

# The impact of conversion on the risk of major complication following laparoscopic colonic surgery

The 2017 European Society of Coloproctology (ESCP) collaborating group; The 2015 European Society of Coloproctology Collaborating Group

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**The impact of conversion on the risk of major complication following laparoscopic colonic surgery: An international, multicentre prospective audit**

The 2015 and 2017 European Society of Coloproctology (ESCP) collaborating groups\*

*\*Collaborating authors listed at end of manuscript*

Correspondence to:

Mr Aneel Bhangu

European Society of Coloproctology (ESCP) Cohort Studies Committee

Department of Colorectal Surgery

University of Birmingham

Heritage Building

Mindelsohn Way

Birmingham, B15 2TH

[a.bhangu@bham.ac.uk](mailto:a.bhangu@bham.ac.uk)

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## Abstract

*Background:* Laparoscopy has now been implemented as a standard of care for elective colonic resection around the world. During the adoption period, studies showed that conversion was may be detrimental to patients, with poorer outcomes than both laparoscopic completed or planned open surgery. The primary aim of this study was to determine whether laparoscopic conversion was associated with a higher major complication rate than planned open surgery in contemporary, international practice. ~~This study aimed to determine the safety profile of laparoscopic conversion in contemporary practice across the world.~~

*Methods:* Analysis of the European Society of Coloproctology 2015 and 2017 audits. Patients were included if they underwent elective resection of a colonic segment from the caecum to the rectosigmoid junction with primary anastomosis. The primary outcome measure was the 30-day major complication rate, defined as Clavien-Dindo grade III-V.

*Results:* Of 3980 patients, 64% (2561/3980) underwent laparoscopic surgery and a laparoscopic conversion rate of 14% (359/2561). The major complication rate was highest after open surgery (laparoscopic 7.4%, converted 9.7%, open 11.6%,  $p < 0.001$ ). After case mix adjustment in a multilevel model, only planned open surgery was associated with increased major complications in comparison to laparoscopic surgery (OR 1.64, 1.27-2.11,  $p < 0.001$ ).

*Conclusions:* Appropriate laparoscopic conversion should not be considered a treatment failure in modern practice. Conversion does not appear to place patients at increased risk of complications versus planned open surgery, supporting broadening of selection criteria for attempted laparoscopy in elective colonic resection.



### **What this study adds**

In modern international practice, 64% of elective colonic resections are started laparoscopically and 14.7% are converted to open. ~~Contradictory to evidence during early adoption,~~ Laparoscopic conversion does not place patients at increased risk of complications when compared to planned open surgery, suggesting colorectal surgeons select patients appropriately for laparoscopic surgery and can convert appropriately. This supports laparoscopy as the primary approach for colonic resection in modern post-implementation practice.

## Introduction

Minimally invasive approaches for colorectal colonic resection are now incorporated into clinical practice in many settings [1]. A number of major international randomised trials (COST, CLASSIC, COLOR I, ALCCaS) have described the safety, feasibility and benefits of laparoscopic segmental resection including reduced intraoperative blood loss, faster return of bowel function and reduced length of stay, without compromise to oncological outcomes [2-7].

Published studies in the initial period of adoption of laparoscopy suggested that patients who undergo conversion from laparoscopic to open surgery had more short-term infections complications and poorer long-term disease-free survival (although oncologically equitable resections) than procedures completed laparoscopically, or those who had planned open surgery [5, 8-10]. Since many units have now overcome unit-level learning curves in the post-implementation era, performance may have changed in terms of indications for conversion, rate of conversion and outcomes when conversion occurs. An Following the IDEAL framework for surgical innovation, up-to-date, multicentre study-surveillance is required to identify need for any practice changes assess the safety and penetrance of laparoscopic colonic resection in contemporary practice (IDEAL stage 4), and to support further roll-out of laparoscopic surgery for novel indications and into new settings.-

The primary aim of this study was to determine whether laparoscopic conversion was associated with a higher major complication rate s than planned open surgery. Our hypothesis was that after adjusted for case-mix, laparoscopic conversion may have a favourable complication profile to primary open surgery within modern post-implementation practice.

## Methods

### *Protocol and centres*

This study combines patients from the 2015 ESCP right hemicolectomy audit and the 2017 ESCP left-sided colorectal resection audit, conducted according to pre-specified protocols (<http://www.escp.eu.com/research/cohort-studies>). Any unit performing elective gastrointestinal surgery was eligible to register to enter patients into the study. No minimum case volume, or centre-specific limitations were specified. Study protocols were disseminated to registered members of the European Society of Coloproctology (ESCP), and through national surgical and colorectal societies, including the European Crohn's and Colitis Organisation.

### *Patient eligibility*

Patients included in this pre-planned analysis were adults ( $\geq 16$  years) undergoing elective segmental colectomy from the caecum to the rectosigmoid colon with a single, primary anastomosis. Open, laparoscopic, and laparoscopic-converted procedures were all included. Patients having robotic or robotic-converted procedures were excluded. Operations with multiple ( $>1$ ) anastomoses were excluded, as were resections including the rectum, those with formation of end colostomy without restoration of gastrointestinal continuity (e.g. Hartmann's procedure) or multivisceral resections. Patients undergoing more extensive resection such as subtotal colectomy or panproctocolectomy were excluded. Both operations for malignant and benign indications were eligible.

### *Data capture*

For right-sided colonic resections, patients were captured over a 6-week period between 15 January 2015 and 15 April 2015. For left-sided colonic resections, patients were included over an 8 week period between 1 February 2017 and 10 May 2017. Teams of up to five surgeons

and surgical trainees worked collaboratively to collect prospective data on all consecutive eligible patients at each centre. All teams included at least one consultant or attending-level surgeon to quality assure data collection. Data was entered contemporaneously on to a secure, user-encrypted online platform (NetSolving and REDCap for 2015 and 2017 audits respectively) without using patient identifiable information. Centres were asked to validate that all eligible patients during the study period had been entered, and to attain >95% completeness of data field entry prior to final submission. Laparoscopic conversion was described as unplanned extension of the primary laparotomy incision, or a secondary laparotomy incision, created intraoperatively for any purpose other than specimen extraction or exteriorization (i.e. to form an anastomosis).

#### *Outcome measure*

The primary outcome measure was the postoperative major complication rate, defined as Clavien-Dindo classification grade 3 to 5 (reoperation, reintervention, unplanned admission to critical care, organ support requirement or death). The secondary outcome measures were (1) overall anastomotic leak, pre-defined as either i) gross anastomotic leakage proven radiologically or clinically, or ii) the presence of an intraperitoneal (abdominal or pelvic) fluid collection on postoperative imaging, ~~and (2) laparoscopic conversion, described as unplanned extension of the primary laparotomy incision, or a secondary laparotomy incision, created intraoperatively for any purpose other than specimen extraction or exteriorization (i.e. to form an anastomosis).~~

#### *Statistical analysis*

This report has been prepared in accordance to guidelines set by the STROBE (strengthening the reporting of observational studies in epidemiology) [11] statement for observational studies. Patient, disease and operative characteristics were compared using Student's t-test for normal,



continuous data, Mann-Whitney U test for non-normal continuous data or Chi-squared test for categorical data. To test the association between the major complications and the main explanatory variables of interest (laparoscopic completed, laparoscopic converted, and open surgery), a mixed-effects logistic regression model was fitted. Clinically plausible patient, disease and operation-specific factors were entered into the model for risk-adjustment, treated as fixed effects. These were defined *a priori* within the study protocol and included irrespective of their significance on univariate analysis. The treating hospital were entered into the model as a random-effect, to adjust for hospital-level variation in outcome. Similar models were created to assess associations with the secondary outcome measures (anastomotic leak and laparoscopic conversion). Effect estimates are presented as odds ratios (OR) with 95% confidence intervals (95% CI) and two-tailed p-values. An alpha level of 0.05 was used throughout. Data analysis was undertaken using R Studio V3.1.1 (R Foundation, Boston, USA).

#### *Ethical approval*

All participating centres were responsible for compliance to local approval requirements for ethics approval or indemnity as required. In the UK, the National Research Ethics Service tool recommended that this project was not classified as research, and the protocol was registered as clinical audit in all participating centres.

## Results

### *Patients and cCentres*

In this study, 3,980 patients, from 566 centres across 48 countries underwent an elective colonic resection (Figure 1). 1,419 (36%) received planned open surgery and 2,561 (64%) had their procedures started laparoscopically. Of these laparoscopic operations, 359 required conversion to open surgery, resulting in a conversion rate of 14.7% (Figure 2).

Compared to those who underwent a planned open resection, laparoscopic converted patients were older (converted vs. open; 35.9% vs. 29.7% aged 70-80 years), more likely to be male (60.7% vs. 51.1%), have a low ASA grade (65.2% vs. 56.0%), be obese (26.5% vs. 20.2%) and were less likely to have a history of ischaemic heart disease/cerebrovascular accident (15.9% vs. 21.7%). Compared to those who underwent a completed laparoscopic resection, patients that required a laparoscopic conversion were older (converted vs. laparoscopic; 16.7% vs. 14.2% aged >80 years), more likely to be male (60.7% vs. 51.5%), have a high ASA grade (ASA 3 to 5; 34.5% vs. 27.3%) and be obese (26.5% vs. 21.3%) (Table 1). ~~Compared to those who underwent a planned open resection, laparoscopic converted patients were older (converted vs. open; 35.9% vs. 29.7% aged 70-80 years), more likely to be male (60.7% vs. 51.1%), have a low ASA grade (65.2% vs. 56.0%), be obese (26.5% vs. 20.2%) and were less likely to have a history of ischaemic heart disease/cerebrovascular accident (15.9% vs. 21.7%).~~

### *Unadjusted postoperative outcomes*

Completed laparoscopic surgery was associated with low rates of major postoperative complications, anastomotic leaks and re-operation (Table 2). When comparing the unadjusted postoperative outcomes between laparoscopic converted and open surgeries, ~~while laparoscopic conversions were associated with higher rates of anastomotic leak (converted vs. open; 9.5% vs. 8.4%) and re-operations (8.1% vs. 6.8%), and lower rates of major postoperative complications (9.7% vs. 11.6%),~~ there were no significant differences in major postoperative

complications (9.7% vs. 11.6%), re-operation (8.1% vs. 6.8%), or anastomotic leak (converted vs. open; 9.5% vs. 8.4%) rates between the groups.

#### *Adjusted postoperative outcomes*

The major complication rate was highest after open surgery (laparoscopic 7.4%, converted 9.7%, open 11.6%,  $p<0.001$ ). After adjustment for confounding factors, in comparison to completed laparoscopic surgery, open surgery was associated with increased major postoperative complications (OR 1.64, 1.27-2.11,  $p<0.001$ ) but laparoscopic converted surgery was not (OR 1.24, 0.83-1.87,  $p=0.30$ ) (Table 3). The anastomotic leak rate was highest after converted surgery (5.4%, 9.5%, 8.4% respectively,  $p<0.001$ ). In the multilevel model, laparoscopic converted surgery (OR 2.07, 1.34-3.21,  $p=0.001$ ) and open surgery (OR 1.87, 1.37-2.56,  $p<0.001$ ) had similar higher risks of leak compared to completed laparoscopic surgery (Table 4).

#### *Predicting laparoscopic conversion to open surgery*

In the multivariable analysis, independent predictors of laparoscopic conversion were (Table 5):

- Age  $\geq 70$  years (age 71-80, OR 1.55, 1.03-2.32,  $p=0.04$ ; age  $>80$ , OR 1.62, 1.00-2.61,  $p=0.05$ )
- Male gender (OR 1.50, 1.17-1.93,  $p=0.001$ )
- ASA grade 3-5 (OR 1.43, 1.07-1.92,  $p=0.02$ )
- Low BMI (Underweight, OR 2.37, 1.18-4.75,  $p=0.02$ )

Patients with a history of ischaemic heart disease or cerebrovascular accident were less likely to have a conversion (OR 0.65, 0.45-0.93,  $p=0.029$ ).

## Discussion

This study showed that laparoscopic converted colonic resection was not associated with increased major complications compared to laparoscopic completed surgery, or with increased anastomotic leaks compared to open surgery. This supports laparoscopic resection as the primary approach when colonic resection is indicated. It suggests that, following widespread implementation of laparoscopic surgery over the last two decades, as surgical experience has increased colorectal surgeons are now able to better select patients appropriately for both a complete laparoscopic operation, and judge intraoperatively ~~thus by inference when~~ to convert to an open operation procedure.

In this multicentre international study, two thirds of patients underwent a planned laparoscopic operation. This is one of the highest rates described worldwide showing the high implementation of laparoscopic approach in contemporary practice [12]. This study did not collect data on previous surgery or size or stage of lesion resection, which may have indicated that an open operation in the first instance was entirely appropriate. We also have not included robotic surgical approaches in this analysis which may underestimate the overall minimally invasive surgery rate. However, our data provides scope to increase the laparoscopic rate in units or areas where it has not yet been implemented (including those in low and middle-income settings).-

The conversion rate was 14%, consistent with a decreasing trend since the introduction of laparoscopic surgery. In 2005, the CLASICC trial showed a laparoscopic conversion rate of 29.0% [3]. Subsequently, several studies showed conversion rates between 10.4% - 29.0% with detrimental outcome [3, 4, 13-15]. More recently, a Dutch national review reported a conversion

rate of 8.6% for colon cancer [13]. The literature has been divided about whether conversion impacts detrimentally on short-term outcomes. Dutch series have reported higher rates of postoperative complications in patients who had laparoscopic conversion when compared to open resections. These rates were significantly higher in those with late conversion (>30 minutes) compared to early conversion (OR 1.34, 1.05-1.72). There was no impact of conversion on mortality in these patients [13]. In contrast, one of the largest series of segmental resections reported, with 207,311 patients operated in the United States, found that conversion had a higher morbidity and mortality than completed laparoscopic procedures, but better outcomes than primary open procedures [16]. Allaix et al. showed no significant differences in short-term postoperative morbidity, mortality, or hospital stay between converted and laparoscopic completed group in a cohort of 1114 patients [5]. The present prospective multicentre study, validates the findings of these retrospective analyses in a modern, within-a real-world cohort, demonstrating that conversion does not place patients at increased risk of major complications, and nor does it alter the baseline risk of leak to that of open surgery. This is likely to reflect satisfactory patient selection for both the initial laparoscopic procedure and also the time to conversion to open surgery; however, we did not collect specific information on early versus later conversions, or the indication for conversion in this study.

Our data demonstrates that male gender, older age, low BMI and higher ASA grade are all associated with a higher risk of laparoscopic conversion. The factors included within this model are not comprehensive; presence of intraabdominal abscess or fistula, previous surgery and surgeon experience were not collected here [17]. Therefore this analysis should be seen as exploratory only. Whilst, this study supports a laparoscopic first approach where feasible, presentation of this data with help tailor informed consent for patients undergoing attempted laparoscopic colonic surgery using simple, easily comprehensible patient factors. Despite

equivalent short-term patient outcomes, laparoscopic conversion is not without consequence to patients and health systems. Health economic data from the United States suggests a prolonged length of stay and significant cost implication to laparoscopic conversion (adjusted mean cost: \$20,165) versus planned open (\$18,797) or laparoscopic completed surgery (\$16,206) [18]. Better understanding of why and when colorectal surgeons choose to convert remains an important focus for future research.

All observational studies have limitations. We have tried to mitigate against some of the limitations of observational studies in our study methods.—In this case, firstly the inherent selection bias for laparoscopic and laparoscopic-open surgery conversion may have varied between centres and surgeons, subjecting patients to different outcomes masked by a pooled analysis. This is-bias is lessened mitigated by collating an international-analysis-dataset that was adjusted using mixed-effects modelling for case-mix, was pre-planned and that allows local units to benchmark their own performance against. The chance of selection and reporting biases was further reduced by the inclusion of all eligible patients at each centre. Other studies have reported contemporary practice in laparoscopic colonic surgery, including larger patient groups than included here. However, these include data from a single country and are retrospective analyses of registries [16, 19]. Prospective data collection, pre-specified analysis plans, and an international cohort from 48 countriesThe high number of countries, centres, and patients increases external validity of our study findings. There was a two-year interval in data collection between right-sided (2015) and left-sided (2017) resections. Increasing surgeon experience over these two years may have led to reduced conversions and improved postoperative outcomes within the left-sided resection group. However, the site of resection was not identified as a significant predictor of conversion, indicating that this short interval did not have a significant impact on this study.

