Volume 14
Supplement 2
September 2009

TM&IH

European Journal *Tropical Medicine & International Health*

The Abstracts of the 6th European Congress on Tropical Medicine and International Health and 1st Mediterranean Conference on Migration and Travel Health

6–10 September 2009

Verona, Italy

Information on this journal can be accessed at http://www.blackwellpublishing.com/tmi

Typeset by SPS Limited, Chennai, India and printed in the UK by the Charlesworth Group

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Directive 2001/20/EC arises the necessity to reinforce the protection of vulnerable people. The common international norms that have also to be respected by sponsors and researchers correspond to the directive obligations linked to the patients' vulnerability (Declaration of Helsinki; Convention of Human Right and Biomedicine; Council for International Organizations of Medical Sciences). Before entering in a clinical trial a vulnerable subject and its legal representative should receive complete and intelligible information, insuring the best interest for the patient. Although these conditions are enforced by law in all EU countries, some issues are still of concern: (1) no consensus on the age at which it is appropriate to get minor's assent; (2) specificity and disparity about the legal representative definition; (3) the cooperation of the treating doctor in the inform consent process; (4) the limit between compensation and financial inducement/incentive; (5) assessment of direct benefit for the group concomitantly to a clear idea of the possible individual direct benefit; (6) ethics of conducting placebo-controlled studies; (7) constant monitoring for non profit research; (8) heterogeneity of Ethical Committee procedures from one country to another. The implementation of clinical trials in less economically developed countries respecting all these rules remains therefore very challenging. The fundamental ethical rules applied to clinical trials have to be respected all over the world. Weakening the ethical standards for less economically developed countries would violate fundamental human rights.

South–north trends in arboviral disease control

T6P2-01

Testing the vertical transmission of chikungunya virus in *Aedes albopictus* using the actors of the 2007 outbreak in Italy

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Experiments were conducted to determine whether transovarial transmission (TOT) of chikungunya virus (CHIKV) occurs in *Aedes albopictus*, the species responsible of the 2007 CHIK outbreak in Emilia-Romagna region (north-eastern Italy) – the first outbreak of this disease in a temperate country. *Ae. albopictus* eggs collected in the epidemic area were reared under standard laboratory conditions and F_1 females were used for the study. In BL3 laboratory, females were orally exposed through a membrane to different concentrations of virus (from $10^{4.5}$ to $10^{7.3}$ $TCID_{50}$/ml) in human washed eritrocites. Two experiments were performed using a strain of CHIKV isolated from mosquitoes collected in the epidemic area and a strain from a viremic patient coming from Cesena. After the first exposition to the viruses, the females were blood fed with two more non infected blood meals in order to obtain two more successive ovipositions. To verify the presence and the diffusion of the virus in the mosquitoes, females were sampled at different time after infection and body and legs were separately tested by Real Time PCR (RT-PCR). The eggs obtained from the three gonotrophic cycles were reared in laboratory and the adults obtained were individually tested by CHIKV RT-PCR. A total of 101 females took the infected blood meals. All the females fed with the two highest concentrations of CHIKV human strain showed virus diffusion, as proved by positive PCR on the mosquito legs at the end of experiment. Whereas only the females fed with the highest concentration of the CHIKV mosquito strain showed the virus diffusion, proved as above. A total progeny of 1056 adults were tested by RT-PCR for the presence of virus and three positive specimens were found in the progeny – 2 males and 1 female – all stemming from the second gonotrophic cycle. Based on these studies, infected females were capable of transmitting the virus vertically to their offspring at a low rate. If the TOT observed in our study represents the natural maximum rate of vertical female capability of transmitting the virus to their progeny, then the observed TOT rate was probably not sufficient to guarantee the maintenance of the virus in a temperate region during the winter period. This supposition could be supported by the observation of no autochthonous cases of CHIK fever in the same area during summer 2008.

T6P2-02

Surveillance on vector-borne diseases in Emilia-Romagna Region, Italy

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In recent years an increase in vector-borne disease activity has been recorded in different regions. The epidemiology of such diseases is conditioned by complex interactions among environment, parasite, vector, man and eventually animal – either domestic or wild – reservoir. Global warming together with the increase of transport of goods, animals and people travels are impacting the risk that exotic species, both of insects and parasites, enter and establish in new territories. For these reasons a regional surveillance program focused on vectored diseases was implemented in Emilia-Romagna. The aim of the project is to create a regional surveillance and risk assessment system based on a multidisciplinary network, with the capability of collecting data about both vector populations dynamics, and possible presence of pathogens in vectors, men and animals. It has therefore been constituted a working group, coordinated by the General Direction for Health and Social Policy of the Emilia-Romagna Region, composed by physicians, veterinarians and entomologists. Activities have been addressed to the activation of an entomological monitoring system for key vectors, to the development of diagnostic procedures of selected zoonosis, to the predisposition of a training program. *Because it is endemic in Emilia-Romagna Region, Leishmaniasis has been selected to test the system.* After only two months from its constitution, the working group had to manage the Chikungunya epidemic occurred in Ravenna and Cervia municipalities during summer of 2007. After only 15 days from the reporting of the first human cases, it has been possible to perform the diagnosis, isolating the virus from the vector (*Aedes albopictus*), to define a reporting system of clinical suspects and diagnostic procedures in man. In the same time an intensive vector control program was carried out in infected areas. The timing organization of a multidisciplinary network focused on vector diseases surveillance and control is producing important positive output in terms of managing capacity of epidemic situation and risk assessment.

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VOLUME 14 SUPPL 2 PP 248–264 SEPTEMBER 2009

Author index

Abadia Barrero, C.E., 113
Abai, M.R., 124
Abastabar, M., 172
Abdellatif, N., 204
Abdollahi, F., 112
Abdollahpour, F., 207
Abdoulaye, D., 7
Abdul Majid, A.M.S., 125
Abdulla, S., 45
Abe, T., 58
Abiou, G., 46
Ablefoni, S., 12
Aboud, S., 69
Aboulhasani, M., 155
Abousaidi, H., 138
Abreu, I., 90
Acevedo, I., 136
Acosta, L., 42
Acqua, S., 58
Adamou Bathiri, S., 172
Adams, E.R., 59
Adegbola, R., 41
Adegnika, A.A., 192
Adhikari, N., 154
Adjei, O., 56, 82
Adjei, S., 56, 82, 213
Adlkofer, J., 58
Adnani Sadat, S.J., 198, 221
Adnani, J., 182
Adoke, Y., 47
Adoubryn, K.D., 55
Adrami, O., 244
Adu-Sarkodie, Y., 33, 58, 161, 216
Affolabi, D., 36
Agatsuma, T., 220
Agbonlahor, D., 121
Aghighi, Z., 98
Aghvami, T., 123
Agnamey, P., 115
Agossou, A., 12
Aguiar, C., 179, 180
Aguilar, V.H., 157
Aguinaco Culebras, R., 185
Agyekum, A., 161
Ahawo, A., 13
Ahmad, R., 194
Ahmed, A., 246
Aiello, K.H., 239
Akbar, F., 187
Akhavan, A.A., 208
Akhlaghi, L., 219, 220
Akhoundi, B., 182
Akiko Ueda Fick de Souza, V., 140
Akkerman, O., 143
Akue, J.P., 170
Al Mudwahi, M., 111
Alansari, H., 242
Alarcão, V., 228
Alavi, F.S., 181
Alba, S., 63, 64
Albajar Vinas, P., 178, 237
Albert, G.R., 231
Albertini, A., 134
Albetoni, S., 14
Albonico, M., 29, 55, 154, 226
Alegret, M., 99
Alexander, M., 64, 81
Alexander, N., 39
Aleyasin, S., 215
Alfarez, D., 48
Alfonso, Y., 178, 199
Ali Mugambwa, B., 121
Ali, S.M., 215
Alirol, E., 76
AlKhawaja, S., 242
Allaii, F., 147
Allan, R., 87
Allen, H., 55
Almazán, F., 211, 240, 243
Almeida, E.A., 179
de Almeida, M.B., 214
Almeida, N., 128, 130
Almeras, L., 122
Almudhwahi, M., 110
Alonso, P., 214, 241, 246
Altamura, M., 229, 233
Alù, M., 177
de Aluja, A.S., 163
Alvar, J., 62
Alvarez Degregori, M.C., 73, 103
Alvarez, A., 99, 113
Alvela-Suarez, L., 203
Amador, C., 240
Ambroise-Thomas, P., 1
Ambrosino, E., 120
Ame, S.A., 37
Ame, S.M., 226, 227
van Amelsfoort, A., 148
van Amerongen, A., 91
Amezcua-Sanchez, A.L., 39
Amin, D.N., 176
Amina, S., 13
Amisi, L., 121
Amoah, A.S., 192
Amor, E., 218, 227, 238
Amouei, A., 222
Amsini, D., 121
Amundaray, A., 134, 136
Anagonou, S., 36
Anderson, E., 60, 186
Andres Esteban, E., 71
Andresen, S., 104
Andreu, M., 243
Andrews, R., 196
Anez, N., 178
Angarano, G., 233
Angelini, P., 49, 49
Ângelo, H., 93, 176
Angheben, A., 74, 84, 122, 171, 226, 227, 235, 240
Angoulvant, A., 206
Anintya, I., 140
Anne, J., 94
Anne-Laure, K., 48
Annerberg, A., 130
Anselmi, M., 53, 74, 80, 91, 108, 171, 235, 240
Antonelli, A., 231
Antonio de Almeida, E., 180
Antunes, M., 197
Aphshary, T., 112
Apiah-Thompson, B., 56
Aquilina, M., 237
Arabpour, M., 212, 215
Arana, B., 39
Arcieri, R., 48
Arduin, P., 117
Arese, P., 3
Aristei, S., 71, 245
Arjona, F., 240
Armani, D., 53, 91, 107, 108
Armesto, F.J., 71
Arnold, U., 43
Arroyo, M.A., 34
Arsenault, I., 103
Artur Dos Santos, O., 97
Artursson, P., 175
Arzese, A., 140
Asgari, Q., 180, 198, 221
Asgarian, F., 222

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Author Index

Ashkani, S., 220
Ashrafi1, H., 212
Ashton, M., 51, 130, 175
Assady, M., 206
Assane, Y., 162
Assar, R., 219
Assmar, M., 98, 119
Assunção, V., 221
Atashi Shirazi, H., 182
Ateba, U., 192
Attala, L., 196
Aubouy, A., 46
Avila Arzanegui, O., 238
Ayim, M., 56
Azaiez, R., 202, 204
Azarian, B., 187
Azizi, S., 208

