.8) | 100/3345 (3.0) | 3.24 (1.94 to 5.40) | <0.0001 |
| Previous digital sympathectomy | 11/228 (4.8) | 58/3341 (1.7) | 2.70 (1.38 to 5.31) | 0.004 |
| Previous arterial reconstruction | 5/227 (2.2) | 21/3336 (0.6) | 3.43 (1.25 to 9.44) | 0.017 |
| Not employed/self-employed | 205/243 (84.4) | 2687/3566 (75.4) | 1.78 (1.22 to 2.61) | 0.003 |
| (B) $M L R^{\ddagger}$ ( $N=2479$ ) | $N=157$ | $N=2322$ |  |  |
| Observation time, mean (SD), weeks | 174.7 (78.7) | 126.2 (78.9) | 1.03 (1.02 to 1.04) | <0.0001 |
| Smoking status |  |  |  |  |
| Current | 27/157 (17.2) | 311/2322 (13.4) | 1.72 (1.07 to 2.77) | 0.025 |
| Former | 47/157 (29.9) | 509/2322 (21.9) | 1.69 (1.14 to 2.51) | 0.009 |
| Number of finger DUs at enrolment |  |  |  |  |
| 1-2 | 60/157 (38.2) | 951/2322 (41.0) | 1.35 (0.90 to 2.03) | 0.144 |
| $3+$ | 46/157 (29.3) | 491/2322 (21.1) | 1.69 (1.09 to 2.62) | 0.020 |
| Anti-Scl 70 | 79/157 (50.3) | 1031/2322 (44.4) | 1.39 (0.99 to 1.96) | 0.058 |
| Previous gangrene | 63/157 (40.1) | 244/2322 (10.5) | 4.67 (3.24 to 6.73) | <0.0001 |
| Previous upper limb sympathectomy | 15/157 (9.6) | 67/2322 (2.9) | 2.21 (1.15 to 4.27) | 0.018 |

*Wald $\chi^{2}$ test.
${ }^{\dagger}$ For the ULR analysis, observation time was a fixed covariate in the model. Data are shown for variables having $p<0.15$ and $n>3000$ for the patients for whom information is available). ${ }^{\ddagger}$ For the MLR analysis, observation time was forced into the model as a fixed covariate and not included by the forward selection procedure; variables were selected with a selection criterion of $p=0.15$. Data are shown for the subset of patients making up the final models ( $n=2479$ ) to allow comparison with the full cohort.
ACA, anticentromere antibody; ANA, antinuclear antibody; DU, digital ulcer; MLR, multivariable logistic regression; PAH, pulmonary arterial hypertension; RNP, ribonucleic protein;
ULR, univariable logistic regression.
similar regarding demographics and SSc characteristics, although more current smokers at enrolment were in the 'ever gangrene' and 'current gangrene' groups than in the 'never gangrene' group, and the 'current gangrene' group had the shortest time between first RP and enrolment (table 1). The proportion of patients with a history of DU-associated complications, interventions and hospitalisations was greater in the 'ever gangrene' group compared with the 'never gangrene' group.

Overall, 3809 patients were eligible for inclusion in the ULR analysis; the final number of patients included in each ULR model varied depending on missing data (table 2A). On MLR analysis, being a current/former smoker, having $\geq 3$ finger DUs, previous gangrene and previous upper limb sympathectomy were independent risk factors at enrolment for development of incident gangrene (table 2B).

This analysis was the largest to date describing an SSc-DU population according to the presence/history of gangrene at enrolment and risk factors for incident gangrene during follow-up. It has demonstrated that, in current practice, gangrene is still a common event occurring in $18 \%$ of patients with

SSc-DUs. Participating centres involved in the DUO Registry are specialist centres for the management of SSc-DUs; this may be selective for patients with more severe vascular disease, and therefore more prevalent gangrene. Multivariate analyses indicated that, in patients with no current gangrene, along with previous gangrene, being a current/former smoker, having $\geq 3$ DUs and previous upper limb sympathectomy were independent risk factors at enrolment for developing incident gangrene. These results will help to risk-stratify patients with SSc-DUs and to evaluate preventive gangrene management strategies.