Although we did not analyse by unit or country (as pre-planned in the study protocol), identifying and reaching units that have low laparoscopy rates—to safely increase patients' access to technology should be a priority. ~~This~~[The introduction of laparoscopic colonic surgery over the past 25 years](#) is a model for dissemination of new surgical techniques and makes this an example of an IDEAL phase 4 study [\[2017\]](#).

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## **Authorship List ([PubMed Citable](#))**

### **Writing Group**

James Glasbey, Anne van der Pool, Alexandra Rawlings, Luis Sánchez-Guillén, [Sara Kuiper](#),  
Ionut Negoii, Nicholas Buchs, [Sara Kuiper](#), Thomas Pinkney, Aneel Bhangu (Chair)

—

### **ESCP Cohort Studies and Audits Committee**

[Alaa El-Hussuna \(2017 Audit Lead\)](#), [Nick J. Battersby](#), [Aneel Bhangu](#), [Nicholas C. Buchs](#),  
[Christianne Buskens](#), [Sanjay Chaudri](#), [Matteo Frasson](#), [Gaetano Gallo](#), [James Glasbey](#), [Ana](#)  
[María Minaya-Bravo](#), [Dion Morton](#), [Ionut Negoii](#), [Dmitri Nepogodiev](#), [Francesco Pata](#), [Luis](#)  
[Sánchez-Guillén](#), [Baljit Singh](#), [Oded Zmora](#), [Thomas Pinkney \(Chair\)](#)

### **Statistical Analysis and Data Management**

[James Glasbey](#), [Dmitri Nepogodiev](#), [Rita Perry](#), [Laura Magill](#), [Aneel Bhangu \(Guarantor\)](#)

### **ESCP Research Committee**

[Dion Morton \(Chair\)](#), [Donato Altomare](#), [Willem Bemelman](#), [Steven Brown](#), [Christianne Buskens](#)  
[Quentin Denost](#), [Charles Knowles](#), [Søren Laurberg](#), [Jérémie H. Lefeuvre](#), [Gabriela Möeslein](#),  
[Tom Pinkney](#), [Carolynne Vaizey](#), [Oded Zmora](#)

### **Collaborators**

[Albania: S. Bilali, V. Bilali \(University Hospital Center Mother Teresa\).](#)

[Argentina: M. Salomon, M. Cillo, D. Estefania, J. Patron Uriburu, H. Ruiz \(Buenos Aires British](#)  
[Hospital\); P. Farina, F. Carballo, S. Guckenheimer \(Hospital Pirovano\).](#)

Australia: D. Proud, R. Brouwer, A. Bui, B. Nguyen, P. Smart (Austin Hospital); A. Warwick, J. E. Theodore (Redcliffe Hospital).

Austria: F. Herbst, T. Birsan, B. Dauser, S. Ghaffari, N. Hartig (Barmherzige Brueder, Wien); A. Stift, S. Argeny, L. Unger (Medical University of Vienna); R. Strouhal, A. Heuberger (Oberndorf b. Salzburg).

Belarus: A. Varabei, N. Lahodzich, A. Makhmudov, L. Selniahina (Minsk Regional Clinical Hospital).

Belgium: T. Feryn, T. Leupe, L. Maes, E. Reynvoet, K. Van Langenhove (AZ Sint-Jan Brugge); M. Nachtergaele (AZ St Jozef); B. Monami, D. Francart, C. Jehaes, S. Markiewicz, J. Weerts (Clinique St Joseph, Liege); K. Van Belle, B. Bomans, V. Cavenaile, Y. Nijs, M. Vertruyen (Europe Hospitals Brussels); P. Pletinckx, D. Claeys, B. Defoort, F. Muysoms, S. Van Cleven (Maria Middelaes Gent); C. Lange, K. Vindevoghel (OLV van Lourdes Hospital Waregem); A. Wolthuis (University Hospital Leuven).

Bosnia and Heregovina: M. Todorovic, S. Dabic, B. Kenjic, S. Lovric, J. Vidovic (JZU Hospital Sveti Vračevi); S. Delibegovic, Z. Mehmedovic (University Clinic Center Tuzla).

Brazil: A. Christiano, B. Lombardi, M. Marchiori Jr, V. Terciotti Jr (Hospital Centro Médico de Campinas).

Bulgaria: D. Dardanov, P. Petkov, L. Simonova, A. Yonkov, E. Zhivkov (Alexandrovska Hospital - First Surgery); S. Maslyankov, V. Pavlov, M. Sokolov, G. Todorov (Alexandrovska Hospital, Second Surgery Clinic); V. Stoyanov, I. Batashki, N. Iarumov, I. Lozev, B. Moshev (Medical

Institute - Ministry of Interior); M. Slavchev, B. Atanasov, N. Belev, P. Krstev, R. Penkov (University Hospital - Eurohospital).

Croatia: G. Šantak, J. Čosić, A. Previšić, L. Vukušić, G. Zukanović (County Hospital Požega); M. Zelić, D. Kršul, V. Lekić Vitlov, D. Mendrila (University Hospital Rijeka).

Czech Republic: J. Orhalmi, T. Dusek, O. Maly, J. Paral, O. Sotona (Charles University Hospital). M. Skrovina, V. Bencurik, M. Machackova (Complex Oncology Centre Novy Jicin, Surgical Department); Z. Kala, M. Farkašová, T. Grollich, V. Procházka (Surgical Department, University Hospital Brno); J. Hoch, P. Kocian, L. Martinek (University Hospital Motol, Prague); F. Antos, V. Pruchova (University Hospital Prague Bulovka).

Denmark: A. El-Hussuna, A. Ceccotti, T. Madsbøll, D. Straarup, A. Uth Ovesen (Aalborg University Hospital); P. Christensen, P. Bondeven, P. Edling, H. Elfeki, V. Alexandrovich Gameza, S. Michelsen Bach, I. Zheltiakova (Aarhus University Hospital/Randers Regional Hospital); PM. Krarup, A. Krogh, H-C. Rolff (Bispebjerg); J. Lykke, A. F. Juvik, H. H. K. Lóven, M. Marckmann, J. T. F. Osterkamp (Herlev Hospital); A. H. Madsen, J. Worsøe (Hospital Unit West); A. Ugianskis (North Denmark Regional Hospital); M. D. Kjær, B. Youn Cho Lee (Odense University Hospital); A. Khalid, M. H. Kristensen (Regional Hospital Viborg).

Egypt: M. El Sorogy, A. Elgeidie, M. Elhemaly, A. El Nakeeb, M. Elrefai (Gastrointestinal Surgery Center, Mansoura University); M. Shalaby, S. Emile, W. Omar, A. Sakr, W. Thabet (Mansoura University Hospital); S. Awny, I. Metwally, B. Refky, N. Shams, M. Zuhdy (Oncology Center Mansoura University).

Finland: A. Lepistö, I. Keränen, A. Kivelä, T. Lehtonen, P. Siironen (Helsinki University Hospital); T. Rautio, M. Ahonen-Siirtola, K. Klintrup, K. Paarnio, H. Takala (Oulu University

Hospital); M. Hyöty, E. Haukijärvi, S-M. Kotaluoto, K. Lehto, T. Tomminen (Tampere University Hospital); H. Huhtinen, A. Carpelan, J. Karvonen, A. Rantala, P. Varpe (Turku University Hospital).

France: E. Cotte, Y. Francois, O. Glehen, G. Passot (Centre Hospitalier Lyon Sud); A. d'Alessandro, E. Chouillard, J. C. Etienne, E. Ghilles, B. Vinson-Bonnet (Centre Hospitalier Poissy Saint Germain en LayeCHIPS); A. Germain, A. Ayav, L. Bresler (CHU Nancy-Brabois); R. Chevalier, Q. Denost, R. Didailler, E. Rullier (Hopital Haut Leveque); E. Tiret, N. Chafai, J. H. Lefevre, Y. Parc (Hôpital Saint-Antoine); I. Sielezneff, D. Mege (Timone Hospital); Z. Lakkis (University Hospital of Besancon); M. Barussaud (University Hospital of Poitiers).

Germany: C. Krones, B. Bock, R. Webler (Marienhospital Aachen); J. Baral, T. Lang, S. Münch, F. Pullig, M. Schön (Städtisches Klinikum Karlsruhe); S. Hinz, T. Becker, T. Möller, F. Richter, C. Schafmayer (University Hospital Schleswig-Holstein, Kiel); J. Hardt, P. Kienle (University Medical Center Mannheim); F. Crescenti, M. Ahmad, Y. Soleiman (Verden KRH).

Greece: I. Papaconstantinou, A. Gklavas, K. Nastos, T. Theodosopoulos, A. Vezakis (Areteion Hospital); K. Stamou, A. Saridaki (Athens Bioclinic); E. Xynos, S. Paraskakis, N. Zervakis (Creta-InterClinic Hospital); G. Skroubis, T. Amanatidis, S. Germanos, I. Maroulis, G. Papadopoulos (General University Hospital of Patras); N. Dimitriou, A. Alexandrou, E. Felekouras, J. Griniatsos, I. Karavokyros (Laiko Hospital); A. Papadopoulos, C. Chouliaras, P. Ioannidis, D. Katsounis, E. Kefalou (Nikaia General Hospital); I. E. Katsoulis, D. Balalis, D. P. Korkolis, D. Manatakis (St. Savvas Cancer Hospital); G. Tzovaras, I. Baloyiannis, I. Mamaloudis (University Hospital of Larissa).

Hungary: G. Lázár, S. Ábraham, A. Paszt, Z. Simonka, I. Tóth (Department of Surgery, University of Szeged); A. Zaránd, Z. Baranyai, G. Ferreira, L. Harsányi, P. Ónody (Semmelweis

University, 1st Clinic of Surgery); B. Banky, Á. Burány, M. Lakatos, J. Marton, A. Solymosi (St. Borbala Hospital); I. Besznyák, A. Bursics, G. Papp, G. Saffics, I. Svastics (Uzsoki Hospital);

Iceland: E. Valsdottir, J. Atladottir, T. Jonsson, P. Moller, H. Sigurdsson (University Hospital of Iceland).

India: S. K. Gupta, S. Gupta, N. Kaul, S. Mohan, G. Sharma (Government Medical College, Jammu, Jammu and Kashmir, India); R. Wani, N. Chowdri, M. Khan, A. Mehraj, F. Q. Parray (Sher-i-Kashmir Institute of Medical Sciences).

Ireland: A. Coveney, J. Burke, J. Deasy, S. El-Masry, D. McNamara (Beaumont Hospital); M. F. Khan, R. Cahill, E. Faul, J. Mulsow, C. Shields (Mater Misericordiae University Hospital); M. E. Kelly, G. Bass, S. T. Martin, R. O'Connell, E. Ryan (St Vincent's Private Hospital); T. Connelly, G. Ahmad, W. Bukhari, F. Cooke (University Hospital Waterford).

Israel: O. Zmora, R. Gold Deutch, N. Haim, R. Lavy, A. Moscovici (Assaf Harofe Medical Center); N. Shussman, R. Gefen, G. Marom, A. Pikarsky, D. Weiss (Hadassah Hebrew University Medical Center); S. Avital, N. Hermann, B. Ragan, M. Slavin, I. White (Meir Medical Center); N. Wasserberg, H. Arieli, N. Gurevich (RMC, Beilinson Campus); M. R. Freund, S. Dorot, Y. Edden, G. Halfteck, P. Reissman, ~~E. Yair~~ (Shaare Zedek ~~Mount Sinai~~ Medical Center); Y. Edden, R. Pery (Sheba Medical Center); H. Tulchinsky, A. Weizman (Sourasky Medical Center).

Italy: F. Agresta, R. Curinga, E. Finotti, G. Savino, L. A. Verza (Adria Hospital); C. R. Asteria, L. Boccia, A. Pascariello (ASST - Mantua); N. Tamini, A. Bugatti, L. Gianotti, M. Totis (Asst-Monza, Ospedale San Gerardo); L. Vincenti, V. Andriola, I. Giannini, E. Travaglio (Azienda

Ospedaliero Universitaria Consorziata Policlinico di Bari); R. Balestri, P. Buccianti, N. Roffi, E. Rossi, L. Urbani (Azienda Ospedaliero Universitaria Pisana); A. Mellano, A. Cinquegrana (Candiolo Cancer Institute IRCCS); A. Lauretta, C. Belluco (Chirurgia Oncologica Generale, IRCCS Centro di Riferimento Oncologico, Aviano ~~Centro di Riferimento Oncologico, IRCCS, Aviano~~); M. Mistrangelo, M. E. Allaix, S. Arolfo, M. Morino, V. Testa (Citta della Salute e della Scienza di Torino); P. Delrio, U. Pace, D. Rega, D. Scala (Division of Colorectal Surgery, Department of Abdominal Surgery, Istituto Nazionale Tumori "Fondazione G.Pascale ", IRCCS ~~Naples Colorectal Surgical Oncology Istituto Nazionale per lo Studio e la Cura dei Tumori~~); G. Gallo, G. Clerico, S. Cornaglia, A. Realis Luc, M. Trompetto (Department of Colorectal Surgery, S. Rita Clinic); G. Ugolini, N. Antonacci, S. Fabbri, I. Montroni, D. Zattoni (Faenza Hospital); C. D'Urbano, A. Cornelli, M. Viti (G. Salvini); M. Inama, M. Bacchion, A. Casaril, H. Impellizzeri, G. Moretto (Hospital Dott. Pederzoli); A. Spinelli, M. Carvello, G. David, F. Di Candido, M. Sacchi (Humanitas Research Hospital); A. Frontali, V. Ceriani, M. Molteni (IRCCS MultiMedica); R. Rosati, F. Aleotti, U. Elmore, M. Lemma, A. Vignali (IRCCS San Raffaele, Department of Gastrointestinal Surgery ~~IRCCS Ospedale San Raffaele~~); S. Scabini, G. Casoni Pattacini, A. Luzzi, E. Romairone (Policlinico ~~IRCCS San Martino, Genoa -IST~~); F. Marino, D. Lorusso, F. Pezzolla (Dept. of General Surgery, IRCCS "Saverio de Bellis", Castellana Grotte (Ba) ~~IRCCS 'Saverio de Bellis'~~); F. Colombo, C. Baldi, D. Foschi, G. Sampietro, L. Sorrentino (L. Sacco University Hospital); S. Di Saverio, A. Birindelli, E. Segalini, D. Spacca (Maggiore Hospital); G. M. Romano, A. Belli, F. Bianco, S. De franciscis, A. Falato (Surgical Oncology Istituto Nazionale Tumori G.Pascale ~~National Cancer Institute -Naples~~); A. Muratore, P. Marsanic (Ospedale Agnelli Pinerolo); S. Grimaldi, N. Castaldo, M. G. Ciolli, P. Picarella, R. Porfidia (Ospedale Convenzionato Villa d' ~~Dei Fiori Acerra~~); S. Di Saverio, A. Birindelli, G. Tugnoli (Ospedale Maggiore); A. Bondurri, D. Cavallo, A. Maffioli, A. Pertusati (Ospedale Sacco Italy); F. Pulighe, F. Balestra, C. De Nisco, M. Podda (Ospedale San Francesco); E. Opocher, M. Longhi, N. M. Mariani, N. Maroni, A. Pisani Ceretti (Ospedale San Paolo); R. Galleano, P. Aonzo, G. Curletti,



L. Reggiani (Ospedale Santa Corona); M. Marconi, L. Del Prete, M. Oldani, R. Pappalardo, S. Zaccone I (Ospedale Santa Maria delle Stelle); M. Scatizzi, M. Baraghini, S. Cantafio, F. Feroci, I. Giani (Ospedale Santo Stefano, Prato); R. Tutino, G. Cocorullo, G. Gulotta, L. Licari, G. Salamone (Policlinico 'P. Giaccone'); P. Sileri, F. Saraceno (Policlinico Tor Vergata); F. La Torre, P. Chirletti, D. Coletta, G. De Toma, A. Mingoli (Policlinico Umberto I 'Sapienza University'); M. Papandrea, E. De Luca, R. Sacco, G. Sammarco, G. Vescio (Policlinico Universitario di Catanzaro); V. Tonini, S. Bianchini, M. Cervellera, S. Vaccari (Policlinico universitario Sant'Orsola-Malpighi, Universita degli Studi di Bologna); N. Cracco, G. Barugola, E. Bertocchi, R. Rossini, G. Ruffo (Sacro Cuore Don Calabria Hospital); A. Sartori, N. Clemente, M. De Luca, A. De Luca, G. Scaffidi (San Valentino Hospital); L. Lorenzon, G. Balducci, T. Bocchetti, M. Ferri, P. Mercantini (Sant'Andrea Hospital); F. Pata, S. Bauce, A. Benevento, C. Bottini, P. R. Crapa (Sant' Antonio Abate Hospital, Gallarate); M. Rubbini, G. Anania, P. Carcoforo, G. Cavallesco, C. Feo (University Hospital of Ferrara).