Babaei, Z., 219, 220, 225
Babamahmudi, F., 50
Babba, H., 202, 204
Babic, M., 231
Babuadze, G., 60
Bacchieri, A., 131
Badiane, M., 115
Badolo, A., 81
Baelmans, R., 42
Bah Maci, A., 13
Bahar, I.H., 186
Bahati, E., 34
Bahizire, E., 34
Bahrami, A., 117
Bahremand, A.R., 96
Bahri, O., 156
Bahsoun, M., 116, 138, 244
Bailo, B., 218, 227
Bajraktarevic, A., 35, 129, 149, 231
Bakar, A., 110
Baker, S., 62, 86, 92
Baldelli, P., 234
Baldelli, R., 49
Baldessin, F., 197
Baldracchini, F., 125
Balmaseda, A., 39
Balqui, J., 216
Baly, A., 167, 168, 169
Bamroongpong, V., 45
Bandala, E., 107
Bandepour, M., 186
Bandera, F., 199
Banderas, D., 168
Banla, M., 12
Baratta, F., 113, 246
Barbieri, A., 177
Barbosa, S.M., 154
Bardaji, A., 246
Barrett, N., 78
Barrett-Connor, E., 174
Bartalesi, F., 148, 196, 239
Bartoloni, A., 131, 148, 196, 239
Basáñez, M.-G., 54
Baseri, H., 159
Bashraheil, M., 45
Basilico, N., 128
Basinga, P., 32
Basir, R., 125
Baskin, H., 186
Bassat, Q., 214
Basseri, H., 71
Basso, B., 177
Batista, A.M., 179
Batista, L., 139
Baudin, E., 43
Baume, C., 86
Bauzon, S., 48
Becher, H., 116
Bechini, A., 148
Beck, H.-P., 93
Beckers, P., 246
Beddow, J., 92
Bedu-Addo, G., 54
Beganovic, A., 35, 149, 231
Begic, Z., 129, 149
Beheton, T., 46
Beijnen, J., 61
Beise, K., 69
Belgacem, K., 184
Belghazi, M., 122
Belguith, M., 202, 204
Belhassen-Garcia, M., 193, 203, 210
Belkâab, N., 12, 14
Belkadi, G., 206
Bell, D., 134
Bellina, L., 66
Bellini, R., 49
Bellobuono, I., 59
Belo, S., 193
Beltrame, A., 80, 140, 232, 241
Beltramello, C., 197
Ben Alaya-Bouafif, N., 156, 184
Ben Nouir, N., 202
Ben Said, M., 183
Ben Salah, A., 184
Benazzo, F., 201
Benchouk, M., 238
Benetti, E., 94
Benitez, J.R., 168
Bentivoglio, M., 7
Bergamaschi, V., 84
Bergel, E., 102
Bergmans, D., 210
Bergstrøm, C.E., 105
Berhe, N., 191
Bernabeo, A., 110
Bernardino, L., 93, 176
Berti, A., 146, 151, 222
Bessala, P., 13
Bettinzoli, M., 53, 141, 146, 151, 222, 223
Beulane, A.J., 139
Bevilacqua, N., 143
Bezzi, M., 227
Bhutta, Z., 145
van de Biezen-Brinkman, M., 58
Bigoni, S., 241
Bigot, A., 36
Bilivogui, P., 12, 13, 14
Bin Shujaa, R.S., 12, 111
Binh, T.Q., 165
Binka, F., 16
Birjandi, M., 207
Bisimwa, G., 34
Bisoffi, Z., 1, 74, 78, 80, 84, 122, 171, 195, 226, 227, 235, 240
Björkman, A., 130
Björkman, S., 175
Black, J., 50
Blanco, A., 218, 227
Blessborn, D., 130
Blouin, B., 145
Boakye, D., 192
Boas, L.S.V., 83
Bobes, R., 72, 163
Bock, H., 42
Bock, W., 155
Bodini, C., 100, 241
Bodon, C., 70
Boelaert, M., 42, 43, 48, 60, 62, 168, 182, 184, 186, 187
Boeree, M., 40
Bompangue, D., 28
Bonafini, S., 227
Bonanni, P., 148
Bonet Gorbea, M., 196
Bonet, M., 33, 90, 99, 113
Bongiorno, G., 19
Bonifacio, E., 74, 240
Bonilauri, P., 49
Bonizzoli, M., 196
Borghini-Fuhrer, I., 45
Bork Simondon, K., 31
Borpoem, J., 142

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Author Index

Borrini, B.M., 49
Borroni, E., 29
Bosco, J., 39
Bosisio, E., 129
Bosmans, M., 20, 25
Botelho Costa, S.C., 179, 180
Bottieau, E., 78, 96, 97, 139
Bouattour, A., 156
Boubaker, G., 202
Boudville, I., 244
Bouillet, L., 133
Boulanger, D., 31
Bouloy, M., 156
Bouraima, A., 57
Bourdon, S., 122
Bourguinat, C., 172
Bousema, T., 115
Bouslikhane, M., 24
Boussinesq, M., 72, 171, 172
Boutsika, K., 114
Braga, E., 133
van Brakel, W., 69
Bras Boqueras, C., 185
Brasseur, P., 115
Bregani, E.R., 53, 141, 146, 151, 222, 223
Briceno, A.B., 179
Briceno, L.G., 179
Brienen, E., 195
Brillo, F., 140, 232
Brindicci, G., 229, 233
Brindley, P.J., 190
Briolant, S., 122
Brito, C.F.A., 94
van de Broek, P., 222
Brooker, S., 82, 195
Brooks, M., 167
Brouwer, A.-M., 246
Bruce, J., 145, 145
Bruna-Romero, O., 133
Brunetti, E., 201
Brusa, P., 59, 111, 113, 246
Buabeng, K.O., 137
Bualombai, P., 135
Buard, V., 43
Buchholz, U., 80
Buelli, F., 33, 101
Bueno, L., 133
Buggisch, P., 213
Bukirwa, H., 82
Burchard, G., 197, 217
Burchard, G.D., 31, 217
Burguillo, F.J., 192
Burruano, L., 68
Busso, M., 229
van Buuren, S., 154
Buvé, A., 47

Cabaret, J., 202, 204
Cabezos, J., 83
Cabrera, L., 216
Cacopardo, B., 90, 205
Caicedo, C., 53, 91, 107, 108
Caicedo, F., 91, 108
Caicedo, J., 53, 91, 108
Caiceido, F., 53
Cala, V., 199
Calain, P., 4, 48
Caligaris, S., 33, 101
Call Ramón, L., 185
Callewaert, A., 52
Caltabiano, E., 205, 245
Calzolari, M., 49, 49
Camardiel, A., 24
Camera Pierrotti, L., 140
Campbell, O., 74
Campo Vazquez, M., 242
Campos, Y., 179
Cañabate, F., 142, 228
Cañas, E., 233
Cancrini, G., 239
Canto, C., 139
Capo, V., 199
Capone, S., 108
Cappellini, M.D., 129
Cappello, E., 90, 183, 205
Cappuccio, P., 110
Capua, I., 21
Carapetis, J., 196
Cardoso da Silva, W., 140
Cargaleiro, H., 228
Carnevalini, M., 231
Caro, E., 211, 243
Carolita, I., 25
Carosi, G., 84, 101
Carranza, P., 59
Carreira, M., 228
Carreño, N., 136
Carrero, J.C., 72
Carrilero, B., 239
Carrillo Casas, E., 96, 97
Caruso, D., 129
Carvalho Rondó, P., 152
Carvalho, A.C., 84, 195
Carvalho, G., 130, 132
Carvalho, L.H., 94
Casapía, M., 145
Casapia, M., 87
Casas, E., 139
Castellani, C., 211
Castelli, F., 14, 33, 101, 108, 131, 195, 241
Castelnuovo, F., 84
Castelobranco, I., 39
Castillo, J., 107
Castillo, S., 76
Castro, I., 177
Castro, M., 167
Cattelan, F., 94
Cattoli, G., 21
Cavallo, A., 196
Cavallo, M., 236
Caviedes, L., 95
Cavrini, F., 49
Ceballos, E., 168
Cecchi, G., 42
Cecconi, D., 201
Cecomet, F.P., 53
Cecomet, H.C., 53
Cecomet, R.S., 53
Cepero, B., 169
Ceravolo, I., 94
Cernat, R.C., 187
Cernuschi, T., 103
Cerón, V., 88
Cervato, C., 234
Cevallos, M.A., 72
Chaccou, C., 123
Chadee, K., 219
Chaiear, N., 142
Chaignat, C.-L., 215
Chaignat, C.L., 37
Chalvatzis, A., 212
Chalwe, V., 121
Chambers, R., 59
Chambi, W., 76, 76
Chandramohan, D., 145
Chanteau, S., 217
Chanturia, G., 60
Chappuis, F., 60, 76, 178, 186, 187, 237, 238
Chatenoud, L., 110
Chavatte, J.-M., 125
Checkley, W., 216
Chen, J.-X., 194
Chen, W.-J., 167
Cheng, A., 196
Chew, R., 95
Chiara, R., 205
Chinikar, S., 159
Chippaux, J.-P., 117, 171
Chitadze, N., 60

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Author Index

Chitra, A., 52
Cholpol, S., 45
Chompoonuch, C., 45
Chotmongkol, V., 174
Choudat, I., 57
Chuenkova, M., 178
Churcher, T., 54
Ciannameo, A., 177, 241
Ciaravino, G., 110
Cibelli, D.C., 233
Cicciò, L., 36, 51, 69
Cinori, E., 229
Ciotti, M., 78
Cirillo, D., 29
Cisse, B., 31
Cisse, M., 115
Clements, A., 195
Cobanoglu, N., 201
Cocorullo, D., 110, 154, 227
Cogollos, R., 218
Cohen, J., 21, 42
Colancecco, A., 129
Colasanti, R., 71
Collipal - Von Wyl, T., 76
Coll-Seck, A., 16
Colombati, R., 118
Colombatti, R., 66, 70, 94
Colucci, A., 207
Comelli, M., 84
Congpuong, K., 45
Cook, J., 115
Coosemans, M., 62, 85, 89, 184
Corachan, M., 1, 17, 171, 246
Corbett, Y., 129
Cordero, M., 203, 210
Cordioli, P., 49
Cordova, K., 157
Coronel, J., 95
Corran, P., 115, 125, 135
Correia, M., 93, 176
Cortelezzi, L., 126
Cortes, M., 228
Cossio, A., 110
Costa e Sousa, B., 193
Costa, A.G.M., 108, 154
Costantino, R., 245
Cot, M., 46, 57, 117
Cottrell, G., 57
Coulibaly, M., 86
Coulibaly, S.O., 57
Coulombier, D., 78
Cousens, S., 74, 190
Cousin, M., 45
Cousiño, B., 23
Cova, M., 237
Cox, J., 74
Cox, M., 92
Cox, R., 199
Crabtree, J., 59
Crabtree, J.E., 216
Cramer, J., 31, 217
Cras, P., 47
Craveiro, I., 148
Crawley, F.P., 47
Creed-Kanashiro, H.M., 145
Cretu, C., 201
Cringoli, G., 226
Crisante, G., 178
Crisanti, A., 125
Cristini, G., 84
Cristovan Sartori, A.M., 75
de la Cruz- Ruiz, M., 50
Cuadros, J., 218
Cucchi, A., 237
Cuerco, H., 108
Cuero, H., 91
Culha, G., 181
Cumba, L., 96, 97, 139
Cunanan, S., 42
Cuomo, R., 231
Curiel- Reyes, R., 39
Cuzzocrea, F., 201