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Collaborators List of DUO investigators in online supplementary appendix.
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Competing interests YA has had consultancy relationships and/or has received research funding in relation to the treatment of systemic sclerosis from Actelion Pharmaceuticals, Bayer, Biogen Idec, Bristol-Myers Squibb, Genentech/Roche, Inventiva, Medac, Pfizer, Sanofi/Genzyme, Servier and UCB. CPD has received consultant and speaker fees from Actelion Pharmaceuticals, GlaxoSmithKline, Bayer, Inventiva and Takeda, and has received grant support from Actelion Pharmaceuticals, CSL Behring, and Novartis. TK has received grant and speaker fees from Actelion Pharmaceuticals. PC is an employee of SDE Services, based 100\% at Actelion Pharmaceuticals. DR and BS are employees of and own shares in Actelion Pharmaceuticals. MM-C has received grant/research support and/or speaker fees from Actelion Pharmaceuticals.
Ethics approval Ethical approval was obtained as required from the institutional ethics committees of the participating centres.
Provenance and peer review Not commissioned; externally peer reviewed.

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## APPENDIX

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S FERNANDEZ
S KANAFFO
TP SANDOVAL
TRV RODRIGUEZ
V VILLAVERDE
VS MANZANEDO
FI - FINLAND
H MAKINEN
K KARSTILA
K-L VIDQVIST
R LOUSIJÄRVI
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FR - FRANCE
A BEREZNE
A COURAUD
A DADBAN
A DUPUY
A GERBER
A HAMADE
A HOT
A KANOTE
A KARAM
A KHAU VAN KIEN
A LE QUELLEC
A LETREMY
A PERLAT
A PLAYE
A RAMASSAMY
A RÉGENT
A SPARSA
A TAIEB
A ZOULIM
A-B DUVAL-MODESTE
A-M GERMOND
A-F CHAIGNEAU
A-L FAUCHAIS
A-M ROGUEDAS-CONTIOS
B COPPERE
B COURET
B GRAFFIN
B GRANEL
B IMBERT
B SASSOLAS
B SPLINGARD
C AGARD
C BELIZNA
C BOULON
C CAZALETS-LACOSTE
C DESCOTES-GENON
C DIVOY
C DOUTRELON
C DROITCOURT
C DURANT
C FARCAS
C FRANCES
C GRANGE
C JORGENSEN
C LANDRON
C LE CLECH
C LECOMTE
C LOK
C MAUSSERVEY
C NADĖGE
C NADIA
C RICHEZ
C ROTH
C SAILLARD
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C SORDET
C TOLEDANO
C ZAINEA
D ADOUE
D BARCAT
D BESSIS
D CHICINAS-BICA
D FARGE
D FERRANDIZ
D JACQUEMART
D LAUNAY
D WAHL
E BELIN
E BERNIT
E BRENAUT
E CHATELUS
E COLLET
E DIOT
E HACHULLA
E KOSTRZEWA
E MONARD
E PASQUALONI
E TRUCHETET
E VIDAL
E WIERZBICKA-HAINAUT
F DUCHENE
F GACHES
F GRANEL-BROCARD
F MAURIER
F SKOWRON
G BLAISON
G GOUDRAN
G KAPLANSKI
G MOULIS
G MULLER
G PUGNET
G WOJTASIK
H ADAMSKI
H BEZANAHARY
H CHARLANNE
H CHIFFLOT
H DESMURS-CLAVEL
H GIL
H KESHTMAND
H MAILLARD
I LAZARETH
I QUÉRÉ
IM NICOL
J BOILEAU
J CABANE
J CHEVRANT-BRETON
J CONSTANS
J MOREL
J NINET
J SÉNÉSCHAL