Japan: T. Yamamoto (Yokkaichi Hazu Medical Centre).

Latvia: A. Sivins, G. Ancans, S. Gerkis, R. Lunis, A. Pcolkins (Latvia Oncology Center).

Lithuania: D. Venskutonis, S. Bradulskis, E. Dainius, A. Subocius, J. Vencius (Department of General Surgery, LSMU, Kaunas Clinical Hospital); P. Zeromskas, V. Eismiontas, V. Nutautiene, D. Simcikis, A. Tamosiunas (Klaipeda University Hospital); S. Svagzdys, T. Latkauskas, P. Lizdenis, Z. Saladzinskas, A. Tamelis (Lithuanian University of Health Sciences Hospital Kauno Klinikos); A. Dulskas, J. Kuliavas, N. E. Samalavicius (National Cancer Institute, Lithuania); T. Poskus, V. Jotautas, S. Mikalauskas, E. Poskus, K. Strupas (Vilnius University).

Malaysia: A. D. Zakaria, N. N.Lah, M. Wong, W. Z. Zain, Z. Zakaria (Department of Surgery, School of Medical Sciences, ~~Hospital~~ Universiti Sains Malaysia / Hospital Universiti Sains Malaysia); L. Mazlan, Z. A. Mohd Azman, I. Sagap (UKM Medical Centre).

Malta: J. Psaila, P. Andrejevic, C. Cini, S. Ellul, K. Pace (Mater Dei Hospital). Morocco: M. Ahallat, M. Hamid, A. Hrorra, M. A. Majbar, M. Raiss (Ibn Sina University Hospital).

Netherlands: E. Westerduin, W. Bemelman, C. Buskens, P. Tanis (Academic Medical Centre); P.C. van der Sluis, P.H. Davids, A. Pronk, A.H.W. Schiphorst, N. Smakman (Diakonessenhuis); D. Zimmerman, T. Koeter, J. Stijns, Y-T. van Loon (Elisabeth TweeSteden Hospital); M. Vermaas, E. de Graaf, P. Doornebosch, P. van Hagen, O. van Ruler (Ijsselland Ziekenhuis); B. Toorenvliet, J. Nonner, I. van den Berg, L. van Steensel, W. Vles (Ikazia); J. Melenhorst, R. Orsini, R. Visschers (Maastricht University Medical Centre); C. Hoff (Medical Center Leeuwarden); R. Blom, H. Marsman (Onze Lieve Vrouwe Gasthuis); I. Mulder, H. Cense, S. de Castro, A. Demirkiran, M. Hunfeld (Rode Kruis Ziekenhuis Beverwijk); A. van Geloven, J. de Groof, E. Hendriks, M. Leeuwenburg, N. van Oorschot (Tergooi); F. Wit, C. Rupert, P. Veldman (Tjongerschans ziekenhuis); M. Keijzers, J. Konsten (VieCuri Medisch Centrum voor Noord Limburg); F. Den Boer, M. Corver (Zaans Medical Center); E. G.-J. Boerma, L. Koolen, M. Martens, K. Van Wijck (Zuyderland Medical Center).

Norway: D. Ignjatovic, R. Breuer, B. Gurpreet, T. Oresland, T. Tetens Moe (Akershus University Hospital); A. Nesbakken, I. Flaaten, Backe, T-A. Wik (Oslo University Hospital); K. Radiya, T. Delhi, P. Gjessing, S. Norderval, K. Woll (University Hospital of North Norway).

Pakistan: M. Anwer, M. S. Qureshi (JPMC WARD 2); A. U. Qureshi, M. Billah, M. Y. Jawad, A. Raza, N. Urooj (King Edward Medical University/Mayo Hospital, Lahore).

People's Republic of China: X. Wang, L. Li (West China Hospital in Sichuan University). Poland: D. Jajtner, B. Gasinski, W. Kabiesz (Beskidian Oncology Center); P. Walega, M. Romaniszyn (Third Department of General Surgery, Jagiellonian University Medical College); M. Zawadzki, R. Czarnecki, Z. Obuszko, M. Rzaca, M. Sitarska (Wojewódzki Szpital Specjalistyczny).

Portugal: P. Silva, A. Duarte, D. Gonçalves, M. Morais (Centro Hospitalar de S. João); N. Rama, J. Nobre, I. Sales (Centro Hospitalar Leiria, EPE); J. Costa Pereira, S. Costa, C. Costa Pereira, C. Insua, I. Romero (Centro Hospitalar Tâmega e Sousa); N. Figueiredo, J. Cunha, H. Domingos, P. Vieira (Champalimaud Foundation); M. Cunha, M. Americano, E. Amorim, J. Rachadell (Cirurgia 2 - CHA - Unidade Portimão); J. M. Carvas, I. Armas, P. Fernandes, C. Pires, R. Reis (Hospital de Bragança); R. Martins, M. Dos Santos, P. Henriques (Hospital de Faro, Centro Hospitalar do Algarve); O. Oliveira, M. Duarte, L. Ferreira, J. Miranda, N. Vilela (Hospital Distrital de Santarém, E.P.E.); J. Corte Real, S. Carlos, M. Frois Borges, P. Moniz Pereira, J. Simões (Hospital Garcia de Orta); P. Silva-vaz, V. Bettencourt, A. Gouveia, H. Perez, R. Rainho (Unidade Local de Saúde de Castelo Branco).

Romania: V. Bintintan, C. Ciuce, G. Dindelegan, R. Scurtu, R. Seicean (Clinica Chirurgie I); D. Cristian, T. Burcos, F. Grama, D. M. Mandi, G. Richiteanu (Coltea Clinical Hospital); A. Miron, V. Calu, O. Enciu, M. Nadragea, R. Parvuletu (Elias Emergency Hospital); S. S. Mogoanta, A. Crafcuic, S. Paitici (Emergency County Hospital of Craiova); I. Negoii, M. Beuran, C. Ciubotaru, A. Prodan, M. Vartic (Emergency Hospital of Bucharest); V. Tomulescu, C. Copaescu (Ponderas Academic Hospital).

Russia: A. Yanishev, A. Abelevich, A. Kokobelyan, M. Lebedeva, R. Luzan (FSBEI HE PRMU MOH); D. Popov, A. Sednev, A. Klimenko, A. Semenov, S. Vasilyev (City Hospital 9); A. Pozdnyakov, D. Cherdancev, D. Mahotin, A. Nesytykh, V. Samsonyuk (Krasnoyarsk Regional

Clinical Hospital); I. Pravosudov, D. Ivlev, A. Karachun, K. Lebedev, D. Samsonov (N.N. Petrov National Medical Research Institute Center of Oncology); R. Aiupov, D. Feoktistov, M. Garipov, S. Nail, N. Tarasov (National Republic Oncology Center); A. Yanishev, A. Abelevich, A. Kokobelyan, M. Lebedeva, R. Luzan (Nizhny Novgorod Regional Clinical Hospital); R. Aiupov, D. Feoktistov, M. Garipov, N. Suleymanov, N. Tarasov (Republican Oncological Centre, Ufa); A. Rasulov, H. Dzhumabaev, Z. Mamedli (Russian Cancer Research Center); A. Bedzhanyan (Russian Research Center of Surgery named after B.V.Petrovsky); D. Popov, A. Sednev, A. Klimenko, A. Semenov, S. Vasilyev (Saint-Petersburg City Hospital 9); A. Khazov, M. Khanevich, G. Khrykov (Saint-Petersburg Clinical Oncological Health Center); S. Katorkin, P. Andreev, A. Chernov, O. Davidova, A. Zhuravlev (Samara State Medical University); S. Achkasov, D. Shakhmatov, Y. Shelygin, O. Sushkov, A. Vardanyan (State Scientific Centre of Coloproctology); A. Ilkanich, N. Barbashinov, V. Darvin, S. Onishchenko, Y. Voronin (Surgut District Hospital).

Serbia: Z. Krivokapić, G. Barišić, I. Dimitrijević, V. Marković, A. Sekulić (Clinic for Digestive Surgery-First Surgical Clinic, Clinical Center of Serbia, University of Belgrade, Medical Faculty); G. Stanojevic, B. Brankovic, M. Nestorovic, V. Pecic, D. Petrovic (Clinic for General Surgery, Clinical Center Nis); I. Kostic, A. Aleksic, D. Dabic, B. Maric, V. Perunicic (General Hospital Cacak); Z. Radovanovic, M. Djuric, D. Lukic, D. Radovanovic (Oncology Institute of Vojvodina); V. Cuk, V. Cuk, J. Juloski, M. Kenic, I. Krdzic (Surgical Clinic KBC Zvezdara).

Singapore: J. C. Ngu, Y. Y. Ng, N. Teo (Changi General Hospital).

Slovak Republic: J. Korcek, A. Lazorisak, (Faculty Hospital Nitra).

Slovenia: M. Rems, Š. Ramovš Trampuš (General Hospital Jesenice); A. Tomazic, J. Grosek, J. Kosir, G. Norcic (University Medical Centre Ljubljana).

Spain: V. Vigorita, N. Caceres, E. Casal, A. Ruano, I. Trostchansky (Alvaro Cunqueiro Hospital); T. Golda, A. Galvez Saldaña, E. Kreisler Moreno, J. Lopez Dominguez, M. Vila Tura (Bellvitge University Hospital); F. Labarga, P. Galvez, V. Maderuelo, C. Suero (Complejo Asistencial Universitario de Palencia); J. Bargallo, L. Cayetano, S. Lamas, M. C. Silva (Consorti Sanitari de Terrassa - Hospital de Terrassa); J. C. Bernal-Sprekelsen, R. Gómez, S. Jareño, A. Ríos, D. Vercher (Consortio Hospital General Universitario); J-M. García-González, J. Cervera-Aldama, J. Ramos-Prada, M. Santamaría-Olabarrieta (Cruces University Hospital); N. Borda, J. M. Enrriquez-Navascués, Y. Saralegui (Donostia University Hospital); A. Calero-Lillo, S. Aznar-Puig, M. A. López-Lara, S. Muñoz-Collado, J. Valverde-Sintas (Fundacio Hospital Esperit Sant); P. Menendez, C. Leon (Gutierrez Ortega Hospital); N. Truan, R. Baldonado, D. Fernández-Martínez, J. Otero, L. Solar-García (Hospital Universitario Central de Asturias); V. Turrado-Rodriguez, F. de Lacy Oliver, A. M. Lacy Fortuny, B. Martin Perez, A. M. Otero Piñeiro (Hospital Clinic Barcelona); J. Paredes, F. Fernandez, M. J. Ladra, A. Paulos, D. Prieto (Hospital Clinico Universitario de Santiago de Compostela); J. P. Beltrán de Heredia, F. Blanco Antona, B. de Andrés Asenjo, C. Ferreras García, A. Romero de Diego (Hospital Clínico Universitario de Valladolid); E. Cordoba Diaz de Laspra, E. Echazarreta Gallego, M. Elia Guedea (Hospital Clinico Universitario de Zaragoza); D. Escola, S. Martinez (Hospital Comarcal Alt Penedes); V. Primo Romaguera, R. Parreño, L. Pastor, E. Rosell (Hospital de Dénia); R. Lozoya Trujillo, R. Alós Company, M. D. Ruiz Carmona, A. Solana Bueno (Hospital de Sagunto); S. Salvans Ruiz, S. Alonso Gonçalves, M. Jiménez- Toscano, M. Pascual Damieta, M. Pera Roman (Hospital Del Mar); E. M. Pellicer-Franco, J. A. Garcia-Marin, M. Mengual-Ballester, V. Soria-Aledo, G. Valero-Navarro (Hospital Morales Mesequer); M. Vicente-Ruiz, C. Garcia-Zamora, A. Gonzalez-Gil, M. J. Montoya-Tabares, M. Paredes-Quiles (Hospital Rafael

Mendez); J. Die Trill, P. Abadía, I. Moreno, J. D. Pina, D. Ramos Rubio (Hospital Ramon y Cajal); J. Escartin, J. L. Blas, J. Fernando, R. Ferrer, J. Garcia Egea (Hospital Royo Villanova); I. Pros, W. Martinez, J. Rius, M. Socías (Hospital Sant Joan de Deu de Martorell); D. Sabia, J. Castellvi Valls, V. Gonzalez Santin, S. Mompert Garcia, L. Viso Pons (Hospital Sant Joan Despi Moises Broggi); D. Julià, A. Codina-Cazador, R. Farrés, N. Gómez, P. Planellas (Hospital Universitari de Girona Doctor Josep Trueta); M. Cuadrado, I. Camps (Hospital Universitari Germans Trias I Pujol); M. Rufas, J. Escoll, A. Fermiñán, P. Muriel, E. Sierra (Hospital Universitario Arnau de Vilanova de Lerida); C. Alvarez-Laso, P. Lora, H. Padin (Hospital Universitario de Cabueñes); J. Garcia-Septiem, C. Bustamante, V. Jimenez, J. Jimenez-Miramón, J. L. Ramos (Hospital Universitario de Getafe); A. B. Gallardo, P. Benito, L. Colao, P. Galindo, C. Garcia (Hospital Universitario de Torrejón de Ardoz); A. Forero-Torres, A. Alonso Poza, B. Dieguez Fernandez, C. Gilsanz Martin, M. Hernandez Garcia (Hospital Universitario del Sureste); J. A. Rojo López, J. M. Gil López, M. González Zunzáren, J. Martínez Alegre, L. P. Zorrilla Matilla (Hospital Universitario Infanta Sofia); A. Navarro-Sánchez, F. J. Alcalá Serrano, J. López-Fernández, D. Montesdeoca Cabrera (Hospital Universitario Insular de Gran Canaria); M. Alvarez-Gallego, J. Guevara, I. Pascual Miquelañez, I. Rubio-Perez (Hospital Universitario La Paz); M. Gomez Ruiz, J. Alonso Martín, C. Cagigas Fernández, J. Castillo Diego (Hospital Universitario Marques de Valdecilla); J. A. Pando, C. Maristany, A. Muñoz-Duyos, A. Rada-Palomino, H. Vargas-Pierola (Hospital Universitario Mutua Terrassa); E. Peña Ros, J. A. Benavides Buleje, J. M. Muñoz Camarena, P. A. Parra Baños, M. Ramirez Faraco (Hospital Universitario Reina Sofía); J. J. Arenal, M. A. Citores, J. L. Marcos, J. Sánchez, C. Tinoco (Hospital Universitario Río Hortega); L. J. García Flórez, R. D. Arias Pacheco, G. Mínguez Ruiz, N. Gutiérrez Rodríguez Corral, A. Rodríguez Infante (Hospital Universitario San Agustín); M. J. Carrillo López, M. M. Carrasco Prats, A. Lage Laredo, Á. Martínez Manzano, P. Rodríguez García (Hospital Universitario Santa Lucia); J. J. Segura-Sampedro, N. Alonso-Hernández, M. Fernandez Isart, M. Gamundi Cuesta, A. Ochogavia Segui (Hospital

Universitario Son Espases); N. Ibañez, J. Abrisqueta, J. Lujan (Hospital Universitario Virgen de la Arrixaca); R. Gómez Pérez, E. Corrales Valero, C. Monje Salazar, E. Sanchiz Cardenas, R. Soler Humanes (Hospital Universitario Virgen de la Victoria); R. M. Jimenez-Rodriguez, F. De la Portilla, J. M. Diaz Pavon, A. M. Garcia Cabrera, M. L. Reyes Diaz (Hospital Universitario Virgen del Rocio); E. Espin, F. Marinello, M. Martí, J. L. Sanchez, F. Vallribera (Hospital Valle de Hebron); F. J. Orts Mico, M. Ortin Navarro, M. Perez Climent, C. Serra Diaz (Hospital Virgen de los Lirios); M. Millan, A. Caro, J. Escuder, B. Espina, F. Feliu (Joan XXIII University Hospital); A. Climent Aira, A. Estévez Diz, M. T. Moreno Asencio, A. Varela Mato, R. Vázquez Bouzán (POVISA Hospital); A. M. Minaya-Bravo, M.M. Diez-Alonso, R. Villeta-Plaza (Principe de Asturias Hospital); H. Guadalajara, D. Alías, D. García Olmo, C. Pastor, I. Valverde (Quironsalud Publicos); A. Sanchez Romero, A. Gardea, M. Gil Santos, T. Nimmersgern, P. Serrano Paz (Unidad de Coloproctología, Hospital Vinalopó-Torrevieja); M. Romero-Simó, T. Blasco-Segura, I. Caravaca-García, D. Costa-Navarro, A. Zarco-Pleguezuelos (University General Hospital of Alicante); L. Sánchez-Guillén, B. Flor-Lorente, M. Frasson, Á. García-Granero, E. García-Granero (University Hospital La Fe Valencia); B. Arencibia, J. Alonso, G. Febles, E. M. Nogués, C. Roque (University Hospital of Gran Canaria Dr. Negrín).