Da, O., 192
Dabagh, N., 206
Dabas, R., 34
Dabiri, H., 219
Dahlan, M., 189
Dahlström, S., 130
Dahmane, A., 52
Daie Ghazvini, R., 172
Dakic, Z., 138
Dalen, N., 153
Damayanti, I.F., 158
Daniel-Ribeiro, C., 25, 128, 130, 132
Danquah, I., 54, 80
Dardi, M., 110
Darvish, A., 159
Das Dores, C., 96, 97
Das, M., 60, 62, 180, 184
Das, P., 62
Dasso, M.C., 177
Davami, M.H., 198
Davari, B., 124
Davies, C., 60, 62, 99, 186
De Blasio, E., 71
De Brouwere, V., 16
De Donato, M., 134, 136
De Jaegere, A., 223
De la Cruz- Ruiz, M., 39
De Meester De Ravestein, C., 223
De Molla, G., 66
De Nicolò, M., 236
De Pieri, M., 83
De Smet, M., 63, 86, 92
De Vivo, E., 38
De Vos, P., 33, 90, 99, 109, 113
De Vries, P., 183
De Weggheleire, A., 96, 97
De, A., 139
Dechavanne, C., 57
Decker, O., 37
Declercq, J., 42
Decroo, T., 96
Dedet, J.-P., 19
Degani, M., 74, 84, 240
Degirolamo, M.G., 229
DeJong, C., 210
del Mar Lleo, M., 23
Del Punta, V., 101
Delgado, M.-J., 78
Delgado-Enciso, I., 50, 166
Delgado-Petrocelli, L., 24, 157
Delieutraz-Marchand, J., 238
Della Valle, B., 31, 126
Dell'Agli, M., 129
Dell'Anna, S., 110
Deloron, P., 46
Demeester, R., 78
Demoitie, M.-A., 42
Depinay, N., 125
Derks, T., 208
Dev, V., 85
Develoux, M., 206
Devi, S., 83
Devkota, S., 180
Dhifallah, I., 156
Di Ciommo, S.M., 71, 245
Di Girolamo, C., 100, 241
Di Muccio, T., 19
Di Pasquale, A., 114
Di Tommaso, M.R., 239
Diaferia, M., 110
Diallo, A., 117
Diallo, B., 86
Diallo, D., 190
Diallo, H., 91
Diana, A., 238
Diarra, A., 42
Dias, S., 228
Diaw, O., 8
Díaz, M., 52

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Author Index

Diaz-Martin, V., 193
Didgar, F., 209
de Diego, J., 177
Dietmann, A., 30
Dietz, E., 80
Diève, T.N., 192
Díez, N., 214
Dillip, A., 63, 64
Dimaano, E., 39
Dinesh, D., 62
Diouani, M.F., 184
Dirgahayu, D., 25
Divon, S.A., 105
Djassoa, G., 12
Djego, J., 36
Djimde, A., 63
Djurdjevic Djulepa, A., 231
Doallo, H., 190
Dogan, Y., 186
Dolsac, I., 67
Domínguez, A., 233
Donnen, P., 34
Doritchamou, J., 46
Dorlo, T., 61, 61, 183
Dorny, P., 163
Dorta-Contreras, A.J., 199
Dottori, M., 49
Dottorini, T., 125
Doua, F., 175
Doustdar, F., 96
Douti, J.K., 12
D'Acremont, V., 46
Drago, M.C., 93, 176
Drakeley, C., 115, 125
D'Alessandro, U., 45, 47, 57, 63, 81, 85, 87, 94
Dramaix, M., 34
D'Antonio, M., 110
Drechsel, H.R., 136
Driul, L., 241
Droghini, L., 232
Druilhe, P., 120
Du, Z.-W., 194
Duarte-Escalante, E., 163
Dubrous, P., 143
Duffini, C., 122, 234
Dujardin, B., 12, 14, 17, 18
Dujardin, J.-C., 62
Dulovic, O., 162, 174
Dumas, M., 30
Dumitru, I.M., 187, 203
Dumoulin, C., 120
Dunkley, S., 62, 86, 92
Duò, O., 113
Duong Duc, T., 106
Duparc, S., 131
Dutta, P., 170
Duwiejua, M., 137

Earnest, A., 244
Ebeja Kadima, A., 47
Ebeja, A., 48
Eberhardt, R., 127
Ebinger, D., 127
Ebrahimi, R., 226
Ebrahimi, S., 159, 220
Eckerle, I., 127
Edalat, H., 117
Edrissian, G., 182
Eggelte, T., 61, 183
Egurbide, M., 238
Egwang, T., 125
Ehlers, S., 41
Ehmen, C., 56
Ehrhardt, S., 31
Ehrig, C., 54
Ehrlich, H., 78
Eichner, M., 116
Eijken, E., 208
Eisenbach, C., 127
Ekchariyawat, P., 155
El Buhaisi, D., 234
El Safi, S., 59
El-Hamad, I., 84
Ellman, T., 76, 76
Emami, S., 159
Enayati, A., 222
Engl, M., 93
Enlund, H., 137
Epp-Graack, G., 32
Erejuwa, O., 224
Erhart, A., 81, 85, 87, 89, 94
Eric, D., 167
Ernould, J.-C., 171
Ertabaklar, H., 181
Ervatti Gama, B., 130
Escobio, P.F., 235
Eslami, A., 123, 226
Esmaeili Rastaghi, A.R., 119
Esmaili, I., 98
Espinoza, M., 179
Espinoza-Gomez, F., 39, 50, 166
Essomba Owona, R., 13
Esteki Bardeh, M., 211
Estévez, L., 52, 65, 67, 75
Esther, E.T., 231
Estrada, K., 72
Eva, A., 67
Evans, C., 95
Evans, J., 58, 161
Ezzedine, K., 37, 167

Fabbri, A., 100, 241
Fabbri, G., 232
Fagioli, P., 110
Failly, M., 125
Fakhar, M., 180
Falahati, M., 159
Falasca, P., 110
Fallah, E., 182
Fallah, M., 156, 219
Faraglia, F., 67
Farahmand, M., 182
Farahnak, A., 206, 208
Farahnak, H., 206
Farahnak, S., 206
Farahyar, S., 159
Faramarzi, A., 221
Fares, A., 96
Farina, C., 140
Färnert, A., 130
Farnia, P., 96
Farnia, S., 225
Farokhnia, M.U., 160
Farooq, M., 68
Farrar, J., 39
Farrokhnia, M., 112
Fasihi Harandi, M., 202
Fathallah, A., 183
Fatuzzo, F., 90, 183
Faucher, J.-F., 46
Favorov, M.O., 216
Fawzi, W., 69
Fazaa, O., 156
Feachem, R., 16
Fekih, H., 156
Feldmeier, H., 209, 221
Felger, I., 93
Fengler, G., 221
Fenwick, A., 54, 55, 172
Feo, O., 118
Fernandez Fuentes, E., 233
Fernández, J.J., 23
Fernandez, J.L., 72
Fernandez-Pelaez, J.M., 233
Fernandez-Soto, P., 193
Ferrari, M., 240
Ferreira, E., 23
Ferreira, M.U., 94
Ferreira-da-Cruz, M.D.F., 128, 130, 130, 132
Ferrer, L., 90

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Author Index

Ferri, G., 177
Ferrinho, P., 148
Figueiredo, L., 89
Filice, C., 201
Filleul, L., 37, 167
Fillippi, L.D., 67
Fillol, F., 31
Finaurini, S., 129
Fink, M.C., 139
Fiore, N., 48
Firmenich, P., 31, 102
Firoozeh, F., 207
Fischer, M., 30, 155, 213
Fiume, C., 236
Flaherty, G., 79
Flores Santos, F., 173
Fobil, J., 33
Focà, E., 33, 101, 108
Fonseca, C., 199
Fontaine, A., 122
Fontaine, J., 84
Fontannaz, D., 24
Fontes, C.J., 133
Foresi, S., 98, 107
Fornabaio, C., 84
Forooghiparvar, F., 198
Foroumadi, A., 159
Fortes, F., 130, 132
Foschia, J.P., 234
Fourquet, P., 122
Frackowiak, K., 225
Fraga, J., 178, 199
Fragoso, G., 72, 163
Franceschi, C., 177
Franceschi, Z., 177
Franco, F., 239
Franco, J., 42
Fraser, C., 114
French, M., 54
Freyre Santiago, J.M., 228
Friberg Hietala, S., 130
Friis, H., 188
Fritzler, J.M., 220
Frusca, T., 241
Fuentes, I., 218, 227
Fuentes, P., 95
Fuentes-Pardo, L., 210
Fujiwara, R., 133
Fukuda, M.M., 155
Fumie Tateno, A., 140
Fusai, T., 120, 122