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J SIBILIA
J WIPFF
JD COHEN
J-F VIALLARD
JG FUZIBET
J-L SCHLUTZ
JM DURAND
J-P BALDUCCHI
JP ORY
J-R HARLE
K MAZODIER
K TALOU
K TIEV
L BLUM
L GUILLEVIN
L LOPEZ
L MISERY
L MOUTHON
L PERARD
L ROUGER
L SAILLER
M ARTIFONI
M DANDURAND
M DINULESCU
M GRECO
M LAMBERT
M MANGIN
M MEDDEB
M SEVESTRE
M-H DIANCOURT
M-H GIRARD-MADOUX
M-P CHAUVEHEID
M-P MOITON
M-S DOUTRE
N ASSOUS
N BENETON
N BOUSSELY
N COQUART-BOUTTIER
N GARCON
N JOURDAIN
N MAGY-BERTRAND
N REPARD
N SCHLEINITZ
O CARTRY
O DEBOVES
O DECAUX
P BACHET
P CARPENTIER
P JEGO
P MANEA
P POUBEAU
P PRIOLLET
P ROBLOT
PRULLIER
P-Y HATRON
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R JEAN
S BERTHIER
S BLAISE
S BLAQUIERE
S DUMONTEIL
S DUPAS
S HESSE
S MADAULE
S MORELL
S PREY
S RIVIERE
S ZUILY
T MARTIN
T MOLINE
T SCHAEVERBEKE
T QUEMENEUR
T ZENONE
U MICHON-PASTUREL
V BRAVETTI
V CANNIEUX
V DOEFFEL-HANTZ
V LEGUY-SEGUIN
V LOUSTAUD-RATTI
V QUEYREL
X KYNDT
Y ALLANORE
Y LEVENEUR
Z REGUIA
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## GR-GREECE

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A ELEZOGLOU
A GARYFALLOS
A KOUTROUMBAS
A ZAHARIOUDAKI
AA DROSOS
B HARALAMBOS
D DIMOPOULOU
D MPASDAGIANNI
D VASILOPOULOS
E KALTSONOUDIS
G VEGOUDAKI
I GKOUGKOURELAS
I KRITIKOS
M MICHAILIDOU
N GALANOPOULOS
N PAPADOPOULOS
N TSIFETAKI
P ATHANASSIOU
P VLACHOYANNOPOULOS
S ASLANIDIS
S KAMALI
T DIMITROULAS
V GALANOPOULOU
IE - IRELAND
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D VEALE
IT - ITALY
AAMOROSO
A BENENATI
A BORTOLUZZI
A CORRADO
A DELLA ROSSA
A GABRIELLI
A GIARDINA
A GIGANTE
A MATHIEU
A MAZZONE
A MUSSI
A NIGRO
A SEVERINO
A VACCA
B CAPUANO
B MARASINI
C FERRI
C LUNARDI
C SALVARANI
C SELMI
CM MONTECUCCO
D GIUGGIOLI
E BATTAGLIA
E DI POI
E FUSARO
E ROSATO
F BELLISAI
F CANTATORE
F COZZI
F FURINI
F GALLUCCIO
F PUPPO
F SALSANO
F TROTTA
G BAJOOCHI
G CUOMO
G FERRACCIOLI
G LAPADULA
G PATUZZO
G POMPONIO
G TRIOLO
G VALENTINI
G VALESINI
G VARCASIA
I CHIAROLANZA
I DE ANDRES
I OLIVIERI
L BELLOLI
L BERETTA
L COLONNA
L SERAFINO
M ANTIVALLE

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M BATTELINO
M BORSETTO
M BRUZZONE
M COLACI
M DE MATTIA
M DE SANTIS
M DOVERI
M GALEAZZI
M MATUCCI CERINIC
M NIVUORI
M RIZZO
M SARACCO
M VASILE
N DEL PAPA
N MALAVOLTA
N TERLIZZI
N UGHI
P AIRȮ
P CIPRIANI
P FAGGIOLI
P MASOLINI
P RUSCITTI
R BUCCI
R CARIGNOLA
R CIMINO
R DE ANGELI
R DE LUCA
R FOTI
R GIACOMELLI
R LA CORTE
R MULE
R PELLERITO
R PERRICONE
R SCORZA
S BELLISSIMO
S BOMBARDIERI
S BOSELLO
S DE VITA
S GATTI
S LOMBARDI
S MAZZUCA
S NEGRINI
S PALLOTTA
S PARISI
S STISI
S TRINCONE
S ZENI
S ZINGARELLI
v CARRARO
v CODULLO
V RICCIERI
W GRASSI
W MAGLIONE
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## NL - THE NETHERLANDS