Sweden: J. Segelman, J. Nygren (Ersta Hospital); G. Nestler (Falu lasarett); M. Abraham-Nordling, M. Egenvall (Karolinska University Hospital); P. Myrelid, B. Jung, P. Loftås (Linköping University Hospital); M-L. Lydrup, N. Azahr, P. Buchwald, P. Mangell, I. Syk (Skane University Hospital); M. Nikberg, J. Carlander, A. Chabok, K. Smedh, C. Tiselius (Västmanlands Hospital Västerås); S. Haapaniemi, A. Benckert (Vrinnevi Hospital Norrköping).

Switzerland: M. Adamina, C. Freil-Lanter, C. Gingert, P. Müller, J. Schäfli (Kantonsspital Winterthur); L. Regusci, M. Brenna, F. Fasolini (Regional Hospital Mendrisio); H. Misteli, P. Kirchhoff, D. Oertli (University Hospital Basel, Switzerland); D. Hahnloser, D. Clerc, M. Hübner

(University Hospital of Lausanne, CHUV); F. Ris, N. C. Buchs, M. Chevally, P. Morel, B. Schiltz (University Hospitals Geneva).

Taiwan: J. Y. Wang, W-C. Su, C-W. Huang, C-J. Ma, H-L. Tsai (Kaohsiung Medical University Hospital).

Turkey: G. S. Özbacı, B. B. Özkan, U. Karabacak (19 Mayıs University Faculty of Medicine); D. Bugra (American Hospital); F. Agalar, H. Baloglu, I. Basoglu (Anadolu Medical Center [in aff with Johns Hopkins Med]); N. Okkabaz, E. Binboga, A. Biricik, A. Celik, E. Yavuz (Bagcilar Training and Research Hospital); A. E. Canda, C. Agalar, M. Fuzun, S. Sokmen, C. Terzi (Dokuz Eylul University); A. Isik (Erzincan University, Mengucek Gazi Training and Research Hospital); B. Karip, A. C. Bilgili (Fatih Sultan Mehmet Training and Research Hospital); S. Leventoglu, B. Aytac, E. Küçükdiler, A. Yıldız, O. Yuksel (Gazi University Medical School); H. Sinan, O. Hancerliogullari, S. Kaymak, O. Kozak, M. T. Ozer (Gulhane Training and Research Hospital); I. S. Sarici, O. Akca, M. U. Kalayci, Y. Kara (Kanuni Sultan Suleyman Training and Research Hospital); D. Bugra, O. Agcaoglu, E. Balik, O. Bayram (Koc University School of Medicine); G. S. Özbacı, B. B. Özkan, U. Karabacak (On Dokuz Mayıs University Faculty of Medicine); U. Sungurtekin, U. Ozgen (Pamukkale University School of Medicine); S. Demirbas (TOBB-ETU University Hospital); E. Öztürk, O. Isik, T. Yilmazlar (Uludag University School of Medicine); E. Colak, S. Karagul, V. Kinas (University of Health Sciences, Samsun Training and Research Hospital).

UK: N. Fearnhead, I. Lord, P. Stewart (Addenbrooke's [Cambridge University] Hospital); M. Zammit (Basildon Hospital); S. Arnold, N. J. Battersby, J. Broadhurst, A. Mehta, S. Moran, F. Seretis (Basingstoke and North Hampshire Hospital); J. Shabbir, C. Jones, J. Kynaston (Bristol Royal Infirmary); D. Vimalachandran, E. Blower, C. McFaul, D. McWhirter, J. Pilkington



(Countess of Chester Hospital); T. Wilson, M. Chowdhary (Doncaster Royal Infirmary); B. Stubbs, M. Abdalkoddus, C. Lai, N. Thavanesan, C. Yao (Dorset County Hospital); T. Agarwal, S. Dindyal, R. M. C. Hill, S. Reade, A. Slesser (Ealing Hospital); H. Paterson, A. Balfour, M. Boland, A. Geraghty, J. O'Kelly (Edinburgh Western General Hospital); P. Patel, S. Tezas (Furness General Hospital); S. Yahia, V. Jadhav, K. Marimuthu, A. Narayanan, B. Piramanayagam (George Eliot Hospital); N. Bradley, F. Buchanan, K. Paul, J. Singh, K. Thomson (Glasgow Royal Infirmary); S. Korsgen, M. Bedford, K. Lee, K. Leong (Good Hope Hospital); D. McArthur, A. Bhangu, S. Malik, I. Mohamed (Heartlands Hospital); P. Cunha, A. Pilavas (Homerton University Hospital NHS Trust); A. Reddy, S. Ahmed, A. Ahmed, J. Voll (James Cook University Hospital); V. Velchuru, R. Lal, B. Mirshekar-Syahkal (James Paget Hospital); M. Kassai, M. Aleem, S. Keogh-Bootland (Jersey General Hospital); P. Sarmah, S. Brown, R. Keegan, A. Kelkar, P. Sen (Kettering General Hospital); M. Oliveira-Cunha, S. Chaudhri, R. Fares, B. Singh, W. M. Thomas (Leicester General Hospital); M. I. Aslam, K. Boyle, D. Hemingway, A. Miller, M. Norwood (Leicester Royal Infirmary); S. Gurjar, M. Al-Saeedi, L. Anandan, A. Sudlow, N. Zampitis (Luton & Dunstable Hospital); K. Malik, M. Bogdan, C. Smart (Macclesfield District General Hospital); M. R. Iqbal, S. Bailey, D. Lawes, G. Omar, R. Tamhane (Maidstone and Tunbridge Wells NHS Trust); M. Evans, S. Ather, J. Lim, H. Nageswaran, G. Taylor (Morrison Hospital); L. Hunt, J. Nicholls (Musgrove Park Hospital); I. Shaikh, F. Muscara, J. O'Brien, E. Photi, A. Stearns (Norfolk and Norwich University Hospital); D. Meylemans, C. Cunningham, R. Hompes (Oxford University Hospitals); A. Tennakoon, N. Kumarasinghe, M. Rao, I. Upanishad (Pilgrim Hospital); ~~S. Smolarek, E. Platt, B. Rossi, J. C. Tham (Plymouth Hospital NHS Trust);~~ J. Khan, N. Ahmad, Z. Shweejawee, S. Stefan (Queen Alexandra Hospital); N. Smart, I. Daniels, T. Gregoir, L. Longstaff, F. McDermott (Royal Devon & Exeter Hospital); M. Varcada, I. Dрами, T. Gala, E. Moggia, K. Ratnatunga (Royal Free Hospital NHS Trust Hampstead); R. Harries, J. Hayes, G. Williams (Royal Gwent Hospital); T. Raymond, C. Bronder, E. Davies, P. Hawkin, O. Ryska (Royal Lancaster Infirmary); K. Ayril, A.

Beveridge, A. Bhowmik, M. Gill, R. Simpson (Royal Preston Hospital); A. Schofield, K. McArdle, M. Parmar (Royal Shrewsbury Hospital); M. Williamson, H. Burton, E. Courtney, C. Grant, A. Saracino (Royal United Hospital Bath); K. Newton, J. Epstein (Salford Royal NHS Foundation Trust); G. Branagan, M. Bignell, M. Symankewicz (Salisbury District Hospital); S. Zaman, R. Mankotia, Z. Siddiqui, A. Torrance (Sandwell General Hospital); D. Artioukh, M. Eggleston, K. Gokul, D. Selwyn (Southport and Ormskirk Hospitals); J. Warusavitarne, P. Chandrasinghe, J. Grainger, C. A. Leo, C. J. Vaizey (St Mark's Hospital); G. Harris, B. Levy, A. Skull (St Richard's Hospital); M. Thaha, S. Ahmed, A. Garg, H. Patel, A. Ramsanahie (The Royal London Hospital, Barts Health NHS Trust); M. Mondragon-Pritchard, K. Cuinas Leon, G. Williams (The Royal Wolverhampton NHS Trust); A. Shukla, H. Brewer, J. Fitzgerald, H. Kho (United Lincolnshire Hospitals NHS Trust); J. Torkington, S. Tate, J. Wheat (University Hospital of Wales); S. Smolarek, E. Platt, B. Rossi, J. C. Tham (University Hospitals Plymouth NHS Trust); J. Knight, J. Richardson, A. Tzivanakis (University Hospital Southampton); M. Gregori, M. A. Ashraf, M. Atif, A. Birindelli, J. Santos (University Hospitals Birmingham NHS FT); N. Saffaf, M. I. Aslam, L. Canning (Warwick Hospital); N. Chandratreya, M. Bowen, B. Graham, Y. Hamad, M. Kaubrys (Weston General Hospital at Weston super Mare); Z. U. Chaudhry, C. Bhan, H. Mukhtar, A. Oshowo, J. Wilson (Whittington Hospital NHS Trust); J. Richardson, N. Gouvas, D. Nicol, S. Pandey, M. Zilvetti (Worcestershire Royal Hospital); A. Sharma, T. Fatayer, S. Mothe, M. Rahman (Wythenshawe Hospital, UHSM); N. Curtis, A. Allison, R. Dalton, N. Francis, J. Ockrim (Yeovil District Hospital).

Ukraine: G. Psaras, H. Dudarovaska, T. Marharint, E. Mostovoy, S. Voloshin (Mariupol Cancer Center); O. Kolesnik, D. Makhmudov (National Cancer Institute, Ukraine).

United States: Y. Altinel (Cleveland Clinic); A. Iqbal, L. Cunningham, K. Go, S. Tan (University of Florida).

-

#### **ESCP Cohort Studies and Audits Committee**

Alaa El-Hussuna (2017 Audit Lead), Aneel Bhangu, Nicholas Buchs, Christianne Buskens, Sanjay Chaudri, Matteo Frasson, Gaetano Gallo, James Glasbey, Ana Minaya, Dion Morton, Ionut Negoii, Dmitri Nepogodiev, Francesco Pata, Luis Sánchez-Guillén, Baljit Singh, Oded Zmora, Thomas Pinkney (Chair)

#### **Statistical Analysis and Data Management**

James Glasbey, Dmitri Nepogodiev, Rita Perry, Laura Magill, Aneel Bhangu (Guarantor)

#### **ESCP Research Committee**

Dion Morton (Chair), Willem Bemelman, Steven Brown, Christianne Buskens-Quentin Denost, Charles Knowles, Søren Laurberg, Jérémie Lefèvre, Gabriela Möeslein, Tom Pinkney, Carolynne Vaizey, Oded Zmora

#### **ESCP 2017 Audit Collaborating Authors**

Albania: S. Bilali, V. Bilali (University Hospital Center Mother Teresa).

Argentina: M. Salomon, M. Cillo, D. Estefania, J. Patron-Uriburu, H. Ruiz (Buenos Aires British Hospital); P. Farina, F. Carballo, S. Guckenheimer (Hospital Pirovano).

Australia: D. Proud, R. Brouwer, A. Bui, B. Nguyen, P. Smart (Austin Hospital); A. Warwick, J. Theodore (Redcliffe Hospital).

Austria: F. Herbst, T. Birsan, B. Dauser, S. Chaffari, N. Hartig (Barmherzige Brüeder, Wien); A. Stift, S. Argeny, L. Unger (Medical University of Vienna); R. Strouhal, A. Heuberger (Oberndorf b. Salzburg).

Belarus: A. Varabei, N. Lahodzich, A. Makhmudov, L. Selniachina (Minsk Regional Clinical Hospital).

Belgium: T. Feryn, T. Leupe, L. Maes, E. Reynvoet, K. Van Langenhove (AZ Sint-Jan Brugge); M. Nachtergaele (AZ St Jozef); B. Monami, D. Francart, C. Jehaes, S. Markiewicz, J. Weerts (Clinique St Joseph, Liege); K. Van Belle, B. Bomans, V. Cavenaille, Y. Nijs, M. Vertruyen (Europe Hospitals Brussels); P. Plotinckx, D. Claeys, B. Defoort, F. Muysoms, S. Van Cleven (Maria Middelaere Gent); C. Lange, K. Vindevoghel (OLV van Lourdes Hospital Waregem); A. Wolthuis (University Hospital Leuven).

Bosnia and Herzegovina: M. Todorovic, S. Dabic, B. Kenjic, S. Lovric, J. Vidovic (JZU Hospital Sveti Vračevi); S. Delibegovic, Z. Mehmedovic (University Clinic Center Tuzla).

Brazil: A. Christiano, B. Lombardi, M. Marchiori Jr, V. Terciotti Jr (Hospital Centro Médico de Campinas).

Bulgaria: D. Dardanov, P. Petkov, L. Simonova, A. Yonkov, E. Zhivkov (Alexandrovska Hospital – First Surgery); S. Maslyanov, V. Pavlov, M. Sokolov, G. Todorov (Alexandrovska Hospital,

Second Surgery Clinic); V. Stoyanov, I. Batashki, N. Iarumov, I. Lozev, B. Moshev (Medical Institute—Ministry of Interior); M. Slavchev, B. Atanasov, N. Belev, P. Krstev, R. Penkov (University Hospital—Eurohospital).

Croatia: G. Šantak, J. Čosić, A. Previšić, L. Vukušić, G. Zukanović (County Hospital Požega); M. Zelić, D. Kršul, V. Lekić Vitlov, D. Mendrila (University Hospital Rijeka).

Czech Republic: J. Orhalmi, T. Dusek, O. Maly, J. Para, O. Sotona (Charles University Hospital). M. Skrovina, V. Bencurik, M. Machackova (Complex Oncology Centre Novy Jicin, Surgical Department); Z. Kala, M. Farkašová, T. Grolich, V. Procházka (Surgical Department, University Hospital Brno); J. Hoch, P. Kocian, L. Martinek (University Hospital Motol, Prague); F. Antos, V. Pruchova (University Hospital Prague Bulovka).

Denmark: A. El Hussuna, A. Ceccotti, T. Madsbøll, D. Straarup, A. Uth Ovesen (Aalborg University Hospital); P. Christensen, P. Bondeven, P. Edling, H. Elfeki, V. Alexandrovich Gameza, S. Michelsen-Bach, I. Zheltiakova (Aarhus University Hospital/Randers Regional Hospital); PM. Krarup, A. Krogh, H.C. Rolff (Bispebjerg); J. Lykke, A. F. Juvik, H. H. K. Lóven, M. Marckman, J. T. F. Osterkamp (Herlev Hospital); A. H. Madsen, J. Worsøe (Hospital Unit West); A. Ugianskis (North Denmark Regional Hospital); M. D. Kjær, B. Youn Cho Lee (Odense University Hospital); A. Khalid, M. H. Kristensen (Regional Hospital Viborg).

Egypt: M. El Sorogy, A. Elgeidie, M. Elhemaly, A. ElNakeeb, M. Elrefai (Gastrointestinal Surgery Center, Mansoura University); M. Shalaby, S. Emile, W. Omar, A. Sakr, W. Thabet (Mansoura University Hospital); S. Awany, I. Metwally, B. Refky, N. Shams, M. Zuhdy (Oncology Center Mansoura University).

Finland: A. Lepistö, I. Keränen, A. Kivelä, T. Lehtonen, P. Siironen (Helsinki University Hospital); T. Rautio, M. Ahonen-Siirtola, K. Klintrup, K. Paarnio, H. Takala (Oulu University Hospital); M. Hyöty, E. Haukijärvi, S.-M. Kotaluoto, K. Lehto, T. Tomminen (Tampere University Hospital); H. Huhtinen, A. Carpelan, J. Karvonen, A. Rantala, P. Varpe (Turku University Hospital).

France: E. Cotte, Y. Francois, O. Glehen, G. Passot (Centre Hospitalier Lyon Sud); A. d'Alessandro, E. Chouillard, J.-C. Etienne, E. Ghilles, B. Vinson-Bonnet (CHIPS); A. Germain, A. Ayav, L. Bresler (CHU Nancy-Brabois); R. Chevalier, Q. Denost, R. Didailler, E. Rullier (Hopital Haut Leveque); E. Tiret, N. Chafai, J. Lefevre, Y. Parc (Hôpital Saint Antoine); I. Siolezneff, D. Mege (Timone Hospital); Z. Lakkis (University Hospital of Besancon); M. Barussaud (University Hospital of Poitiers).