Gabrielli, S., 239
Gabrysch, S., 74, 218
Gabutti, G., 237
Gaczkowski, R., 39, 83
Gaied Meksi, S., 183
Gaiera, G., 80, 164, 207
Galama, J., 246
Galindo, I., 203, 210
Galli, G.V., 129
Galli, L., 131
Gallo, M., 233
Gam, L.H., 125
Gama, B., 128, 130
Gamboa, D., 87, 94
Gamboa, H., 148
Gantin, R.G., 12
Gárate, T., 218
Garba, A., 8, 55, 172
García, A., 57, 167
Garcia, D., 188
Garcia, L., 37, 169
Garcia-Mingo, A., 193
Garciarrubio, A., 72
Gardon, J., 171
Gardon-Wendel, N., 171
Gargate, M.J., 93, 176
Gargouri, J., 156
Gascon, J., 241, 246
Gasem, M.H., 222
Gaspoz, J.-M., 237
Gastañaga, T., 238
Gatchalian, S., 42
Gatti, S., 164
Gaye, O., 115
Gaytan, P., 72
Gazanion, E., 188
Gbenou, J., 36
Gehring, F.K., 136
Geis, S., 34
Geldmacher, C., 34
Genton, B., 46, 81
Gerard, S., 63
Gerardo, M., 171
Gerhardt, M., 34
Germano, A., 59, 111, 113, 246
Gerstl, S., 62, 86, 92
Gestoso, I., 230
Getahun, H., 11
Gétaz, L., 76, 237
Gething, P., 195
Ghabri, S., 43
Ghanbari, A., 215
Ghani, A., 115
Gherardin, T., 244
Ghorashian, S., 43
Ghram, A., 184
Gianinazzi, C., 202
Giao, P.T., 165
Giavarini, F., 129
Gibbons, L., 102
Gibbons, M., 99
Gidwani, K., 60, 182, 186, 187
Gies, S., 57
Gil, P., 130
Gil-Fournier, N., 146
Gillet, P., 139
Gilman, R., 95, 216
Gimeno Feliu, L.A., 67, 71
Ginorio, D., 199
Giordani, S., 232
Giorgobiani, E., 60
Giovannucci, E., 69
Giri, D., 55
Girot, R., 234
Giry, C., 167
Giuffrida, S., 237
Giuliani, R., 241
Giuliano, M., 246
Glorieux, C., 223
Glover, M., 136
Gluderer, D., 93
Gning, B., 117
Gnudi, M., 110
Gobbi, F., 74, 84, 122, 171, 226, 235, 240
Gobbo, M., 84, 171, 195, 226, 227
Golestani, A., 206
Golmohamadi, T., 206
Gomes, F., 130, 132
Gómez Bertomeu, F.F., 200
Gómez Echevarría, J., 162, 173
Gomez Morillo, M., 235
Gomez, D., 168
Gomez, L.E., 235
Gomez-Munuera, M., 203
Gomo, E., 188
Gomonda, E., 197
Gonçalves, L., 193
Gontijo, E.D., 176
Gonzales, J.J., 123
Gonzalez, F., 230, 238
González, I., 134
Gonzalez, V.M., 72
Goodman, C., 4
Gorcii, M., 202
Gorzkiewicz, A., 119
Gosoniu, L., 82
Gostner, C., 93
Gotthardt, D., 127

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Author Index

Gottstein, B., 202
Grácio, A., 193
Gradoni, L., 19
Graefe, S., 155
Gramiccia, M., 19
Gramishoar, M., 172
Grande, R., 137
Gray, J., 125
Greenwood, B., 31
Griffin, J., 115
Grigoriadis, S., 224
Grobler, A., 127
Grout, L., 72
Gruner, A.C., 125
Guariento, M.E., 179, 180
Gubert, F.D.A., 108, 154
Guedes de Oliveira, S., 209
Guedes, S., 243
Guerra, J., 57
Guerra, M., 33, 90, 109
Guerrieri, A., 71
Guido, C., 23
Guidotti, G., 245
Guilbeogo, M., 81
Guilharde, A.O., 83
Guillen-Perez, F., 228
Guimarães, T., 176
Guindo, A., 86
Guionnet, A., 52, 65, 67, 75
Gulletta, M., 80, 195
Gundersen, S.G., 188, 191
Gutierrez Duenas, P., 123
Gutierrez, F., 240
Gutiérrez-Cisneros, M., 218, 227
Guzman, M.G., 39, 83
Gwanzura, L., 188
Gyapong, J., 41
Gyorkos, T., 21, 87, 145

Habib, M., 204
Habimana, L., 223
Habluetzel, A., 129
Hadad Zadeh, A.A., 158
Hadighi, R., 187
Hagen, L.M., 99
Hagen, R., 58, 155, 216
Haghighi, A., 219
Hajjaran, H., 187
Halidou, T., 47
Hamm, D.M., 12
Hamouda, B., 204
Hang, V.T.T., 83
Harmen, S., 221
Haro, J.L., 233
Harris, E., 39
Hartskeerl, R., 246
Hasballah, K., 125
Hashemi, S.J., 172
Hashemzadeh, M., 141
Hasker, E., 42, 182
Hassan, A., 213
Hassan, A.-W., 213
Hassan, N., 98, 187
Hatam, G., 180
Hatam, G.R., 182, 221
Hatz, C., 55
Hayes, D., 154
Haynes, R., 127
Haynes, R.K., 128
Hazeleger, F., 89
Heidari, A., 133, 135
Helbok, R., 30
Helena Bustos, R., 136
Helleberg, M., 191
Helm, F., 155
Hemingway, J., 222
Hempel, C., 31, 126
Hendrickx, D., 43, 62
Hennequin, C., 206
Henriques, V., 173
Heptinstall, J., 92
Herawati, D.M.D., 158
Herb, F., 41
Hererra, B., 95
Hernandez Neuta, G.E., 166
Hernandez, D., 157
Hernani, D., 69
Herr, J., 31
Herrera-Martínez, A., 38, 164, 177
Herrero, J.M., 52
Herreros, B., 230
Hertzmark, E., 69
Heshmatollah, A., 206
Hetzel, M., 63
Heukelbach, J., 221
Heuschkel, C., 12
Hidalgo, L., 127
Hien, T.T., 39
Hill, A., 41
Hinojosa, L., 164
Hoang Thi, P., 106
Hoang, L.P., 39
Hoelscher, M., 34
Hogan, B., 82
Hogerzeil, H.V., 3, 101
Holakouie, K., 71
Hollo, V., 80
Holst, M., 178, 237
Holzer, J., 218
Honarmand, H., 215
Hong, S.-J., 220
Hopman, J., 246
Horstick, O., 39, 83
Horstmann, R., 41
Horta, R., 228
Hoseini Vasoukolaei, N., 50, 155, 159
Hoseinpur, L., 172
Houze, P., 46
Houze, S., 46
ten Hove, R., 188
Hrdy, I., 220
Hubatsch, I., 175
Huenger, F., 58, 216
Hui, D., 78
Huitema, A., 61
Hung, L.Q., 165
Hung, N.T., 39
Hünger, F., 161
Hunter, D., 69
Hurst, S., 48
Hutubessy, R., 215
Huyse, T., 188
van Huysteen, E., 128

Iacobello, C., 183
Iacobiciu, I., 144, 204, 205, 242, 243
Ibarra, S., 53
Iborra, A., 239
Iglesias-Gomez, A., 203, 210
Ignatiadi, I., 244
Ignatius, R., 209
Ilunga, M., 43
Inceboz, T., 186
Indjic, N., 138
Ingham, C., 96
Ingstad Sandberg, K., 104
Inojosa, W., 197
Intanakom, S., 45
Intapan, P., 174
Intemann, C., 41
Ippolito, G., 143
Iqbal, P., 139
Iranmanesh, F., 244
Ismail, S., 125
Issifou, S., 30
Ivory, C., 219

Jackson, D., 102
Jackson, Y., 76, 178, 237, 238
Jacobs, J., 139

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Author Index

Jacquet, D., 42
Jaeggi, T., 114
Jaenisch, T., 83
Jagoe, G., 5
Jahangiri Esfahani, B., 155
Jahangiri Esfahani, T., 155
Jahhaf, A., 14, 111
Jahuira, M.H., 216
Jamshidi, M., 161
Jamshidi, S., 182
Janer, J.M., 235
Janetzko, A., 224
Jänisch, T., 39, 116
Jannin, J., 178, 237
Janssens, M., 42
Jansson-Löfmark, R., 175
Jaouadi, L., 183
Jarilla, B., 220
Jean, M., 152
Jeffs, B., 4
Jesus Maria, B., 96
Jiang, J.-Y., 194
Jimenez, L., 72
Jimenez, N., 199
Jitpimolmard, S., 174
Johansson, C.-C., 175
Johnson, R.C., 36
Jongkaewwattana, A., 155
Joseph, S.A., 145
Jovanovic, M., 162, 174
Juan-Hua, Q., 198
Juarez, M.S., 72
Juillet, Y., 15
Juma Shame, A., 110
Juma, E., 63
Junco Diaz, R., 196
Junghanss, T., 39, 127, 201
Kaabia, N., 183
Kabanywanyi, A., 81
Kabatereine, N., 8
Kaboré, S.C.M., 108
Kabwe, C., 163
Kacprzak, E., 225
Kade, M., 14, 111
Kager, P., 91
Kager, P.A., 44
Kahama-Maro, J., 46
Kakrin, M., 149
Kakudji, L., 31, 102
Kalantari, M., 180, 198, 221
Kalayanarooj, S., 39
Kalenga, P., 223
Kambale Kivu, A., 144
Kamgno, J., 72, 171, 172
Kamhawi, S., 60
Kanbara, H., 119
Kande, V., 42, 43
Kanobana, K., 163, 196
Kanoi, B., 125
Kapoor, N., 87
Karunakara, U., 43
Kasim, M., 69
Kasparian, S., 43
Kayibanda, M., 125
Kazadi-Kyanza, S., 43
Kazemi, B., 182, 186, 219
Kazemi, F., 98
Kearns, T., 196
Kegels, G., 5
Keiser, J., 55, 191
Kelleher, D., 216
Keramidas, I., 244
Kesari, S., 62, 62
Keshavarz, H., 133, 135, 198
Kessy, F., 63, 64
Keuter, M., 222, 246
Keygnaert, I., 25
Keygnaert, J., 25
Khairandish, S., 117
Khamis, I.S., 8, 56
Khan, A.M., 170
Khan, S.A., 170
Khanal, B., 60, 180, 187
Khanjani, S., 181
Khatib, A.M., 215
Kheirandish, F., 207
Kheiri, S., 199
Khosravi, A., 96, 141
Kia, E.B., 202, 208
Kiema, D., 108, 108
Kijak, G.H., 34
Kim, J.H., 34
Kindelan, J.M., 233
Kines, K.J., 190
Kinung'hi, S., 189
Kjetland, E.F., 188
Kluge, S., 217
Knerer, G., 39
Knobloch, U., 12, 14
Knopp, S., 56
Koama, P., 108
Kobbe, R., 56, 82
Ködmön, C., 80
Koehler, R.N., 34
Koepfli, C., 93
Kofoed, P.-E., 44
Kokwaro, E.D., 85
Kolaczinski, J., 195
Kombo Khamis, R., 110
Konate, M., 86
Korac, N., 129
Korac, S., 129
Korenkova, V., 220
Kotelnikov, V., 22
Kotze, A., 127, 128
Kovačević, M., 156
Kozar, M.P., 120
Kremsner, P., 30
Kreuels, B., 56, 213
Kreuzberg, C., 56, 155, 213
Kristensson, K., 7, 176
Kristiansson, C., 148
Kroeger, A., 39, 83, 184
Krugu, J., 148
ter Kuile, F., 154
Kumar, A., 34, 50
Kumar, S., 34, 50
Kumar, V., 62
Kum-Arb, U., 155
Kuna, A., 126
Kurniawan, A., 189
Kurtzhals, J., 31, 126
Kushadiwijaya, H., 194
Kvåle, G., 6