A SCHOUFFOER
AE HAK
AE VAN DEN BIJL
AE VAN DER BIJL
A VOSKUYL
AH GERARDS
AHM HEURKENS
AJ PEETERS
A SMIT
AJL DE JONG
A SCHUERWEGH
C VAN DURME
C VAN GULDENER
C LEBRUN
C DEN HENGST
D SIEWERTSZ VAN REESEMA
D VAN ZEBEN
DG KUIPER-GEERTSMA
DJ MULDER
E KNIJFF-DUTMER
E TON
ESG STROES
F UBELS
F VAN DEN HOOGEN
F VAN NEER
G BRUIJN
GJM VAN VEEN
H BOOTSMA
H HULSMANS
H VAN PAASSEN
H VISSER
H WILLEMS
HAH KAASJAGER
HKA KNAAPEN
I VAN GAMEREN
J BULTHUIS
J EWALS
J GROENENDAEL
J REMANS
JD MOOLENBURGH
JHLM GROENENDAEL
JM VAN WOERKOM
JN STOLK
KH HAN
K RONDAY
L BROUWER
M BIJL
M DE BOIS
M JANSSEN
M NOORDZIJ
M VAN KRUGTEN
M WALRAVENS
M DE KANTER

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M GEURTS
M VAN HAGEN
M VONK
MJ VAN DER VEEN
ML WESTEDT
MS VAN BRUSSEL
N MOLDERS
P BAUDOIN
P FRETTER
P JANSEN
P PAASSEN
P SEYS
P VAN DAELE
P VOS
PBJ DE SONNAVILLE
PJC JACOBS
P LANTING
R GOEKOOP
R VALENTIJN
R WESTRA
R DOLHAIN
T HURKENS
TR ZIJLSTRA
TWJ HUIZINGA
V GERDES
W HISSINK MULLER
ZN JAHANGIER DE VEEN
NO - NORWAY
A BENDVOLD
AJ KRUGER HAESTAD
A-M HOFFMANN-VOLD
B GRANDAUNET
B-Y NORDVAG
CG GJESDAL
EK STRAND
G BAKLAND
G KORNELUK-THOR
H BITTER
HK ASLAKSEN
J SKOMSVOLL
M SEIP
O MIDTVEDT
RS THOMSEN
S KALSTAD
T PEDERSEN
TM MADLAND
V BAKKEHEIM
W KOLDINGSNES
PT - PORTUGAL
A CORDEIRO
A GRILO
C PONTE
C RESENDE
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C SANTOS
F SILVA
I ALMEIDA
I CAMARA
I SILVA
J ALVES
J COSTA
L SANTOS
M GOMES
MJ SALVADOR
N RISO
P COELHO
PA FERREIRA
S OLIVEIRA
SE - SWEDEN
A MOHAMMAD
A NORDIN
A OSTENSON
B MOLLER
C STAHL HALLENGREN
E HERMANSSON
G ABDIU
H HELLSTROM
K ALBERTSSON
M HEMBERG
M RIZK
M SODERLIN
P-J HEDIN
R HESSELSTRAND
S TEGMARK
T BRACIN
T VINGREN
T WEITOFT
Y RYDVALD
Z FABIENNE

## SI - SLOVENIA

AS DOLNICAR
SK - SLOVAKIA
J LUKAC
K BRAZDILOVA
M ÖETTEROVA
M ZARIKOVA
Z KILLINGER
Z KMECOVA
Z MACEJOVA
UK - UNITED KINGDOM
A HERRICK
A SINHA
A SMYTH
C BAINES
C CHATTOPADHYAY

C DENTON
C KELSEY
D D'CRUZ
E BAGULEY
E ROUSSOU
F ABDUL
F HALL
G CHELLIAH
H GUNAWARDENA
H HARRIS
H SYKES
H YOUSSEF
J BELCH
J COPPOCK
L-A BISSELL
M ANDERSON
M BUCH
M NISAR
N MCHUGH
P ATHIVEER
PGORDON
R MADHOK
R MOOTS
S DUBEY
S JARRETT
S MILES