Germany: C. Krones, B. Bock, R. Webler (Marienhospital Aachen); J. Baral, T. Lang, S. Münch, F. Pullig, M. Schön (Städtisches Klinikum Karlsruhe); S. Hinz, T. Becker, T. Möller, F. Richter, C. Schafmayer (University Hospital Schleswig-Holstein, Kiel); J. Hardt, P. Kienle (University Medical Center Mannheim); F. Crescenti, M. Ahmad, Y. Soleiman (Verden KRH).

Greece: I. Papaconstantinou, A. Gklavas, K. Nastos, T. Theodosopoulos, A. Vezakis (Areteion Hospital); K. Stamou, A. Saridaki (Athens Bioclinic); E. Xynos, S. Paraskakis, N. Zervakis (Creta InterClinic Hospital); G. Skroubis, T. Amanatidis, S. Germanos, I. Maroulis, G. Papadopoulos (General University Hospital of Patras); N. Dimitriou, A. Alexandrou, E. Felekouras, J. Griniatsos, I. Karavokyros (Laiko Hospital); A. Papadopoulos, C. Chouliaras, P. Ioannidis, D. Katsounis, E. Kefalou (Nikaia General Hospital); I. Katsoulis, D. Balalis, D. Manatakis (St. Savvas Cancer Hospital); G. Tzovaras, I. Baloyiannis, I. Mamaloudis (University Hospital of Larissa).

Hungary: G. Lázár, S. Ábraham, A. Paszt, Z. Simonka (Department of Surgery, University of Szeged); A. Zaránd, Z. Baranyai, G. Ferreira, L. Harsányi, P. Ónody (Semmelweis University, 1st Clinic of Surgery); B. Banky, Á. Burány, M. Lakatos, J. Marton, A. Solymosi (St. Borbala Hospital); I. Besznyák, A. Bursics, G. Papp, G. Saftics, I. Svastics (Uzsoki Hospital);

Iceland: E. Valsdottir, J. Atladottir, T. Jonsson, P. Moller, H. Sigurdsson (University Hospital of Iceland).

India: S. K. Gupta, S. Gupta, N. Kaul, S. Mohan, G. Sharma (Government Medical College, Jammu, Jammu and Kashmir, India); R. Wani, N. Chowdri, M. Khan, A. Mehraj, F. Parray (Sher-i-Kashmir Institute of Medical Sciences).

Ireland: A. Coveney, J. Burke, J. Deasy, S. El Masry, D. McNamara (Beaumont Hospital); M. F. Khan, R. Cahill, E. Faul, J. Mulsow, C. Shields (Mater Misericordiae University Hospital); M. E. Kelly, G. Bass, S. T. Martin, R. O'Connell, E. Ryan (St Vincent's Private Hospital); T. Connelly, G. Ahmad, W. Bukhari, F. Cooke (University Hospital Waterford).

Israel: O. Zmora, R. Gold Deutch, N. Haim, R. Lavy, A. Moscovici (Assaf Harofe Medical Center); N. Shussman, R. Gefen, G. Marom, A. Pikarsky, D. Weiss (Hadassah Hebrew University Medical Center); S. Avital, N. Hermann, B. Raguán, M. Slavin, I. White (Meir Medical Center); N. Wasserberg, H. Arieli, N. Gurevich (RMC, Beilinson Campus); M. R. Freund, S. Dorot, G. Halfteck, P. Reissman, E. Yair (Shaare Zedek Mount Sinai); Y. Eden, R. Pery (Sheba Medical Center); H. Tulchinsky, A. Weizman (Sourasky Medical Center).

Italy: F. Agresta, R. Curinga, E. Finotti, G. Savino, L. A. Verza (Adria Hospital); C. R. Asteria, L. Boccia, A. Pascariello (ASST – Mantua); N. Tamini, A. Bugatti, L. Gianotti, M. Totis (Asst-

Monza, Ospedale San Gerardo); L. Vincenti, V. Andriola, I. Giannini, E. Travaglio (Azienda Ospedaliero Universitaria Consorziale Policlinico di Bari); R. Balestri, P. Buccianti, N. Roffi, E. Rossi, L. Urbani (Azienda Ospedaliero Universitaria Pisana); A. Mellano, A. Cinquegrana (Candiolo Cancer Institute IRCCS); A. Lauro, C. Belluco (Centro di Riferimento Oncologico, IRCCS, Aviano); M. Mistrangelo, M. E. Allaix, S. Arolfo, M. Morino, V. Testa (Citta della Salute e della Scienza di Torino); P. Delrio, U. Pace, D. Rega, D. Scala (Colorectal Surgical Oncology Istituto Nazionale per lo Studio e la Cura dei Tumori); G. Gallo, G. Clerico, S. Cornaglia, A. Realis-Luc, M. Trompetto (Department of Colorectal Surgery, S. Rita Clinic); G. Ugolini, N. Antonacci, S. Fabbri, I. Montroni, D. Zattoni (Faenza Hospital); C. D'Urbano, A. Cornelli, M. Viti (G. Salvini); M. Inama, M. Bacchion, A. Casaril, H. Impellizzeri, G. Moretto (Hospital-Dott. Pederzoli); A. Spinelli, M. Carvello, G. David, F. Di Candido, M. Sacchi (Humanitas Research Hospital); A. Frontali, V. Ceriani, M. Molteni (IRCCS MultiMedica); R. Rosati, F. Aleotti, U. Elmore, M. Lemma, A. Vignali (IRCCS Ospedale San Raffaele); S. Scabini, G. Casoni Pattacini, A. Luzzi, E. Romairone (IRCCS San Martino IST); F. Marino, D. Lorusso, F. Pezzolla (IRCCS 'Saverio de Bellis'); F. Colombo, C. Baldi, D. Foschi, G. Sampietro, L. Sorrentino (L. Sacco University Hospital); S. Di Saverio, A. Birindelli, E. Segalini, D. Spacca (Maggiore Hospital); G. M. Romano, A. Belli, F. Bianco, S. De franciscis, A. Falato (National Cancer Institute Naples); A. Muratore, P. Marsanic (Ospedale Agnelli Pinerolo); S. Grimaldi, N. Castaldo, M. G. Ciolli, P. Picarella, R. Porfidia (Ospedale Convenzionato Villa Dei Fiori); S. Di Saverio, A. Birindelli, G. Tugnoli (Ospedale Maggiore); A. Bondurri, D. Cavallo, A. Maffioli, A. Pertusati (Ospedale Sacco Italy); F. Pulighe, F. Balestra, C. De Nisco, M. Podda (Ospedale San Francesco); E. Opocher, M. Longhi, N. M. Mariani, N. Maroni, A. Pisani Ceretti (Ospedale San Paolo); R. Galleano, P. Aonzo, G. Curletti, L. Reggiani (Ospedale Santa Corona); M. Marconi, L. Del Prete, M. Oldani, R. Pappalardo, S. Zaccone I (Ospedale Santa Maria delle Stelle); M. Scatizzi, M. Baraghini, S. Cantafio, F. Feroci, I. Giani (Ospedale Santo Stefano, Prato); R. Tutino, G. Coccorullo, G. Gulotta, L. Licari, G. Salamone (Policlinico 'P. Giaccone'); P. Sileri, F. Saraceno (Policlinico Tor



Vergata); F. La Torre, P. Chirletti, D. Coletta, G. De Toma, A. Mingoli (Policlinico Umberto I 'Sapienza University'); M. Papandrea, E. De Luca, R. Sacco, G. Sammarco, G. Vescio (Policlinico Universitario di Catanzaro); V. Tonini, S. Bianchini, M. Cervellera, S. Vaccari (Policlinico universitario Sant'Orsola-Malpighi, Università degli Studi di Bologna); N. Cracco, G. Barugola, E. Bertocchi, R. Rossini, G. Ruffo (Sacro Cuore-Don Calabria Hospital); A. Sartori, N. Clemente, M. De Luca, A. De Luca, G. Scaffidi (San Valentino Hospital); L. Lorenzon, G. Balducci, T. Bocchetti, M. Ferri, P. Mercantini (Sant'Andrea Hospital); F. Pata, S. Bauce, A. Benevento, C. Bottini, P. R. Crapa (Sant'Antonio-Abate Hospital, Gallarate); M. Rubbini, G. Anania, P. Carcoforo, G. Cavallesco, C. Feo (University Hospital of Ferrara).

Japan: T. Yamamoto (Yokkaichi Hazu Medical Centre).

Latvia: A. Sivins, G. Ancans, S. Gerkis, R. Lunis, A. Pcolkins (Latvia Oncology Center).

Lithuania: D. Venskutonis, S. Bradulskis, E. Dainius, A. Subocius, J. Vencius (Department of General Surgery, LSMU, Kaunas Clinical Hospital); P. Zeromskas, V. Eismiontas, V. Nutautiene, D. Simcikis, A. Tamosiunas (Klaipeda University Hospital); S. Svagzdys, T. Latkauskas, P. Lizdenis, Z. Saladzinskas, A. Tamelis (Lithuanian University of Health Sciences Hospital Kauno Klinikos); A. Dulskas, J. Kuliavas, N. E. Samalavicius (National Cancer Institute, Lithuania); T. Poskus, V. Jotautas, S. Mikalauskas, E. Poskus, K. Strupas (Vilnius University).

Malaysia: A. Zakaria, N. N. Lah, M. Wong, Z. Zain, Z. Zakaria (Hospital Universiti Sains Malaysia); L. Mazlan, Z. A. Mohd Azman, I. Sagap (UKM Medical Centre).

Malta: J. Psaila, P. Andrejevic, C. Cini, S. Ellul, K. Pace (Mater Dei Hospital). Morocco: M. Ahallat, M. Hamid, A. Hrra, M. A. Majbar, M. Raiss (Ibn Sina University Hospital).

Netherlands: E. Westerduin, W. Bemelman, C. Buskens, P. Tanis (Academic Medical Centre); P.C. van der Sluis, P.H. Davids, A. Pronk, A.H.W. Schiphorst, N. Smakman (Diakonessenhuis); D. Zimmerman, T. Koeter, J. Stijns, Y.T. van Loon (Elisabeth TweeSteden Hospital); M. Vermaas, E. de Graaf, P. Doornebosch, P. van Hagen, O. van Ruler (Ijsselland Ziekenhuis); B. Toorenvliet, J. Nonner, I. van den Berg, L. van Steensel, W. Vles (Ikazia); J. Melenhorst, R. Orsini, R. Visschers (Maastricht University Medical Centre); C. Hoff (Medical Center Leeuwarden); R. Blom, H. Marsman (Onze-Lieve-Vrouwe Gasthuis); I. Mulder, H. Cense, S. de Castro, A. Demirkiran, M. Hunfeld (Rode Kruis Ziekenhuis Beverwijk); A. van Geloven, J. de Groef, E. Hendriks, M. Leeuwenburg, N. van Oorschot (Tergooi); F. Wit, C. Rupert, P. Veldman (Tjongerschans ziekenhuis); M. Keijzers, J. Konsten (VieCuri Medisch Centrum voor Noord Limburg); F. Den Boer, M. Corver (Zaans Medical Center); E.J. Boerma, L. Koolen, M. Martens, K. Van Wijck (Zuyderland Medical Center).

Norway: D. Ignjatovic, R. Breuer, B. Gurpreet, T. Oresland, T. Tetens Moe (Akershus University Hospital); A. Nesbakken, I. Flateh Backe, T.A. Wik (Oslo University Hospital); K. Radiya, T. Dehli, P. Gjessing, S. Norderval, K. Woll (University Hospital of North Norway).

Pakistan: M. Anwer, M. S. Qureshi (JPMC WARD 2); A. U. Qureshi, M. Billah, M. Y. Jawad, A. Raza, N. Urooj (King Edward Medical University/Mayo Hospital, Lahore).

People's Republic of China: X. Wang, L. Li (West China Hospital). Poland: D. Jajtner, B. Gasinski, W. Kabiesz (Beskidian Oncology Center); P. Walega, M. Romaniszyn (Third Department of General Surgery, Jagiellonian University Medical College); M. Zawadzki, R. Gzarnecki, Z. Obuszko, M. Rzaca, M. Sitarska (Wojewódzki Szpital Specjalistyczny).

Portugal: P. Silva, A. Duarte, D. Gonçalves, M. Morais (Centro Hospitalar de S. João); N. Rama, J. Nobre, I. Sales (Centro Hospitalar Leiria, EPE); J. Costa Pereira, S. Costa, C. Costa Pereira, C. Insua, I. Romero (Centro Hospitalar Tâmega e Sousa); N. Figueiredo, J. Cunha, H. Domingos, P. Vieira (Champalimaud Foundation); M. Cunha, M. Americano, E. Amorim, J. Rachadell (Cirurgia 2—CHA—Unidade Portimão); J. Carvas, I. Armas, P. Fernandes, C. Pires, R. Reis (Hospital de Bragança); R. Martins, M. Dos Santos, P. Henriques (Hospital de Faro, Centro Hospitalar do Algarve); O. Oliveira, M. Duarte, L. Ferreira, J. Miranda, N. Vilela (Hospital Distrital de Santarém, E.P.E.); J. Corte Real, S. Carlos, M. Frois Borges, P. Moniz Pereira, J. Simões (Hospital Garcia de Orta); P. Silva-vaz, V. Bettencourt, A. Gouveia, H. Perez, R. Rainho (Unidade Local de Saúde de Castelo Branco).

Romania: V. Bintintan, C. Ciuce, G. Dindelegan, R. Scurtu, R. Seicean (Clinica Chirurgie I); D. Cristian, T. Burcos, F. Grama, D. M. Mandi, G. Richiteanu (Coltea Clinical Hospital); A. Miron, V. Calu, O. Enciu, M. Nadragea, R. Parvuletu (Elias Emergency Hospital); S. S. Mogoanta, A. Crafcuic, S. Paitici (Emergency County Hospital of Craiova); I. Negoii, M. Beuran, C. Ciubotaru, A. Prodan, M. Vartic (Emergency Hospital of Bucharest); V. Tomulescu, C. Copsescu (Ponderas Academic Hospital).

Russia: D. Popov, A. Sednev, A. Klimenko, A. Semenov, S. Vasilyev (City Hospital 9); A. Pozdnyakov, D. Cherdancev, D. Mahotin, A. Nesytykh, V. Samsonyuk (Krasnoyarsk Regional Clinical Hospital); I. Pravosudov, D. Ivlev, A. Karachun, K. Lebedev, D. Samsonov (N.N. Petrov Research Institute of Oncology); R. Aiupov, D. Feoktistov, M. Garipov, S. Nail, N. Tarasov (National Republic Oncology Center); A. Yanishev, A. Abelevich, A. Kokobelyan, M. Lebedeva, R. Luzan (Nizhny Novgorod Regional Clinical Hospital); A. Rasulov, H. Dzhumabaev, Z. Mamedli (Russian Cancer Research Center); A. Bedzhanyan (Russian Research Center of Surgery named after B.V. Petrovsky); A. Khazov, M. Khanevich, G. Khrykov (Saint Petersburg Clinical Oncological Health Center); S. Katorkin, P. Andreev, A. Chernov, O. Davidova, A.

Zhuravlev (Samara State Medical University); S. Achkasov, D. Shakhmatov, Y. Shelygin, O. Sushkov, A. Vardanyan (State Scientific Centre of Coloproctology); A. Ilkanich, N. Barbashinov, V. Darvin, S. Onishchenko, Y. Voronin (Surgut District Hospital).

Serbia: Z. Krivokapić, G. Barišić, I. Dimitrijević, V. Marković, A. Sekulić (Clinic for Digestive Surgery I Surgical Clinic, Clinical Center of Serbia); G. Stanojevic, B. Brankovic, M. Nestorovic, V. Pecic, D. Petrovic (Clinic for General Surgery, Clinical Center Nis); I. Kostic, A. Aleksic, D. Dabic, B. Maric, V. Perunicic (General Hospital Cacak); Z. Radovanovic, M. Djuric, D. Lukic, D. Radovanovic (Oncology Institute of Vojvodina); V. Cuk, V. Cuk, J. Juloski, M. Kenic, I. Krdzic (Surgical Clinic KBC Zvezdara).

Singapore: J. C. Ngu, Y. Y. Ng, N. Teo (Changi General Hospital).

Slovak Republic: J. Korcek, A. Lazorisak, (Faculty Hospital Nitra).