La Rosa, R., 183
van de Laar, M., 84
Labuda, L., 192
Lacaux, J.-P., 24
Lackner, P., 30
Laclette, J.P., 72
Lacovazzi, T., 67, 235
Lafaye, M., 24
Lagioia, A., 233
Lagro-Janssen, A., 70
Lailang, V., 45
Laing, R., 101
Lallemand, E., 125
Lalou, R., 44
Lambot, L., 223
Lamfri, M., 22
Landa, A., 72
Langley, N., 128
Laokri, S., 18
Laouini, D., 184
Lapierre, D., 42
Larocca, A., 71
Larocca, L., 183
Larralde, C., 72, 163
Larsen, M.L., 86
Lasheras, M., 67
Lass, A., 119, 200

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Author Index

Laufer, S., 136
Lavadinovic, L., 138, 162, 174
Lawyer, P., 60
Lazzarin, A., 164
Lazzarotto, F., 234
Le Hesran, J.Y., 44
Le Khan, T., 81
Le Khanh, T., 85
Le Loup, G., 234
Le Port, A., 57
Le Xuan, H., 58, 64, 81, 85, 94
Le, Q.H., 39
Lefèvre, G., 63
Lefèvre, P., 43, 90, 109, 167
Lehmann, U., 27
Leila, B., 204
Leimkugel, J., 148
Lejon, V., 42
Lell, B., 30
Lemos, M., 228
Lengeler, C., 16, 46, 63, 64, 81, 114
Lenhart, A., 169
Lerdprom, R., 138
Leroy, E., 170
Lescure, X., 234
Lesshafft, H., 209, 221
Letaief, A., 183
Letang, E., 246
Leussenkamp, R., 143
Levi, J., 83, 139
Lewis, D., 131
Leyva, A., 99
Li Volsi, S., 205
Li, X.-Q., 128
Liberal, L., 24
Liesenfeld, O., 221
van Lieshout, L., 195
Ligabue, M., 110
Likatavicius, G., 84
Lima, M.A., 76
Limon Lasson, J., 72
Limpawattana, P., 142, 174
Limsalakpetch, A., 155
Lin, A., 120
Lindegårdh, N., 130
Lionnet, F., 234
Liu, X., 106
Livramento, L., 139
Lizioli, A., 237
Llanos Cuentas, A., 87, 94
Loag, W., 33, 161
Lodesani, C., 67
Lokuge, K., 4
Lomartire, L., 177
López González, A., 147, 211
López, M., 167
López-Abán, J., 192
Lopez-Gonzalez, A., 70
Lopez-Lemus, U.A., 166
López-Vélez, R., 52, 65, 67, 75, 218
Lorenzini, P., 245
Lorenzo-Morales, J., 225
Lotfali, E., 159
Louis, V., 81, 115
Loutan, L., 15
Low, W., 125
Lowe, S., 210
Lozano, A., 233
Luang-Suarkia, D., 166
Lucantoni, L., 129
Luechters, G., 213
Luiselli, D., 177
Lujan, H., 59
Lum, L., 39
Lunardi, M., 234
Luquetti, A., 178, 237
Lutucuta Kosi, F., 130, 132
Lutumba, P., 42, 43, 47, 48, 163
Luxemburger, C., 50
Luzón, L., 67
Lyimo, J., 45, 63
Lyytikäinen, O., 243

Mabaso, M., 114
Maboko, L., 34
McBride, J., 166
McCall, P.J., 169
McCarthy, J., 196
McCutchan, F.E., 34
McDade, J., 244
Machevo, S., 45, 214
Macipe Costa, R.M., 71
Maendaenda, R., 96, 97, 139
Maes, P., 86
Maestrello, L., 234
Mafwila, D., 121
Magalhaes, D., 147
Magallón-Botaya, M., 67, 71
Maganga, L., 34
Maghsood, A.H., 219
Magill, A.J., 120
Magis-Escurra, C., 40
Maglajlic Abduzaimovic, J., 231
Magliocco, S., 245
Magnani, C., 176
Magnani, G., 80
Magne, D., 206
Magrini, F., 241
Mahanonda, R., 155
Mahanta, J., 170
Mahendradhata, Y., 194
Maheu-Giroux, M., 87
Mahjoub, N., 183
Mahmoudi, M., 182, 194, 208
Mahmud, R., 125
Maiga, H., 45
Maikere, J., 62, 86, 92
Maire, N., 116
Majori, G., 1
Makame, H., 45
Maketa, V., 47, 48
Makoutode, P., 46
Makumbi, M., 36
Malaviya, P., 182
Maleki, A., 123, 226
Malik, A.A., 114
Malila, A., 81
Malvy, D., 37, 167
Mamishi Tehran, S., 143
Manaseki-Holland, S., 145
Mancini, S., 31
Mandakova, Z., 247
Mande, S., 108
Manenti, F., 146
Mangiagalli, M., 74
Manissero, D., 80
Mann, V.H., 190
Manneck, T., 191
Manong, D., 166
Manouchehri Naeini, K., 199, 211
Mantella, A., 239
Mantero, J., 78
Manzardo, C., 83
Marcellus, F., 216
Marchal, B., 5
Marconi, M., 137
Maria, V.T., 231
Mariella, A., 107
Marin, C., 70
Marin, S., 246
Marincu, I., 144, 204, 205, 242, 243
Marks, F., 161, 216
Marocco, S., 171, 235
Maroli, M., 19
Maroof, Z., 145
Marquez, M., 53, 91, 107, 108
Marra, A., 117
Marrast, A.-C., 63
Marta, B., 241, 241
Martelli, C.M., 83
Mårtensson, A., 130
Marti, H., 56

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Author Index

Martin, A., 36
Martin, C., 125
Martin, E., 228
Martinez Astorkiza, T., 238
Martinez de Tejada, B., 238
Martinez Parra, A.G., 113
Martinez Torres, E., 39
Martinez, A., 136
Martínez, L.C., 67
Martinez-Fernandez, A., 133
Martínez-Ibarra, J., 177
Martínez-Ruíz, R., 218, 227
Martini, E., 49
Martini, L., 37
Martín-Navarro, C.M., 225
Martino, A., 100, 241
Martín-Rabadan, P., 218
Martins Batista, A., 180
Martins, E., 94
Mascarello, M., 171
Maschi, O., 129
Masher, M.I., 145
Mason, C.J., 155
Mason, P.R., 188
Massoud, J., 207, 208
Massougbodji, A., 57
Matchett, E., 50
Matelon, R., 92
Maternowska, C., 20
Mathema, P., 55, 154
Matowe, L., 137
Matteelli, A., 84
Mattioli, R., 42
Mauduit, M., 125
Maugeri, M., 66
Maurelli, M.P., 226
Mauris, A., 178, 237, 238
May, J., 33, 56, 58, 82, 161, 213, 216
May, L., 195
Mayanga, D., 121
Mayumana, I., 63, 64
Mazier, D., 125
Mazzoleni, G., 125
Mbacham, W., 105
Mbarouk, H., 143
Mbou-Moutsimbi, R.A., 170
Mboup, B.M., 117
Mboup, S., 192
Mbow, M., 192
Md Salleh, M.S., 224
Mduluza, T., 188
Meamar, A.R., 219, 220
Meda, N., 91, 190
Medici, A., 49
Meenakshisundaram, R., 40, 52, 77
Mehdipoor, D., 117
Meheus, F., 186
Mehta, S., 69
Mekki, M., 202, 204
Mekonnen, W., 77
Melendez, V., 120
Melink, A., 156
Mellini, S., 71
Mello Neto, J., 152, 152
Melnikov, V., 39, 50, 166
Mendes de Oliveira, C., 140
Mendoza, L., 72
Menocal Heredia, L., 196
Mens, P.F., 44, 59, 91, 92
Menten, J., 122
Merino, F.J., 218, 227
Merino, P., 230, 238
Merkler, C., 204, 205, 242
Mero, C., 53
Meslin, F., 27
Mestre, N.M., 170
Meurs, L., 188, 192
Meyer, C.G., 41, 216
Meyerhans, A., 48
Mezhoud, H., 202, 204
Mfinanga, S.G., 95
Miahipoor, A., 208
Miaka, C., 144
Miccoli, A., 231
Michael, N.L., 34
Michel, P., 22
Midzi, N., 188
Mignot-Nabias, F., 57
Milic, D., 129
Millán, R., 227
Mills, A., 3
Milosevic, B., 138, 162, 174
Milosevic, I., 138, 162
Minn, N.N., 40
Mirhendi, H., 202
Mirzaei, T., 160
Mishra, S., 23
Missoni, E., 66
Mistretta, M., 84, 227, 235
Mitashi, P., 42, 43
Mititelu, M., 204
Moattari, A., 212, 215
Mobedi, I., 208
Mockenhaupt, F., 54, 80
Moendandzé, A., 37, 167
Mohamed Ali, S., 110
Mohammed, K.A., 56
Mohebali, M., 182, 186, 187, 208, 225
Mohseni Moghadam, F., 160
Mohyaddini, A., 160
Moji, K., 58
Mokhtari, F., 160
Molaei Rad, M.B., 206, 208
Moldovan, R., 204, 205, 242
Moll Cervera, F., 162, 173
Mollet, T., 78
Molyneux, D., 10
Momen, H., 8
Momeni, Z., 208
Monge, B., 65
Mongui, A., 133
Monno, L., 229, 233
Montalvo, A.M., 178
Monteiro, G., 235
Monteiro, L., 93, 176
Monterio, G., 234
Monti, M., 71, 245
Montineri, A., 90, 183
Montoya, J., 42
Monzani, V., 53, 141, 151, 222, 223
Moradynasab, M., 98
de Moraes Vasconcelos, D., 75
Morais, C., 133
Morais, L., 214
Morales Montor, J., 72
Morales, J., 163
Morales, M.E., 190
Morandi, M., 232, 241
Mordmüller, B., 12, 136
Moreira, J., 53, 91
Moreira, J.-M., 37, 107
Morenikeji, O., 37
Moreno, J., 134, 136
Morett, E., 72
Moretti, E., 177
Morgano, M.A., 152
Morgoglione, M.E., 226
Moris, P., 42
Morkve, O., 95
Moro, M.L., 232
Mortezaei, S., 199
Mosca, W., 179
Moscardelli, S., 71
Moschochoritis, K., 67
Moshfe, A., 182
Mosquera, L., 123
Motazedian, M., 180, 182, 198
Motiei, M., 159
Moudachirou, M., 36