Slovenia: M. Rems, Š. Ramovš Trampuš (General Hospital Jesenice); A. Tomazic, J. Grosek, J. Kosir, G. Norcic (University Medical Centre Ljubljana).

Spain: V. Vigorita, N. Caceres, E. Casal, A. Ruano, I. Trostchansky (Alvaro Cunqueiro Hospital); T. Golda, A. Galvez Saldaña, E. Kreisler Moreno, J. Lopez Dominguez, M. Vila Tura (Bellvitge University Hospital); F. Labarga, P. Galvez, V. Maderuelo, C. Suero (Complejo Asistencial Universitario de Palencia); J. Bargallo, L. Cayetano, S. Lamas, M. C. Silva (Consorci Sanitari de Terrassa—Hospital de Terrassa); J. C. Bernal Sprekelsen, R. Gómez, S. Jareño, A. Ríos, D. Vercher (Consorcio Hospital General Universitario); J.M. García-González, J. Cervera-Aldama, J. Ramos Prada, M. Santamaría Olabarrieta (Cruces University Hospital); N. Borda, J. M. Enríquez-Navascués, Y. Saralegui (Donostia University Hospital); A. Calero-Lillo, S. Aznar-

Puig, M. A. López-Lara, S. Muñoz-Collado, J. Valverde-Sintas (Fundacio Hospital Esperit Sant); P. Menendez, C. Leon (Gutierrez-Ortega Hospital); N. Truan, R. Baldonado, D. Martínez, J. Otero, L. Solar (Hospital Central de Asturias); V. Turrado-Rodriguez, F. de Lacy Oliver, A. M. Lacy Fortuny, B. Martin Perez, A. M. Otero Piñeiro (Hospital Clinic Barcelona); J. Paredes, F. Fernandez, M. J. Ladra, A. Paulos, D. Prieto (Hospital Clinico Universitario de Santiago de Compostela); J. P. Beltrán de Heredia, F. Blanco Antona, B. de Andrés Asenjo, C. Ferreras García, A. Romero de Diego (Hospital Clínico Universitario de Valladolid); E. Cordoba Diaz de Laspra, E. Echazarreta Gallego, M. Elia Guedea (Hospital Clinico Universitario de Zaragoza); D. Escola, S. Martinez (Hospital Comarcal Alt Penedes); V. Primo Romaguera, R. Parreño, L. Pastor, E. Rosell (Hospital de Dénia); R. Lozoya-Trujillo, R. Alós Company, M. D. Ruiz Carmona, A. Solana Bueno (Hospital de Sagunto); S. Salvans Ruiz, S. Alonso Gonçalves, M. Jiménez-Toscano, M. Pascual Damieta, M. Pera Roman (Hospital Del Mar); E. M. Pellicer-Franco, J. A. Garcia Marin, M. Mengual Ballester, V. Soria Aledo, G. Valero Navarro (Hospital Morales Meseguer); M. Vicente Ruiz, C. Garcia-Zamora, A. Gonzalez-Gil, M. J. Montoya-Tabares, M. Paredes-Quiles (Hospital Rafael Mendez); J. Die Trill, P. Abadia, I. Moreno, J. D. Pina, D. Ramos Rubio (Hospital Ramon y Cajal); J. Escartin, J. L. Blas, J. Fernando, R. Ferrer, J. Garcia Egea (Hospital Royo Villanova); I. Pros, W. Martinez, J. Rius, M. Socías (Hospital Sant Joan de Deu de Martorell); D. Sabia, J. Castellvi Valls, V. Gonzalez Santin, S. Mompert Garcia, L. Viso Pons (Hospital Sant Joan Despí Moises Broggi); D. Julià, A. Codina-Cazador, R. Farrés, N. Gómez, P. Planellas (Hospital Universitari de Girona Doctor Josep Trueta); M. Cuadrado, I. Camps (Hospital Universitari Germans Trias i Pujol); M. Rufas, J. Escoll, A. Fermián, P. Muriel, E. Sierra (Hospital Universitario Arnau de Vilanova de Lerida); C. Alvarez-Laso, P. Lora, H. Padin (Hospital Universitario de Cabueñes); J. Garcia-Septiem, C. Bustamante, V. Jimenez, J. Jimenez-Miramón, J. L. Ramos (Hospital Universitario de Getafe); A. B. Gallardo, P. Benito, L. Colao, P. Galindo, C. Garcia (Hospital Universitario de Torrejón de Ardoz); A. Forero-Torres, A. Alonso Poza, B. Dieguez Fernandez, C. Gilsanz Martin, M.

Hernandez Garcia (Hospital Universitario del Sureste); J. A. Rojo López, J. M. Gil López, M. González Zunzárren, J. Martínez Alegre, J. P. Zorrilla Matilla (Hospital Universitario Infanta Sofía); A. Navarro Sánchez, F. J. Alcalá Serrano, J. López Fernández, D. Montesdeoca Cabrera (Hospital Universitario Insular de Gran Canaria); M. Alvarez-Gallego, J. Guevara, I. Pascual Miguelañez, I. Rubio Perez (Hospital Universitario La Paz); M. Gomez Ruiz, J. Alonso Martín, C. Cagigas Fernández, J. Castillo Diego (Hospital Universitario Marques de Valdecilla); J. A. Pando, C. Maristany, A. Muñoz-Duyos, A. Rada-Palomino, H. Vargas-Pierola (Hospital Universitario Mutua Terrassa); E. Peña Ros, J. A. Benavides Buleje, J. M. Muñoz Camarena, P. A. Parra Baños, M. Ramirez Faraco (Hospital Universitario Reina Sofía); J. J. Arenal, M. A. Citores, J. L. Marcos, J. Sánchez, C. Tinoco (Hospital Universitario Río Hortega); L. J. García Flórez, R. D. Arias Pacheco, G. Mínguez Ruiz, N. Rodríguez Corral, A. Rodríguez Infante (Hospital Universitario San Agustín); M. J. Carrillo López, M. M. Carrasco Prats, A. Lage Laredo, Á. Martínez Manzano, P. Rodríguez García (Hospital Universitario Santa Lucía); J. J. Segura-Sampedro, N. Alonso-Hernández, M. Fernandez Isart, M. Gamundi Cuesta, A. Ochogavia Segui (Hospital Universitario Son Espases); N. Ibañez, J. Abrisqueta, J. Lujan (Hospital Universitario Virgen de la Arrixaca); R. Gómez Pérez, E. Corrales Valero, C. Monje Salazar, E. Sanchiz Cardenas, R. Soler Humanes (Hospital Universitario Virgen de la Victoria); R. M. Jimenez Rodriguez, F. De la Portilla, J. M. Diaz Pavon, A. M. Garcia Cabrera, M. L. Reyes Diaz (Hospital Universitario Virgen del Rocío); E. Espin, F. Marinello, M. Martí, J. L. Sanchez, F. Vallribera (Hospital Valle de Hebron); F. J. Orts Mico, M. Ortin Navarro, M. Perez Climent, C. Serra Diaz (Hospital Virgen de los Lirios); M. Millan, A. Caro, J. Escuder, B. Espina, F. Feliu (Joan XXIII University Hospital); A. Climent Aira, A. Estévez Diz, M. T. Moreno Asencio, A. Varela Mato, R. Vázquez Bouzán (POVISA Hospital); A. M. Minaya Bravo, M.M. Diez-Alonso, R. Villeta-Plaza (Principe de Asturias Hospital); H. Guadalajara, D. Alías, D. García Olmo, C. Pastor, I. Valverde (Quironsalud Publicos); A. Sanchez-Romero, A. Gardea, M. Gil Santos, T. Nimmersgern, P. Serrano Paz (Unidad de Coloproctología, Hospital Vinalopó-

Torre Vieja); M. Romero-Simó, T. Blasco-Segura, I. Caravaca-García, D. Costa-Navarro, A. Zarco-Pleguezuelos (University General Hospital of Alicante); L. Sánchez-Guillén, B. Flor-Lorente, M. Frasson, Á. García-Granero, E. García-Granero (University Hospital La Fe Valencia); B. Arencibia, J. Alonso, G. Febles, E. M. Nogués, C. Roque (University Hospital of Gran Canaria-Dr. Negrín).

Sweden: J. Segelman, J. Nygren (Ersta Hospital); G. Nöstler (Falun lasarett); M. Abraham-Nordling, M. Egenvall (Karolinska University Hospital); P. Myrelid, B. Jung, P. Loftås (Linköping University Hospital); M. L. Lydrup, N. Azahr, P. Buchwald, P. Mangell, I. Syk (Skane University Hospital); M. Nikberg, J. Carlander, A. Chabok, K. Smedh, C. Tiselius (Västmanlands Hospital Västerås); S. Haapaniemi, A. Benckert (Vrinnevi Hospital Norrköping).

Switzerland: M. Adamina, C. Freil-Lanter, C. Gingert, P. Müller, J. Schäfli (Kantonsspital Winterthur); L. Regusci, M. Brenna, F. Fasolini (Regional Hospital Mendrisio); H. Misteli, P. Kirchhoff, D. Oertli (University Hospital Basel, Switzerland); D. Hahnloser, D. Clerc, M. Hübner (University Hospital of Lausanne, CHUV); F. Ris, N. C. Buchs, M. Chevallay, P. Morel, B. Schiltz (University Hospitals Geneva).

Taiwan: J. Y. Wang, W. C. Su, C. W. Huang, C. J. Ma, H. L. Tsai (Kaohsiung Medical University Hospital).

Turkey: G. S. Özbacı, B. B. Özkan, U. Karabacak (19 Mayıs University Faculty of Medicine); D. Bugra (American Hospital); F. Agalar, H. Baloglu, I. Basoglu (Anadolu Medical Center [in aff with Johns Hopkins Med]); N. Okkabaz, E. Binboga, A. Biricik, A. Celik, E. Yavuz (Bageilar Training and Research Hospital); A. E. Canda, C. Agalar, M. Fuzun, S. Sokmen, C. Terzi (Dokuz Eylul University); A. Isik (Erzincan University, Mengucek Gazi Training and Research Hospital); B. Karip, A. C. Bilgili (Fatih Sultan Mehmet Training and Research Hospital); S.

Leventoglu, B. Aytac, A. Yıldız, O. Yuksel (Gazi University Medical School); H. Sinan, O. Hancerliogullari, S. Kaymak, O. Kozak, M. T. Ozer (Gulhane Training and Research Hospital); I. S. Sarici, O. Akca, M. U. Kalayci, Y. Kara (Kanuni Sultan Suleyman Training and Research Hospital); D. Bugra, O. Agcaoglu, E. Balik, O. Bayram (Koc University School of Medicine); U. Sungurtekin, U. Ozgen (Pamukkale University School of Medicine); S. Demirbas (TOBB ETU University Hospital); E. Öztürk, O. Isik, T. Yilmazlar (Uludag University School of Medicine); E. Colak, S. Karagul, V. Kinas (University of Health Sciences, Samsun Training and Research Hospital).

UK: N. Fearnhead, I. Lord, P. Stewart (Addenbrooke's [Cambridge University] Hospital); M. Zammit (Basildon Hospital); S. Arnold, N. Battersby, J. Broadhurst, A. Mehta, F. Seretis (Basingstoke and North Hampshire Hospital); J. Shabbir, C. Jones, J. Kynaston (Bristol Royal Infirmary); D. Vimalachandran, E. Blower, C. McFaul, D. McWhirter, J. Pilkington (Countess of Chester Hospital); T. Wilson, M. Chowdhary (Doncaster Royal Infirmary); B. Stubbs, M. Abdalkoddus, C. Lai, N. Thavanesan, C. Yao (Dorset County Hospital); T. Agarwal, S. Dindyal, R. M. C. Hill, S. Reade, A. Slessor (Ealing Hospital); H. Paterson, A. Balfour, M. Boland, A. Geraghty, J. O'Kelly (Edinburgh Western General Hospital); P. Patel, S. Tezas (Furness General Hospital); S. Yahia, V. Jadhav, K. Marimuthu, A. Narayanan, B. Piramanayagam (George Eliot Hospital); N. Bradley, F. Buchanan, K. Paul, J. Singh, K. Thomson (Glasgow Royal Infirmary); S. Korsgen, M. Bedford, K. Lee, K. Leong (Good Hope Hospital); D. McArthur, A. Bhangu, S. Malik, I. Mohamed (Heartlands Hospital); P. Cunha, A. Pilavas (Homerton University Hospital NHS Trust); A. Reddy, S. Ahmed, A. Ahmed, J. Voll (James Cook University Hospital); V. Velchuru, R. Lal, B. Mirshekar Syahkal (James Paget Hospital); M. Kassai, M. Aleem, S. Keogh-Bootland (Jersey General Hospital); P. Sarmah, S. Brown, R. Keegan, A. Kelkar, P. Sen (Kettering General Hospital); M. Oliveira Cunha, S. Chaudhri, R. Fares, B. Singh, W. M. Thomas (Leicester General Hospital); M. I. Aslam, K. Boyle, D. Hemingway, A. Miller, M.



Norwood (Leicester Royal Infirmary); S. Gurjar, M. Al-Saeedi, L. Anandan, A. Sudlow, N. Zampitis (Luton & Dunstable Hospital); K. Malik, M. Bogdan, C. Smart (Macclesfield District General Hospital); M. R. Iqbal, S. Bailey, D. Lawes, G. Omar, R. Tamhane (Maidstone and Tunbridge Wells NHS Trust); M. Evans, S. Ather, J. Lim, H. Nageswaran, G. Taylor (Morrison Hospital); L. Hunt, J. Nicholls (Musgrove Park Hospital); I. Shaikh, F. Muscara, J. O'Brien, E. Photi, A. Stearns (Norfolk and Norwich University Hospital); D. Meylemans, C. Cunningham, R. Hompes (Oxford University Hospitals); A. Tennakoon, N. Kumarasinghe, M. Rao, I. Upanishad (Pilgrim Hospital); S. Smolarek, E. Platt, B. Rossi, J. C. Tham (Plymouth Hospital NHS Trust); J. Khan, N. Ahmad, Z. Shweejawee, S. Stefan (Queen Alexandra Hospital); N. Smart, I. Daniels, T. Gregoir, L. Longstaff, F. McDermott (Royal Devon & Exeter Hospital); M. Varcada, I. Drami, T. Gala, E. Moggia, K. Ratnatunga (Royal Free Hospital NHS Trust Hampstead); R. Harries, J. Hayes, G. Williams (Royal Gwent Hospital); T. Raymond, C. Bronder, E. Davies, P. Hawkin, O. Ryska (Royal Lancaster Infirmary); K. Ayrat, A. Beveridge, A. Bhowmik, M. Gill, R. Simpson (Royal Preston Hospital); A. Schofield, K. McArdle, M. Parmar (Royal Shrewsbury Hospital); M. Williamson, H. Burton, E. Courtney, C. Grant, A. Saracino (Royal United Hospital Bath); K. Newton, J. Epstein (Salford Royal NHS Foundation Trust); G. Branagan, M. Bignell, M. Symankewicz (Salisbury District Hospital); S. Zaman, R. Mankotia, Z. Siddiqui, A. Torrance (Sandwell General Hospital); D. Artioukh, M. Eggleston, K. Gokul, D. Selwyn (Southport and Ormskirk Hospitals); J. Warusavitarne, P. Chandrasinghe, J. Grainger, C. A. Leo, C. J. Vaizey (St Mark's Hospital); G. Harris, B. Levy, A. Skull (St Richard's Hospital); M. Thaha, S. Ahmed, A. Garg, H. Patel, A. Ramsanahie (The Royal London Hospital, Barts Health NHS Trust); M. Mondragon Pritchard, K. Cuinas Leon, G. Williams (The Royal Wolverhampton NHS Trust); A. Shukla, H. Brewer, J. Fitzgerald, H. Kho (United Lincolnshire Hospitals NHS Trust); J. Torkington, S. Tate, J. Wheat (University Hospital of Wales); J. Knight, J. Richardson, A. Tzivanakis (University Hospital Southampton); M. Gregori, M. A. Ashraf, M. Atif, A. Birindelli, J. Santos (University Hospitals Birmingham NHS FT); N. Saffaf, M. I. Aslam, L. Canning (Warwick

Hospital); N. Chandratreya, M. Bowen, B. Graham, Y. Hamad, M. Kaubrys (Weston General Hospital at Weston super Mare); Z. U. Chaudhry, C. Bhan, H. Mukhtar, A. Oshowo, J. Wilson (Whittington Hospital NHS Trust); J. Richardson, N. Gouvas, D. Nicol, S. Pandey, M. Zilvetti (Worcestershire Royal Hospital); A. Sharma, T. Fatayer, S. Mothe, M. Rahman (Wythenshawe Hospital, UHSM); N. Curtis, A. Allison, R. Dalton, N. Francis, J. Ockrim (Yeovil District Hospital).  
Ukraine: G. Psaras, H. Dudarovaska, T. Marharint, E. Mostovoy, S. Voloshin (Mariupol Cancer Center); O. Kolesnik, D. Makhmudov (National Cancer Institute, Ukraine).