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Author Index

Moukana, H., 170
Mountford, A., 192
Mowlavi, G.R., 208
Mpanya, A., 43
Mrad, M., 202
Mrad, S., 204
M'rad, M., 204
M'rad, S., 202, 204
Msamanga, G., 69
Mshinda, H., 63, 64
Mshindo, O., 227
Mtasiwa, D., 46
Mueller, I., 93
Mueller, M., 155
Mugasa, C.M., 59, 175
Mughal, M.A., 114
Mughal, Z., 145
Mughini, M.T., 245
Mugusi, F., 69
van den Muijsenbergh, M., 70
Mukhtar, A., 62, 86, 92
Mulalic, Z., 35, 129, 149, 231
Mulaya, N., 85
Mulder, B., 58, 96, 143, 208
Müller, J., 191
Müller, O., 81
Mulure, N., 45
Mungai, M., 90
Munier, A., 117
Muñoz, J., 241
Muñoz, M., 23, 228, 239
Muñoz-Bellvis, L., 210
Murcia Flores, L., 239
Murillo, J., 53, 91
Muro, A., 133
Muro-Alvarez, A., 192, 193
Musabegovic, J., 129
Mushin, J., 143
Mutangala, W., 43
Mutombo, W., 43
Mwisongo, A., 32
Myjak, P., 119, 126, 200
Myrvang, B., 191

Na-Bangchang, K., 39, 175
Naddaf, S.R., 119, 181
Nagataki, M., 220
Nagelkerke, N., 39, 165
Nahorski, W., 119, 126
Nahrevanian, H., 182
Nahum, A., 45, 63
Nakazawa, S., 58
Nali, L., 139
Nam, N.V., 165
Namgyal, K., 34, 50
Nana-Djeunga, H., 72, 172
Narvaez, E., 37
Nasher, J., 111
Nasimidoost, M., 207
Nasiri, A., 159
Nateghpour, M., 119
Nathalie, M., 152
Nathan, R., 64
Navarro, M., 52, 65, 67, 75
Navarro, R., 246
Navaza, B., 52, 65, 67, 75
Nazemalhosseini Mojarad, E., 206, 219
Nazemi, S., 112, 161
Ndhlovu, P.D., 188
Ndiaye, O., 117
Ndione, J.A., 24
Neghina, A.M., 144, 204, 205, 242, 243
Neghina, R., 144, 204, 205, 242, 243
Negrutiu, L., 144, 243
Nejoua, B., 13
Nekouie, H., 187
Newman, D., 92
Newton- Sanchez, O.A., 39, 50, 166
Newton, P., 15
Nga, T.T.T., 165
Ngadaya, E., 95
Ngandu, D., 121
Ngasala, B., 130
Ngo Duc, T., 81, 85, 94
Ngouama, D., 43
Ngoungou, E.B., 30
Ngum Wonghi, J., 13
Nguyen Khan, P., 106
Nguyen Manh, H., 94
Nguyen Ngoc, T., 85
Nguyen Quang, T., 58
Nguyen Thi Mai, O., 106
Nguyen Van, H., 94
Nguyen Xuan, X., 81, 85, 94
Nguyen, V.N., 39
Nhamposa, T., 214
Nhanca, M., 173
Nicastri, E., 143
Nicolaidou, P., 201
Nicoletti, R., 71, 245
Niemann, S., 41
Nigro, L., 90, 183, 205, 245
Nikiema, B., 72
Niksic, H., 129, 231
Nishiura, H., 165
Nissack, F.M., 13
Niyyati, M., 225
Njamnshi, A.K., 7
Nkoghe, D., 170
Nkrumah, B., 161
Nmorsi, O., 189
Nochi, Z., 206, 219
Nolsen, K., 96
Noori, T., 84
Norberto, C., 80
Norman, F., 65
Northoff, H., 136
Nougtara, A., 13
Nouri, A., 202, 204
Nourian, M., 147
Novo-Veleiro, I., 203
N'Goran, E., 55
N'Guessan, N., 55
Ntege, E.H., 125
Nti, C., 54
Nuhi, A.S., 181
Nurwidayati, A., 189
Nwaiwu, O., 45

Obrist, B., 63, 64
Odendaal, R., 128
Odeny, L., 85
Odhiambo, O., 85
Odolini, S., 33, 101, 108
Ofori-Anyinam, O., 42
Ofori-Belic, I., 138
Ogwang, M., 93
Oh, H., 78
Ojeniran, M., 105
Okatcha, T.I., 190
Okell, L., 115, 115
Okenge, A., 144
Oleaga, A., 193
Olga, H.A., 231
Oliveira, C.M., 214
Oliveira, F., 221
Olliaro, P., 115
Omar, M., 37
Omodeo-Salè, F., 126
Omotoyo, E.O., 54
Oormazdi, H., 219, 220
O'Brien, T., 79
O'Callaghan, C., 214
Orduñez-García, P., 109
Oriti, A., 67
O'Neil, M.T., 120
Ortiz, G.Z., 228
Ortiz-Bautista, R.J., 228
Oryan, A., 208
Oshaghi, M.A., 50, 159

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Author Index

Oshiiwa, M., 152
Ostyn, B., 60, 187
Otero, S., 83
Othigo, M.J., 20
Otieno, L., 45
Ouaissi, A., 188
Ouattara, F.T., 57
Oude Lashof, A., 210
Ouedraogo, J.-B., 192
Ouendo, E., 46
Ouerghi, O., 184
Ouma, P., 45
Oury, B., 188
Oviedo, M., 169
Owusu-Dabo, E., 41
Ozbel, Y., 181
Ozensoy Toz, S., 181, 186

Pacheco Coral, A.D.P., 166
Pacifici, L.E., 231
Pagán, J., 239
Paglia, M.G., 143
Paiva, M.C., 108
Paixão, G.M., 176
Paixão, L., 176
Palazzo, S., 110
Palermo, F., 205
Pallecchi, L., 148
Palma, P.P., 4, 76
Paltrinieri, G., 110
Pandey, S., 55
Panei, P., 48
Pannuti, C., 140
Pannuti, C.S., 83, 214
Paone, M., 42
Paraninfo, G., 84
Parapini, S., 128
Pardo-Lledias, J., 203, 210
Paredes, B., 23
Parmar, D., 32
Parola, P., 80
Parruque David, A., 73
Pascali, G., 71
Pasnik, F., 27
Patarroyo, M.A., 133
Pattaro, C., 122
Paudel, I., 60
Paudyal, N., 154
Paul, E., 18
Paul, M., 225
Pavlova, B., 78
Pavlovic, M., 138, 162
Peeters Grietens, K., 47, 87, 94
Peeters, K., 81
Pelemis, M., 138, 162, 174
Pellissier, N., 37, 227
Penali, L., 45
Penava, S., 149
Penkowa, M., 31, 126
Penny, M., 116
Penny, M.E., 145
Peralta, F., 108
Pereverzev Alexceevich, V., 157, 236
Pérez de Ayala, A., 75
Perez de la Hoz, R., 177
Pérez del Villar Moro, L., 192
Perez, D., 167
Perez, K., 167
Pérez-Molina, J., 52, 65, 75
Peris, A., 196
Perkins, M., 134
Perrazzolo, C., 234
Perriens, J., 11
Perrin, M., 178
Perva, N., 231
Peters, B., 110
Petmitr, P., 136
Petrini, G., 137
Pettener, D., 177
Pettinato, D., 125
Pettinelli, F., 167
Pham Van, K., 85
Pham, M., 106
Phan, L., 206
Phan, T.G., 39
Philips, M., 26, 31, 33, 52, 63, 102
Phillips, A., 55, 172
Phuong, H.L., 165
Pialoux, G., 234
Piarroux, R., 28
Piazza, C., 234
Picado, A., 60, 62, 182, 184, 186, 187
Picazo, J., 230, 238
Pichyangkul, S., 155
Pickering, J., 62
Pierobon, M., 66
Pierre Kabuayi, J., 144
Pietkiewicz, H., 119, 200
Pietra, V., 33, 101, 108
Pignatelli, S., 33, 101
Piñar, D., 211
Pinazo, M., 241, 246
Pincay, T., 37
Pineda, B., 118
Pinheiro, P., 108, 154
Pini, A., 78, 195
Pinxten, W.L., 35, 140
Pinyoratanachote, A., 45, 138
Pion, S., 72, 171, 172
Piot, P., 9, 10
Pizzi, C., 146
du Plessis, L., 127, 128
Poglayen, G., 49
Pohlig, G., 43
Pokharel, R., 154
Polderman, T., 195
Pollisard, L., 50
Polman, K., 163, 188, 192, 196
Polo, V., 167, 169
Poluga, J., 138
Pomier, O., 199
Poncin, M., 48
Ponsar, F., 31, 33, 63, 102
Pontello, M., 37, 227
Poormirzaee, H., 158
Pophillat, M., 122
Porcasi, X., 22
Portaels, F., 36
Portilla, J., 211, 243
Posada, E., 241
Poulakida, E., 244
Poumerol, G., 16
Praet, N., 163
Prandi, R., 53, 91, 107, 108
Prati, F., 80
Pratlong, F., 204
Premji, Z., 130
Preux, P.M., 30
Prichard, R.K., 172
Priesnitz, S., 58, 155
Prikazsky, V., 80
Priotto, G., 43
Pritsch, M., 34
Proietti, C., 125
Protano, D., 237
Prucca, C., 59
Prugger, C., 93
Pullan, R., 82
Punzi, G., 233
Putoto, G., 98, 107
Putri, L.P., 158
Pyae Phyo, A., 45