United States: Y. Altinel (Cleveland Clinic); A. Iqbal, L. Cunningham, K. Go, S. Tan (University of Florida).

#### **ESCP 2015 Audit Collaborating Authors**

Argentina: M. Cillo, D. Estefania, J. Patron Uriburu, H. Ruiz, M. Salomon (Hospital Britanico de Buenos Aires).

Belarus: A. Makhmudov, L. Selnyahina, A. Varabei, Y. Vizhynis (Surgical Department of the Belarusian Medical Academy of Postgraduate Education).

Belgium: D. Claeys, B. Defoert, F. Muysoms, P. Pletinckx, V. Vergucht (AZ Maria Middelaes Gent); I. Debergh, T. Feryn, H. Reusens (AZ Sint Jan); M. Nachtergaele (AZ St Jozef Malle); D. Francart, C. Jhaes, S. Markiewicz, B. Monami, J. Weerts (Clinique St Joseph, Liege); W. Bouckaert, B. Houben, J. Knol, G. Sergeant, G. Vangertruyden (Jessa Hospital Hasselt); L. Haeck, C. Lange, C. Sommeling, K. Vindevoghel (OLV van Lourdes Ziekenhuis); S. Castro, H. De Bruyn, M. Huyghe (St Augustinus General Hospital); E. De Wolf, D. Reynders (St Vincentius

General Hospital); A. D'Hoore, A. de Buck van Overstraeten, A. Wolthuis (University Hospitals Leuven).

Bosnia and Herzegovina: S. Delibegovic (University Clinical Center Tuzla).

Brazil: A. Christiani, M. Marchiori Jr, C. Rocha de Moraes, V. Terciotti Jr (Centro Médico Campinas).

Bulgaria: E. Arabadjieva, D. Bulanov, D. Dardanov, V. Stoyanov, A. Yonkov (First Surgical Department, University Hospital Alexandrovska); K. Angelov, S. Maslyankov, M. Sokolov, G. Todorov, S. Toshev, (Second Surgery Clinic, Sofia Medical University). Y. Georgiev, A. Karashmalakov, G. Zafirov (Virgin Mary Hospital, Burgas).

China: X. Wang, (West China Hospital).

Croatia: D. Condic, D. Kraljik, H. Mrkovic, V. Pavkovic, K. Raguž (GCH Dr Josip Benčević Slavenski Brod).

Czech Republic: V. Bencurik, E. Holášková, M. Skrovina (Hospital & Oncological Centre Nový Jičín); M. Farkašová, T. Grolich, Z. Kala (Masaryk University Hospital); F. Antos, V. Pruchova (Nemocnice Na Bulovce); O. Sotona, M. Chobola, T. Dusek, A. Ferko, J. Örhalmi (University Hospital Hradec Kralove); J. Hoch, P. Kocian, L. Martinek (University Hospital Motol).

Denmark: I. Bernstein, K. Gotschalek Sunesen, J. Leunbach, O. Thorlacius Ussing, A. Uth Ovesen (Aalborg University Hospital); P. Christensen, S. Dahl Chirstensen, V. Gamez, M. Oeting, U. Schou Loeve, A. Ugianskis (Randers Regional Hospital/Aarhus University Hospital); M. Jessen, P. Krarup, K. Linde (Bispebjerg Hospital); Q. Mirza, J. Overgaard Stovring (Esbjerg Hospital); L. Erritzøe, H. Loft Jakobsen, J. Lykke, E. Palmgren Colov (Herlev Hospital); A.

Husted Madsen, T. Linde Friis (Herning Regional Hospital); J. Amstrup Funder, R. Dich (Hospitalsenheden Horsens); S. Kjær, S. Rasmussen, N. Schlesinger (Hvidovre Hospital); M. Dilling Kjaer, N. Qvist (OUH, Svendborg); A. Khalid (Regionshospitalet Viborg); G. Ali, A. El-Hussuna, S. Hadi, L. Rosell Walker (Slagelse Hospital).

Finland: A. Kivelä, T. Lehtonen, A. Lepistö, T. Scheinin, P. Siironen (Helsinki University Central Hospital); J. Kössi, P. Kuusanmäki, T. Tomminen, A. Turunen (Kanta-Häme Central Hospital); T. Rautio, M. Vierimaa (Oulu University Hospital); H. Huhtinen, J. Karvonen, M. Lavonius, A. Rantala, P. Varpe (Turku University Hospital).

France: E. Cotte, Y. Francois, O. Glehen, V. Kepenekian, G. Passot (Centre Hospitalier Lyon-Sud); L. Maggiori, G. Manceau, Y. Panis (CHU Beaujon); M. Gout (CHU Le Bocage); E. Rullier, B. van Geluwe (Hôpital Saint André); N. Chafai, J. H. Lefevre, Y. Parc, E. Tiret (Hôpital Saint-Antoine); C. Couette, E. Duchalais (University Hospital of Nantes).

Germany: A. Agha, M. Hornberger, A. Hungbauer, I. Iesalnieks, I. Weindl (Klinikum Bogenhausen); F. Crescenti (Klinikum Verden); M. Keller, N. Kolodziejcki, R. Scherer, D. Sterzing (Krankenhaus Waldfriede); B. Bock, G. Boehm, M. El Magd, C. Krones, M. Niewiera (Marienhospital Aachen); J. Buhr, S. Cordesmeier, M. Hoffmann, K. Krückemeier, T. Vogel (Raphaelsklinik Münster); M. Schön, J. Baral, T. Lukoschek, S. Münch, F. Pullig (Städtisches Klinikum Karlsruhe); K. Horisberger, P. Kienle, J. Magdeburg, S. Post (Universitätsmedizin).

Greece: K. Batzalexis, S. Germanos (General University Hospital of Larissa); C. Agalianos, C. Dervenis, N. Gouvas, P. Kanavidis, A. Kottikias (Konstantopouleio Hospital of Athens); I. E. Katsoulis, D. Korkolis, G. Plataniotis, G. Sakorafas (St. Savvas Cancer Hospital, Athens); I. Akrida, M. Argentou, C. Kollatos, C. Lampropoulos, S. Tsochatzis (University Hospital of Patras).

Hungary: I. Besznyák, A. Bursics, T. Egyed, G. Papp, I. Svastics (Uzsoki Hospital).

Iceland: J. Atladottir, P. Möller, H. Sigurdsson, T. Stefánsson, E. Valsdottir (The National University Hospital in Iceland).

Ireland: E. Andrews, N. Foley, D. Hechtl, M. Majeed, M. McCourt (Cork University Hospital); A. Hanly, J. Hyland, S. Martin, P. R. O'Connell, D. Winter (St Vincent's University Hospital); T. Connelly, W. Joyce, P. Wrafter (The Galway Clinic).

Israel: R. Berkovitz (Hadassah Medical Center); S. Avital, I. Haj-Yahia, N. Hermann, B. Shpitz, I. White (Meir Medical Center); Y. Lishtzinsky, A. Tsherniak, N. Wasserberg (Rabin Medical Center, Beilinson Campus); N. Horesh, U. Keler, R. Pery, R. Shapiro, O. Zmora (Sheba Medical Centre); H. Tulchinsky (Tel Aviv Sourasky Medical Center); B. Badran, K. Dayan, A. Iskhakov, J. Lecaros, N. Nabih (Wolfson Medical Center).

Italy: I. Angrima, R. Bardini, E. Pizzolato, M. Tonello (Azienda Ospedaliera—Università degli Studi di Padova); F. Arces, R. Balestri, C. Ceccarelli, V. Prospero, E. Rossi (Azienda Ospedaliero-Universitaria Pisana); I. Giannini, L. Vincenti (Azienda Ospedaliero-Universitaria Policlinico Bari); F. Di Candido, M. Di Iena, A. Guglielmi, O. Caputi-Iambrenghi (Department of Emergency and Organ Transplantation, University of Bari); P. Marsanic, A. Mellano, A. Muratore (Candiolo Cancer Institute—FPO—IRCCS); M. Anecchiarico, L. Bencini, S. Amore Bonapasta, A. Coratti, F. Guerra (Careggi Hospital); C. R. Asteria, L. Boccia, L. Gerard, A. Pascariello (ASST—Mantova); G. Manca, F. Marino (Di Summa—Perrino Hospital); A. Casaril, M. Inama, G. Moretto (Hospital “Dott. Pederzoli” Peschiera del Garda—Verona); C. Bacchelli, M. Garvello, N. Mariani, M. Montorsi, A. Spinelli (Humanitas Research Hospital); E. Romairone, S. Scabini (IRCCS San Martino IST); A. Belli, F. Bianco, S. De Franciscis, G. Maria Romano

(Istituto Nazionale dei Tumori, Napoli, Unità di Oncologia Addominale); P. Delrio, U. Pace, D. Rega, C. Sassaroli, D. Scala, (Istituto Nazionale Tumori Napoli); R. De Luca, E. Ruggieri (National Cancer Research Center Istituto "G. Paolo II" IRCCS BARI); C. Elbetti, A. Garzi, L. Romoli, M. Scatizzi, A. Vannucchi (Ospedale S. Stefano); G. Curletti, V. Durante, R. Galleano, F. Mariani, L. Reggiani (Ospedale Santa Corona); R. Bellomo, A. Infantino (Ospedale Santa Maria dei Battuti); L. Franceschilli, P. Sileri (Policlinico di Tor Vergata); I. Clementi, D. Coletta, F. La Torre, A. Mingoli, F. Velluti (Policlinico Umberto I "La Sapienza" University of Rome); A. Di Giacomo, A. Fiorot, M. Massani, L. Padoan, C. Ruffolo (Regional Hospital Cà Foncello, Treviso); S. Caruso, F. Franceschini, R. Laessig, I. Monaci, M. Rontini (S.M. Annunziata Azienda Sanitaria Firenze 10); P. De Nardi, U. Elmore, M. Lemma, R. Rosati, A. Tamburini (San Raffaele Scientific Institute and Vita Salute University); M. De Luca, A. Sartori, (San Valentino Hospital); A. Benevento, C. Bottini, C. C. Ferrari, F. Pata, G. Tessera (Sant'Antonio Abate Hospital, Gallarate); G. Pellino, F. Selvaggi (Second University of Naples); A. Lanzani, F. Romano, G. Sgroi, F. Steccanella, L. Turati (Treviglio Hospital).

Japan: T. Yamamoto (Yokkaichi Hazu Medical Centre).

Latvia: G. Ancans, S. Gerkis, M. Leja, A. Pcolkins, A. Sivins (Riga East University Hospital, Latvia Oncology Center);

Lithuania: T. Latkauskas, P. Lizdenis, Ž. Saladžinskas, S. Švagždys, A. Tamelis (Lithuanian University of Health Sciences, Faculty of Medicine, Department of Surgery); A. Razbadauskas, M. Sokolovas (Klaipeda Seamen's Hospital); A. Dulskas, N. Samalavicius (National Cancer Institute); V. Jotautas, S. Mikalauskas, E. Poskus, T. Poskus, K. Strupas (Vilnius University Hospital Santariskiu Klinikos).

Malta: C. Camenzuli, C. Cini, A. Predrag, J. Psaila, N. Spiteri (Mater Dei Hospital).

Netherlands: W. Bemelman, C. Buskens, E. J. de Groof, J. Gooszen, P. Tanis (Academic Medical Center Amsterdam); E. Belgers (Atrium Medical Center Heerlen); P. Davids, E. Furnee, E. Postma, A. Pronk, N. Smakman (Diakonessenhuis); S. Clermonts, D. Zimmerman (Elisabeth-Tweesteden); J. Omloo, E. van der Zaag, P. van Duijvendijk, E. Wassenaar (Gelre Hospital Apeldoorn); M. Bruijninckx, E. de Graff, P. Doornebosch, G. Tetteroo, M. Vermaas (Jsselland Ziekenhuis); G. Iordens, S. Knops, B. Toorenvliet (Ikazia Ziekenhuis); H. L. van Westereenen (Isala Hospital Zwolle); E. Boerma, P. Coene, E. van der Harst, A. Van Der Pool (Maasstad Ziekenhuis); M. Raber (Medisch Spectrum Twente Hospital); J. Melenhorst (MUMC+/AZM); S. de Castro, M. Gerhards (Onze Lieve Vrouwe Gasthuis); M. Arron, A. Bremers, H. de Wilt, F. Ferenschild, S. Yauw (Radboud University Medical Center); H. Cense, A. Demirkiran, M. Hunfeld, I. Mulder (Rode Kruis Hospital); J. Nonner (Sint Franciscus Gasthuis); H. Swank, B. van Wagenveld (Sint Lucas Andreas Ziekenhuis); M. Bolmers, J. Briel, A. van Geloven, C. van Rossem (Tergeoi Hospital Hilversum); V. Klemann, J. Konsten, B. Leenders, T. Schok (VicCuri Medical Center voor Noord-Limburg); W. Bleeker (Wilhelmina Hospital Assen).

Northern Ireland: A. Gidwani, R. Lawther, P. Loughlin, B. Skelly, R. Spence (Altnagelvin Hospital).

Norway: M. Brun, M. Helgeland, D. Ignjatovic, T. Øresland, P. Yousefi (Akershus University Hospital); I. Flåten-Backe, O. Helmer Sjø, A. Nesbakken, M. Tandberg-Eriksen (Oslo University Hospital); A. Cais, J. Hallvard Træland, R. Herikstad, H. Kørner, N. Lauvland (Stavanger University Hospital).

Poland: D. Jajtner, W. Kabiesz, M. Rak (Beskidian Oncological Center); L. Gmerek, K. Horbacka, N. Horst, P. Krokowicz (General and Colorectal Surgery Department University of Medical Sciences); A. Kwiatkowski, K. Pasnik (Military Institute of Medicine); P. Karcz, M. Romaniszyn, T. Rusek, P. Walega (Third Department of General Surgery, Jagiellonian

University Medical College); R. Czarencki, Z. Obuszko, M. Sitarska, W. Wojciech, M. Zawadzki (Wroclaw Regional Hospital).

Portugal: S. Amado, P. Clara, A. Couceiro, R. Malaquias, N. Rama (Centro Hospitalar de Leiria); A. Almeida, E. Barbosa, E. Cernadas, A. Duarte, P. Silva (Centro Hospitalar s. João); S. Costa, C. Martinez Insua, J. Pereira, C. Pereira, M. Sacchetti (Centro Hospitalar Tâmega e Sousa); B. Carvalho Pinto, P. Jorge Vieira Sousa, R. Marques, A. Oliveira (Centro Hospitalar Trás-os-Montes e Alto Douro); R. Cardoso, S. Carlos, J. Corte Real, P. Moniz Pereira, R. Souto (Garcia de Orta); C. Carneiro, R. Marinho, V. Nunes, R. Rocha, M. Sousa (Hospital Prof. Dr. Fernando Fonseca); J. Leite, F. Melo, J. Pimentel, L. Ventura, C. Vila Nova (Universidade Coimbra). Romania: C. Copăescu (Ponderas Hospital); V. Bintintan, C. Ciuce, G. Dindelegan, R. Scurtu, R. Seicean (Univeristy Emergency Hospital Cluj Napoca).

Russia: N. Domansky, A. Karachun, A. Moiseenko, Y. Pelipas, A. Petrov, I. Pravosudov (N.N.Petrov Research Institute of Oncology); R. Aiupov, Y. Akmalov, A. Parfenov, N. Suleymanov, N. Tarasov (Oncological Centre); H. Jumabaev, Z. Mamedli, A. Rasulov (Russian Cancer Research Center); I. Aliev, I. Chernikovskiy, V. Kochnev, K. Komyak, I. Pravosudov, A. Smirnov (St. Petersburg Clinical Research Center); S. Achkasov, K. Bolikhov, Y. Shelygin, O. Sushkov, A. Zapolskiy (State Scientific Center of Coloproctology).