Qamar, S.A., 117
Quang Binh, T., 45
Queiroz, D., 216
Quetin-Leclercq, J., 36
Quiñones, M.L., 123
Quiñonez Pinzón, M.L., 166
Quinonez, M., 91
Quintero, Y., 75

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Author Index

Rabiee, S., 156
Racalbuto, V., 143
Rachaphaew, N., 138
Rachas, A., 57
Rached, A., 204
Raeisi, A., 71, 119
Ragheb, M., 213
Ragona, G., 110
Rahalison, L., 217
Raharjo, T., 194
Rahimi, F., 225
Rahlenbeck, S., 77
Rahman, W., 124
Raine, R., 102
Rajabalian, S., 159
Rajan, A., 112
Rajerison, M., 217
Ralafiarisoa, L.A., 217
Ramajo, V., 193
Ramazanzadeh, R., 160, 222
Ramin, E., 124
Ramos Oropeza, S., 157
Ramos, J.M., 41, 240
Ramos, S., 24, 157
Ramosi, J.M., 146
Rana, R., 154
Raoult, D., 80
Rassi, Y., 124
Ratnam, I., 50
Ratsitorahina, M., 217
Ratti, D., 164
Raule, N., 177
Ravaglia, C., 110
Raven, J., 106
Raviglione, M., 10
Ravinetto, R., 47, 48, 67
Razavi, M.R., 181
Razmjou, E., 219, 220
Re, T., 223
Ready, P., 19
Reechaipichitkul, W., 142
Reichert, F., 209
Reid, T., 52
Reindl, M., 30
Reinel, D., 235
Reis, C., 238
Rekic, D., 51
Remoué, F., 31, 120
Renault, P., 37
Renia, L., 125
Resi, D., 232
Rey, S., 227
Reyes Rabell, F., 146
Reyes, A., 167, 169
Reyes, F., 41, 146
Reyes-Montes, R., 163
Reynaldi, S.M., 59
Rezaei, M., 219
Rezaeian, M., 116, 141, 161, 219, 225
Rezaie, S., 219, 220, 225
Rezza, G., 10
Riccardi, F., 94, 118
Riccardo, F., 231
Richard, F., 16
Rigby, R., 154
Rigoli, E., 234
Rijal, A., 180
Rijal, S., 60, 62, 180, 184, 187
Riley, E., 115, 125
Rinaldi, J.-G., 190
Rinaldi, L., 226
Risley, P., 135
Rivas Muñoz, F.A., 166
Riveau, G., 31
Rivero, F., 59
Robb, M.L., 34
Robert, A., 18, 32, 223
Roca, A., 214
Rocha, C., 39
Rocha, G.A., 216
Roddy, P., 4
Rodrigues Coura, J., 21
Rodrigues, A., 44
Rodrigues, J.C., 214, 214
Rodriguez, A., 33, 99, 109, 113, 164, 168
Rodríguez, A., 90
Rodriguez, E.M., 179
Rodriguez, I., 178
Rodriguez, K., 168
Rodriguez, M., 168
Rodriguez-Morales, A., 38, 164, 177
Rodriguez-Osorio, J., 39
Rodulfo, H., 134, 136
Roels, B., 46
Rogier, C., 120, 122
Rohnavaz, M., 206
Rojas Rivero, L., 196
Rojas Cortez, M., 76
Rojas, J., 133
Rolando, E., 59, 113
Rollinson, D., 8, 56
Romano, M.C., 164
Romão, R.M., 214
Rombo, L., 44
Romeo, S., 129
Rompão, H., 193
Römsing, S., 130
Rondini, S., 148
Ronzoni, L., 129
Roohnavaz, M., 208
Rorato, G., 140, 232, 241
de la Rosa, O., 4
Rosas, A., 118
Rosenberger, K., 39, 116
Röshammar, D., 51
Ross, A., 116
Rossanese, A., 171, 235
Rosseti, N., 176
Rossetto, A., 70
Rostad, B., 150
Rostami Nejad, M., 206, 219
Rotela, C., 22
Rottenberg, M., 176
Rouamba, J., 91
Rouamba, N., 47
Rouhani Kalagari, S., 194, 207
Rousselle, T., 125
Rovellini, A., 53
Rowland, M., 62
Roy, L., 62, 184
Rubano, F., 147
Rueangweerayut, R., 45
Rugina, S., 187, 203
Rugna, G., 49
Ruiz Espinosa, A., 196
Ruiz, J., 42
Rulisa, S., 57, 64
Russo, G., 231
Russo, R., 205
Russomando, G., 23
Rycken, L., 223

Saâdia, A., 13
Saathoff, E., 34
Sabando, R., 91
Sabatinelli, G., 15
Saboriara, M., 67
Sabzali Touran, H., 98
Sacks, D., 60
Sadjjadi, S.M., 182, 208
Saghrouni, F., 183
Sagnon, N., 81
Sahebekhtiari, N., 219
Said Haji, H., 143
Sainati, L., 66, 70
Saito, M., 216
Salah, B., 14
Salehi Fard, A.Z., 199
Salehi, F., 209
Salim Abadi, Y., 124

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Author Index

Salim, A., 40
Salimabadi, Y., 158
Sallas, W.M., 63
Salleh, S.Md., 54
Salvador, V., 164
Samb, B., 11
Sambri, V., 49
Sánchez Benítez de Soto, M.L., 142
Sanchez, A., 72, 142, 228
Sanchez, E., 41
Sanchez, J., 241
Sanchez, L., 167
Sanchez-Salas, J., 107, 228
Sandberger de Canas, B., 217
Sanders, D., 2, 5, 9
Sane Schepisi, M., 143
San-Feliciano, A., 133
Sani, S., 131
Sanogo, K., 33, 101
Sanoussi, N., 36
Santoro, A., 177
Santos, F., 128
Santos-O'Connor, F., 78, 80, 84
Santos-Peña, M., 109
Sanz, S., 214
Sapienza, M., 205
Saracino, A., 233
Sarkari, B., 182, 198
Sarmadian, H., 209
Sarnevesht, J., 198
Sarpong, N., 33, 58, 161, 216
Sarr, J.B., 31
Sarrassat, S., 44
Sarvgad, M.R., 112
Sashindran, V.K., 34, 50
Sati, S., 13
Sauerborn, R., 32, 114, 115
Sauerwein, R., 246
Saunders, D., 120
Saura, A., 59
Savadogo, G., 32
Savage, L., 92
de Savigny, D., 114
Savorelli, E., 110
Sawa, P., 44, 91
Sawanyawisuth, K., 142, 174
Say, L., 102
Sayadi, T., 202, 204
Scaccabarozzi, D., 126
Scarparo, C., 140
Scavuzzo, M., 22, 23
Schaetti, C., 215
Schallig, H., 44, 59, 91, 92, 134, 175, 181
Scheid, P., 155
Schirvel, C., 34
Schittek, B., 218
Schlagenhauf, P., 9, 16, 50
Schleucher, R., 218
Schlienger, R., 81
Schmid, C., 43
Schmidt, S., 235
Schmiedel, S., 31
Schmutzhard, E., 30
Schnabel, P.A., 127
Schneider, A., 12, 14
Schnellbach, K.P., 12, 14
Schockaert, L., 66
Schoepflin, S., 93
Schöer, T., 81
Schoevers, M., 70
Schoone, G.J., 59, 175
Schou, A., 109
Schulze, A., 63, 64
Schulz-Key, H., 12
Schuster, A., 209
Schwarz, N.G., 33, 161
Schwarzer, E., 3
Schwehm, M., 116
Sciutto, E., 72, 163
Scorzolini, L., 231
Scott, A., 79
Screm, C., 140
Scrivano, F., 237
Sebastian, A., 238
Sedaghat, M.M., 159
Seghatoleslami, S., 141
Segovia, M., 239
Segurado, A., 139
Seixas, J., 173
Selimovic, A., 35, 149, 231
Selwi, K., 114
Semporé, J., 33
Seni, A., 197
Senn, N., 166
Senou, N., 36
Senthong, V., 174
Sepe, A., 235
Sera, D., 36, 51, 69
Serenelli, C., 237
Sereno, D., 188
Serrato Pomar, I.M., 166
Serre, N., 246
Seveno, M., 188
Sevini, F., 177
Shademan, M., 155
Shafiee, A., 159
Shahabi, G.A., 211
Shahabi, S., 186
Shahandeh, K., 71
Shahbazi, F., 186
Shahryary-Rad, E., 208
Sharbatkhori, M., 202
Sheikh Bin Shujaa, R.G., 14
Sheikh, Y., 110
Shelbaya, A., 131
Shemshad, K., 155
Shiffman, J., 11
Shikanai Yasuda, M.A., 75
Shin, C.-S., 45
Shirzadi, M.R., 181
Shmueil, A., 105
Shojaee, S., 198
Shrestha, R., 55
Siadat, S.D., 161
Siba, P., 166
Sibilia, C., 241
Sicuri, E., 241
Sié, A., 32, 115
Sihombing, B., 69
da Silva Filho, L.V.R., 214
Silva Vieira, C., 94, 118
da Silva Wanderley, J., 179, 180
Silva, A., 228
Silva, N., 135
Silvani, I., 137
da Silva-Nunes, M., 94
Simango, M., 99
Simarro, P., 42
Simmons, C.P., 83
Simoes, C., 119
Simões, C., 126
Simondon, F., 31
Simoneschi, B., 137
Simonović, Z., 156
Simons, S., 33
Simporé, J., 33, 101
Singh, R., 182
Singh, S., 60, 182, 186, 187
Sirajudeen, K., 224
Sirajudeen, K.N.S., 54
Siribal, S., 136
Sirichaisinthop, J., 138
Sirima, B.S., 26
Sirisinha, S., 155
Sissoko, D., 37, 167
Sizonenko, S., 238
Skorokhod, O., 3
Skovmand, O., 85
Slabbert, C., 128
Smith, F., 137
Smith, T., 116

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Author Index

Snounou, G., 125
Snoussi, M.A., 184
Snow, R., 82
Soaré, Y., 13
Soares, I., 133
Soares, T.F., 216
Soberon, X., 72
Soboslay, P.T., 12
Sochantha, T., 89
Socheat, D., 45
Sodiomont, S.B., 122
Sojkova, N., 247
Sokhna, C., 31
Soleimani, M., 155
Solon, J.A., 42
Sommerfelt, H., 6
Sorge, F., 27
Sorgho, D., 108
Sorgho, H., 192
Soriano Arandes, A., 185, 200
Sosa, I., 90, 109
Souares, A., 32, 114
Souza, J., 130
Souza, J.M., 128
de Souza, L., 147
de Souza, S., 147
Souza, V.A.U., 83
Souza-Silva, F., 94
Spada, V., 100, 241
Spannbrucker, N., 195
Speare, R., 196
Speich, B., 56
Spencer, L., 115, 127
Speybroeck, N., 85
Spiegelman, D., 69
Spilioti, A., 244
Sporisevic, L., 35, 149
Spreafico, I., 74, 107, 240
Sprecher, A., 4
Squarcia, C., 245
Srisajjarak, W., 138
Staedke, S., 82
Stankovic, K., 234
Stasinopoulos, M., 154
Stefaniak, J., 225
Stefanini, A., 100, 241
Stefanini, C., 102
Steffen, H., 218
Steffens, I., 80
Steinmann, P., 194
Stejskal, F., 220, 247
Stelma, F., 246
Stelma, F.F., 210
Sterk, E., 4
Stevanovic, G., 138, 162, 174
Steyn, D., 127
Stingl, P., 12
Stojkovic, M., 201
Stokx, J., 139
Stosovic, B., 162, 174
Stothard, J.R., 56
Stothard, R., 8, 8
Stremmel, W., 127
Strohmeyer, M., 148, 196, 239
Sturm, P., 246
Sturrock, H., 195
Subirats, M., 218, 227
Sudeck, H., 197, 217
Sufian, M., 209
Suhaimi Ab Wahab, M., 54
Suhaimi, M., 224
Sukhyun, R., 157
Sulaiman, S., 224
Sulaiman, S.A., 54
Suljevic, I., 35
Sumbu, J., 163
Sumintardja, E.N., 35
Sumita, L., 139
Sunahara, T., 58
Sundar, S., 60, 182, 186, 187
Suoranta, J., 100
Surinova, M., 220
Suryanto, A., 222
Suter, F., 74, 240
Suvedi, B.K., 73
Suzuki, T., 220
Swai, N., 46
Sweni, S., 40, 52, 77
Sylla, M., 13
Szostakowska, B., 119, 200
Sztajzel, J., 237

Taghriri, A., 211
Tais, S., 74, 84, 226, 227, 240
Tajeddin, L., 159
Takahashi, K., 142, 174
Talamo, M., 74, 240
Talhari, S., 209, 216
Talisuna, A., 16, 47
Tall, A., 120
Tamarozzi, F., 201
Tamba, M., 49
Tambyah, P., 78
Tan, L.H., 39
Tanner, M., 16, 116
Tannich, E., 58, 155
Tape, J.-F., 31
Taramelli, D., 128, 129
Tardin, A., 76, 237
Tashakori, M., 112, 160
Tateno, A.F., 83, 214
Tatfeng, M., 121
Tavakoli Yazdi, E., 160
Tawfik, M., 213
Taylor, W., 115
Tchuem Tchuenté, L.-A., 8
Teggi, A., 201
Tellez, S.R., 228
Tello, A., 211, 243
Telmadarraiy, Z., 50, 155, 158, 159
Temmerman, M., 20, 25
Tendero, D.T., 78
Terlouw, D., 154
Tesfamariam, A., 41, 146
Tetik, A., 181
Tetteh, K., 125
Tewari, R., 125
Teymoor, K., 177
Thai, K.T.D., 165
Thi Tien, N., 45
Thirumalaikolundusubramanian, P., 40, 52, 77
Thitithanyanont, A., 155
Thoft Nielsen, R., 44
Thomas, F., 27
Thomas, J., 87
Thomas, S., 26
Thuy, T.T., 39
Thybo, S., 191
Thye, T., 41
Tiamkao, S., 174
Tiendrebeogo, G., 52
Tinne, L., 167
Tinto, H., 45, 122, 192
Tiwari, S., 73
Tobar, K., 118
Tognoni, G., 53, 91, 107, 108
Tokuhiro, S., 220
Toledo, M.E., 167, 168, 169
Tolhurst, R., 106
Tomasi, A., 237
Tomasoni, L., 80, 108, 131, 241
Tommasini, S., 131
de la Torre, P., 72
Torreele, E., 43
Torres, D., 169
Torresani, E., 137
Torresi, J., 50
Torrus, D., 211, 240
Torrús, D., 243
Tort, J.F., 190
Tosic, T., 162, 174

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Author Index

Tostmann, A., 40
Toumanian, S., 143
Toure, S., 190
Touré-Baldé, A., 120
Tourre, Y.M., 24
Tovanabutra, S., 34
Tozetto Mendoza, T., 75, 140
Tran, Q.B., 39
Tran, T.N., 39
Traore, A.S., 86
Traore, G., 91
Traore, S.F., 86
Trape, J.-F., 120
Treviño, B., 83
Triana, O., 178
Triki, H., 156
Trillo, G., 229, 233
Trinh Dinh, T., 58
Trisakti, B., 25
Trninic, S., 35, 231
Trojanek, M., 247
Tschan, S., 136
Tsobo, M., 131, 132
Tsolova, S., 84
Tumusherure, E., 51
Turchi, M.D., 83
Turk, K., 156
Tylleskar, T., 91

Ubben, D., 131
Uda, K., 220
Uemura, H., 119
Unganda, L., 121
Uranw, S., 60
Urbano, P., 139
Urbon, J., 238
Ursing, J., 44
Utaisincharoen, P., 155
Uthaisin, C., 45
Utzinger, J., 55, 56, 194, 226

Vaideeswaran, M., 52
Vaillant, M., 115
Vairo, F., 143
Valadkhani, Z., 98
Valdes, V., 72
Valdéz, R.A., 164
Valecha, N., 45
Valencia, T., 95
Valenzuela, M.J., 72
van der Valk, P., 143
Valladares, B., 225
Vallejos, Y., 148
Valls, M., 246
Van Belle, S., 147
Van den Bergh, G., 77
Van den Broeck, F., 188
Van den Ende, J., 2, 17, 78, 94, 122
Van der Roost, D., 18
Van der Stuyft, P., 33, 90, 99, 109, 113, 167, 168, 169
Van Der Veken, W., 42
Van Geertruyden, J.-P., 89
Van Herp, M., 4, 31, 63, 102
Van Lieshout, L., 188
Van Malderen, C., 223
Van Overmeir, C., 94
Vanesa, G., 231
Vanlerberghe, V., 167, 168, 169
Vannberg, F., 41
Varedi, M., 212
Varela, G., 210
Vargas Loza, L., 76
Vargas, D., 118
Vasanthakumari, M., 52
Vasconcelos, P., 78
Vastert-Koop, D., 58
Vatandoost, H., 124, 159
Vaziri, B., 187
Vega, R., 163
Velasco-Tirado, V., 193, 203, 210
Vella, S., 48
Veloci, S., 131
van der Ven, A., 246
Venturelli, C., 49
Venturi, L., 49, 110
Verdejo, F., 142
Vereecken, K., 196
Vergnes, B., 188
Veronesi, C., 71
Verucchi, G., 176
Verweij, J., 195
Verweij, J.J., 188
Vettenburg, N., 25
Vial, H., 8
Viale, P., 140, 232
Vieira, F., 94
Vieira, N.F.D., 108, 154
Viganò, A., 37
Vigano', A., 227
Vigl, M., 93
Vignolles, C., 24
Vilares, A., 93, 176
Villagran, A.L., 148
Villagrán, M., 177
Villalobos, I., 39
Villard, C., 122
Villegas, E., 39, 169
Villegas, L., 134, 136
Vinals, C., 42
Virdone, R., 201
Visser, L., 78
Vitas, A., 212, 224
Volckaert, F., 188
Vommaro, Z., 126
Vonatsou, P., 55
Vounatsou, P., 82, 114
Vranic, B., 129
de Vries, P., 39, 61, 165
Vullo, V., 231
Vulule, J., 85
Vutova, K., 201
Vythilingam, I., 29, 94

Walter, B., 221
Wandwalo, E., 95
Wanji, S., 72, 172
Wears, L., 92
Webster, B., 8, 8
Webster, J., 55, 172
Wehde, T., 224
Weinfeld, M., 136
Weiss, M.G., 215
Welburn, S., 43
Welcome Osain, M., 157, 236
Wernsdorfer, W., 28, 93
Wetsteyn, J., 78
Wiboon-ut, S., 155
Wichmann, D., 31
Wiemer, D., 155
Wilder-Smith, A., 40, 69, 78, 244
Wilhelm-Solomon, M., 35
Williamson, C., 34
Willms, K., 164
Wills, B., 38, 39
Win, A.N., 40
Windle, H., 216
Witter, S., 16
Woerdemann, M., 196
Wolff, F., 125
Wroczyńska, A., 119, 126
Wu, Y., 128
Wyler, C.-A., 238
Wymenga, A.N.M., 208

Xu, Z.-Y., 216

Yaacoub, A., 183
Yamamoto, S., 114, 115
Yanez, J., 72
Yang Yao, D., 177
Yang, C.-F., 167

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Author Index

Yaqub Ibraim, K., 75
Yazdanbakhsh, M., 192
Yegemberdiyeva, R., 169, 170
Yemoa, A., 36
Yildiz Zeyrek, F., 181
Yondo, D., 12, 13, 14
Yongvanitchit, K., 155
Yousefi, H., 160
Yuen, K., 78
Yulihane, R., 69
Yun, O., 76, 76
Yuruhan, L., 23

Zabsonre, E., 91
Zagas, K., 212, 224
Zahabi, F., 156
Zahabiun, F., 208
Zahirnia, A., 124
Zali, M.R., 206, 219
Zalis, M., 128
Zammarchi, L., 131
Zamora, G., 169
Zangeneh, M., 161
Zanger, P., 218
Zannoni, U., 71
Zarei, Z., 182, 208
Zareichian, Z., 215
Zarinfar, N., 209
Zauli, T., 80
Zavarise, G., 74, 240
Zebardast, N., 199
Zebardast, N.Z., 211
Zeeb, H., 213
Zelena, H., 247
Zerbinati, R., 214
Zhou, H., 194
Zhou, X.-N., 194
Zhu, G., 220
Zia Sheikholeslami, N., 116, 138, 141, 161, 244
Zibaei, M., 207
Zibafar, E., 172
Ziem, J., 195
Zimic, M., 95
Zimmermann, P., 93
Ziniel, P., 80
Zinnen, V., 18, 32
Zogo Ongolo, P., 13
Zoss, B., 147
Zuñiga, G., 163
Zwahlen, M., 201

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