Serbia: M. Gvozdenovic, D. Jovanovic, Z. Lausevic (Center of Emergency Surgery, Clinical Center of Serbia); D. Cvetković, M. Maravić, B. Milovanovic, N. Stojakovic, I. Tripković (City Hospital Valjevo); D. Mihajlovic, M. Nestorovic, V. Pecic, D. Petrovic, G. Stanojevic (Clinical Centre Nis); G. Barisic, I. Dimitrijevic, Z. Krivokapic, V. Markovic, M. Popovic (First Surgical Clinic, Cilinical Centre of Serbia, Belgrade); A. Aleksic, D. Dabic, I. Kostic, A. Milojkovic, V. Perunicic (General Hospital Cacak); D. Lukic, T. Petrovic, D. Radovanovic, Z. Radovanovic



(Oncology Institute of Vojvodina); V. M. Cuk, V. V. Cuk, M. Kenic, B. Kovacevic, I. Krdzic (University Clinical Center Zvezdara).

Slovakia: J. Korcek (Teaching Hospital Nitra).

Slovenia: M. Rems, J. Toplak (General Hospital Jesenice).

Spain: J. Escarrá, M. Gil-Barrionuevo, T. Golda, E. Kreisler Moreno, C. Zerpa-Martin (Bellvitge University Hospital); C. Álvarez-Laso, P. Cumplido, H. Padin (Cabueñes); J. Baixauli-Fons, J. Hernández-Lizoain, P. Martínez-Ortega, M. Molina-Fernández, C. Sánchez-Justicia (Clínica Universidad de Navarra); J. Antonio-Gracia-Solanas, E. Córdoba-Díaz-de-Laspra, E. Echazarreta-Gallego, M. Elia-Guedea, J. Ramirez (Clínico-Universitario, Zaragoza); J. Arredondo-Chaves, P. Díez-González, T. Elosua, J. Sahagún, A. Turienzo-Frade (Complejo Asistencial Universitario de León); J. Álvarez-Conde, E. Castrillo, R. Díaz-Maag, V. Maderuelo, L. Saldarriaga (Complejo Asistencial Universitario de Palencia); I. Aldrey-Gao, X. Fernández-Varela, S. Núñez-Fernández, A. Parajó-Calvo, S. Villar-Álvarez (Complejo Hospitalario de Ourense); I. Blesa-Sierra, A. Duarte, R. Lozano, M. Márquez, O. Porcel (Complejo Hospitalario Torrecárdenas); P. Menendez (Gutierrez-Ortega); M. Fernández-Hevia, L. Flores-Sigüenza, M. Jimenez-Toscano, A. Lacy-Fortuny, J. Ordoñez-Trujillo (Hospital Clínic de Barcelona); A. Espi, S. Garcia-Botello, J. Martín-Arévalo, D. Moro-Valdezate, V. Pla-Martí (Hospital Clínic Universitario de Valencia); F. Blanco-Antona (Hospital Clínic Universitario de Valladolid); J. Abrisqueta, N. Ibañez-Canoas, J. Lujan-Mompean (Hospital Clínic Universitario Virgen de la Arrixaca); D. Escolá-Ripoll, S. Martínez-González, J. Parodi (Hospital Comarcal de Vilafranca); A. Fernández-López, M. Ramos-Fernández (Hospital Costa del Sol); J. Castellvi-Valls, L. Ortiz-de-Zarate, R. Ribas, D. Sabia, L. Viso (Hospital de Sant Joan Despí Moisès Broggi); S. Alonso-Gonçalves, M. José-Gil-Egea, M. Pascual-Damieta, M. Pera, S. Salvans-Ruiz (Hospital del Mar);

J. Bernal, F. Landete (Hospital General de Requena); G. Ais, J. Etreros (Hospital General de Segovia); J. Aguiló-Lucía, A. Boscá, S. Deusa, J. García-del Caño, V. Viciano (Hospital Lluís Alcanyís); J. García-Armengol, J. Roig (Hospital NISA 9 de Octubre); J. Blas, J. Escartin, J. Fatás, J. Fernando, R. Ferrer (Hospital Royo-Villanova); R. Arias Pacheco, L. García-Flórez, M. Moreno-Gijón, J. Otero-Díez, L. Solar-García (Hospital San Agustín); F. Aguilar-Teixido, C. Balaguer-Ojo, J. Bargallo-Berzosa, S. Lamas-Moure (Hospital Terrassa); J. Enrique-Sierra, A. Fermiñán, F. Herrerías, M. Rufas, J. Viñas (Hospital Universitari Arnau de Vilanova); A. Codina-Gazador, R. Farrés, N. Gómez, D. Julià, P. Planellas (Hospital Universitari de Girona-Doctor Josep Trueta); J. López, A. Luna, C. Maristany, A. Muñoz-Duyos, N. Puértolas (Hospital Universitari Mútua-Terrassa); M. Alcantara-Moral, X. Serra-Aracil (Hospital Universitari Pare Taulí de Sabadell); P. Concheiro-Coello, D. Gómez (Hospital Universitario de A Coruña); C. Carton, A. Miguel, F. Reoyo-Pascual, X. Valero-Cerrato, R. Zambrano-Muñoz (Hospital Universitario de Burgos); J. Cervera-Aldama, J. García-González, J. Ramos-Prada, M. Santamaría-Olabarrieta, A. Urigüen-Echeverría (Hospital Universitario de Cruces); R. Covas-Alcover, J. Espinosa-Soria, E. Fernández-Rodríguez, J. Hernandis-Villalba, V. Maturana-Ibañez (Hospital Universitario De Elda); F. De la Torre-González, D. Huerga, E. Pérez-Viejo, A. Rivera, E. Ruiz-Ucar (Hospital Universitario de Fuenlabrada); J. García-Septiem, V. Jiménez, J. Jiménez-Miramón, J. Ramons-Rodríguez, V. Rodríguez-Alvarez (Hospital Universitario de Getafe); A. Garcea, L. Ponchietti (Hospital Universitario de Torre Vieja); N. Borda, J. Enriquez-Navascues, Y. Saralegui (Hospital Universitario Donostia); G. Febles-Molina, E. Nogues, Á. Rodríguez-Méndez, C. Roque-Castellano, Y. Sosa-Quesada (Hospital Universitario Dr. Negrín); M. Álvarez-Gallego, I. Pascual, I. Rubio-Pérez, B. Díaz-San-Andrés, F. Tone-Villanueva (Hospital Universitario La Paz); J. Alonso, C. Cagigas, J. Castillo, M. Gómez, J. Martín-Parra (Hospital Universitario Marqués de Valdecilla); M. Mengual-Ballester, E. Pellicer-Franco, V. Soria-Aledo, G. Valero-Navarro (Hospital Universitario Morales-Meseguer); E. Caballero-Rodríguez, P. González-De-Chaves, G. Hernández, A. Pérez-Alvarez, A. Soto-Sánchez,

(Hospital Universitario Ntra Sra de Candelaria); F. Cesar Becerra Garcia , J. Guillermo Alonso Roque , F. López Rodríguez Arias, S. R. Del Valle Ruiz, G. Sánchez De La Villa (Hospital Universitario Rafael Méndez); A. Compañ, A. García Marín, C. Nofuentes, F. Orts Micó, V. Pérez Auladell (Hospital Universitario San Juan de Alicante); M. Carrasco, C. Duque Perez, S. Gálvez Pastor, I. Navarro Garcia, A. Sanchez Perez (Hospital Universitario Santa Lucía); D. Enjuto, F. Manuel Bujalance, N. Marcolin, M. Pérez, R. Serrano García (Hospital Universitario Severo Ochoa); A. Cabrera, F. de la Portilla, J. Díaz Pavon, R. Jimenez-Rodriguez, J. Vazquez Monchul (Hospital Universitario Virgen del Rocío); J. Daza González, R. Gómez Pérez, J. Rivera Castellano, J. Roldán de la Rúa (Hospital Virgen de la Victoria); J. Errasti Alustiza, L. Fernandez, J. Romeo Ramirez, J. Sardon Ramos, B. Cermeño Toral (Hospital Universitario Araba); D. Alias, D. Garcia Olmo, H. Guadalajara, M. Herreros, P. Pacheco (Quironsalud); F. del Castillo Díez F. Lima Pinto, J. Martínez Alegre, I. Ortega, A. Picardo Nieto Antonio (Infanta Sofia University Hospital); A. Caro, J. Escuder, F. Feliu, M. Millan (Joan XXIII University Hospital); R. Alos Company, A. Frangi Caregnato, R. Lozoya Trujillo, R. Rodríguez Carrillo, M. Ruiz Carmona (Sagunto); N. Alonso, D. Ambrona Zafra, B. Amilka Ayala Candia J. Bonnin Pascual, C. Pineño Flores (Son Espases); J. Alcazar Montero, M. Angoso Clavijo, J. Garcia, J. Sanchez Tocino (Universitario de Salamanca); C. Gómez Alcazar, D. Costa Navarro, J. Ferri Romero, M. Rey Riveiro, M. Romero Simó (University General Hospital of Alicante); B. Arencibia, P. Esclapez, M. Frasson, E. García Granero, P. Granero (University Hospital La Fe); F. J. Medina Fernández, A. B. Gallardo Herrera, C. Diaz López, E. Navarro Rodriguez, E. Torres Tordera (University Hospital Reina Sofía de Córdoba); J. Arenal, M. Citores, J. Marcos, J. Sánchez, C. Tinoco (University Hospital Río Hortega); E. Espin, A. Garcia Granero, L. Jimenez Gomez, J. Sanchez Garcia, F. Vallribera (Valle de Hebron).

Sweden: J. Folkesson, F. Sköldberg (Akademiska Sjukhuset); K. Bergman, E. Borgström, J. Frey, A. Silfverberg, M. Söderholm (Blekingesjukhuset); J. Nygren, J. Segelman (Karolinska

Institutet and Ersta Hospital); D. Gustafsson, A. Lagerqvist, A. Papp, M. Pelczar (Hudiksvalls Hospital); M. Abraham-Nordling, M. Ahlberg, A. Sjövall (Karolinska University Hospital); J. Tengstrom (Lidköping); K. Hagman (Ryhov County Hospital); A. Chabok, E. Ezra, M. Nikberg, K. Smedh, C. Tiselius (Västmanlands Hospital Västerås).

Switzerland: N. Al-Naimi, M. Dao Duc, J. Meyer, M. Mormont, F. Ris (Geneva University Hospitals); G. Prevost, P. Villiger (Kantonsspital Graubünden); H. Hoffmann, C. Kettelhack, P. Kirchhoff, D. Oertli, B. Weixler (University Hospital Basel).

Turkey: B. Aytac, S. Leventoglu, B. Mentec, O. Yuksel (Gazi University Medical School, Dep. of Surg); S. Demirbas (Gülhane Military Medical Academy, School of Medicine); B. Busra Ozkan, G. Selçuk Özbacı (Ondokuz Mayıs University Medical Faculty); U. Sungurtekin (Pamukkale University School of Medicine); B. Gülcü, E. Ozturk, T. Yilmazlar (Uludag University School of Medicine Hospital).

UK: C. Challand, N. Fearnhead, R. Hubbard, S. Kumar (Addenbrooke's Hospital); J. Arthur, C. Barben, P. Skaife, S. Slawik, M. Williams (Aintree University Hospitals NHS Foundation Trust); M. Zammit (Basildon Hospital); J. Barker, J. French, I. Sarantis, C. Slawinski (Blackpool Victoria); R. Clifford, N. Eardley, M. Johnson, C. McFaul, D. Vimalachandran (Countess of Chester); S. Allan, A. Bell, E. Oates, V. Shanmugam (Darlington Memorial Hospital); A. Brigie (Doncaster Royal Infirmary); M. Halls, P. Pucher, B. Stubbs (Dorset County Hospital); T. Agarwal, A. Chopada, S. Mallappa, M. Pathmarajah, C. Sugden (Ealing Hospital); C. Brown, E. Macdonald, A. McKay, J. Richards, A. Robertson (Forth Valley Royal Hospital); M. Kaushal, P. Patel, S. Tezas, N. Touqan (Furness General Hospital); S. Ayaani, K. Marimuthu, B. Piramanayagam, M. Vourvachis (George Eliot Hospitals NHS Trust); N. Iqbal, S. Korsgen, C. Seretis, U. Shariff (Good Hope Hospital); S. Arnold, N. Battersby, H. Chan, E. Clark, R.

Fernandes, B. Moran (Hampshire Hospitals NHS Trust); A. Bajwa, D. McArthur (Heartlands Hospital); K. Cao, P. Cunha, H. Pardoe, A. Quddus, K. Theodoropoulou (Homerton Hospital); C. Bolln, G. Denys, M. Gillespie, N. Manimaran, J. Reidy (Inverclyde Royal Hospital); A. I. Malik, A. Malik, J. Pitt (Ipswich Hospital NHS Trust); K. Aryal, A. El-Hadi, R. Lal, A. Pal, V. Velchuru (James Paget University Hospital); S. Chaudhri, M. Oliveira-Cunha, B. Singh, M. Thomas (Leicester General Hospital); S. Bains, K. Boyle, A. Miller, M. Norwood, J. Yeung (Leicester Royal Infirmary); L. Goian, S. Gurjar, W. Saghir, N. Sengupta, E. Stewart-Parker (Luton & Dunstable Hospital); S. Bailey, T. Khalil, D. Lawes, S. Nikolaou, G. Omar (Maidstone and Tunbridge Wells NHS Trust); R. Church, B. Muthiah (Manor Hospital); W. Garrett, P. Marsh, N. Obeid (Medway Maritime Hospital); S. Chandler, P. Coyne, M. Evans (Morriston Hospital); L. Hunt, J. Lim, Z. Oliphant, E. Papworth, H. Weaver, (Musgrove Park Hospital); K. Cuiñas Leon, G. Williams, (New Cross Hospital); J. Hernon, S. Kapur, R. Moosvi, I. Shaikh, L. Swafe (Norfolk and Norwich University Hospital); M. Aslam, J. Evans, U. Ihedioha, P. Kang, J. Merchant (Northampton General Hospital); R. Hompes, R. Middleton (Oxford University Hospitals); A. Broomfield, D. Crutten-Wood, J. Foster, G. Nash (Poole General Hospital); M. Akhtar, M. Boshnaq, S. Eldesouky, S. Mangam, M. Rabie (QEQM Hospital, EKHUF Trust); J. Ahmed, J. Khan, N. Ming Goh, A. Shamali, S. Stefan (Queen Alexandra Hospital); D. Nepogodiev, T. Pinkney, C. Thompson (Queen Elizabeth Hospital Birmingham); A. Amin, J. Docherty, M. Lim, K. Walker, A. Watson (Raigmore Hospital); M. Hossack, N. Mackenzie, M. Paraoan (Royal Albert Edward Infirmary); N. Alam, I. Daniels, S. Narang, S. Pathak, N. Smart (Royal Devon and Exeter Hospital); A. Al-Qaddo, R. Codd, O. Rutka, G. Williams, (Royal Gwent Hospital); C. Bronder, I. Crighton, E. Davies, T. Raymond (Royal Lancaster Infirmary); L. Bookless, B. Griffiths, S. Plusa (Royal Victoria Infirmary); G. Carlson, R. Harrison, N. Lees, C. Mason, J. Quayle (Salford Royal NHS Foundation Trust); G. Branagan, J. Broadhurst, H. Chave, S. Sleight (Salisbury District Hospital); F. Awad, A. Bhangu, N. Cruickshank, H. Joy (Sandwell General Hospital); C. Boereboom, P. Daliya, A. Dhillon, N. Watson, R. Watson (Sherwood

Forest Hospitals NHS Foundation Trust); D. Artioukh, K. Gokul, M. Javed, R. Kong, J. Sutton (Southport & Ormskirk Hospital); O. Faiz, I. Jenkins, C. A. Leo, S. F. Samaranayake, J. Warusavitarne (St Mark's Hospital); S. Arya, C. Bhan, H. Mukhtar, A. Oshowo, J. Wilson (The Whittington Hospital); S. Duff, T. Fatayer, J. Mbuvi, A. Sharma (University Hospital of South Manchester NHS Trust); J. Cornish, L. Davies, R. Harries, C. Morris, J. Torkington (University Hospital of Wales); J. Knight, C. Lai, O. Shihab, A. Tzivanakis (University Hospital Southampton); A. Hussain, D. Luke, R. Padwick, A. Torrance, A. Tsiamis (University Hospitals of North Midlands); P. Dawson (West Middlesex University Hospital); A. Balfour, R. Brady, J. Mander, H. Paterson (Western General Hospital); N. Chandratreya, H. Chu, J. Cutting, S. Vernon, C. Wai Ho (Weston General Hospital); S. Andreani, H. Patel, M. Warner, J. Yan Qi Tan (Whipps Cross University Hospital).

USA: A. Iqbal, A. Khan, K. Perrin, A. Raza, S. Tan (University Hospital of Florida).

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