

SUPPLEMENTARY DATA

Neoplasms Reported With Liraglutide or Placebo in People With Type 2 Diabetes: Results From the LEADER Randomized Trial

Michael A. Nauck, MD; Thomas Jon Jensen, MD PhD; Carina Rosenkilde, MSc; Salvatore Calanna, MD PhD; John B. Buse, MD PhD; the LEADER Publication Committee on behalf of the LEADER Trial Investigators

Corresponding author: Michael A. Nauck, Diabetes Center Bochum-Hattingen, Department of Medicine I, St. Josef-Hospital, Ruhr-University Bochum, Gudrunstr. 56, 44791 Bochum, Germany. Tel: +49-(0)234-5096332; Email: michael.nauck@rub.de

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ECG reviewer: Gregory Piazza, Brigham and Women's Hospital, Boston, MA, USA

Study Investigators

Australia: Sally Abell, St. Vincent's Hospital, Fitzroy, VIC; Tim Davis, University of Western Australia, School of Medicine and Pharmacology, Fremantle Hospital, Fremantle, WA; Michael D'Emden, Royal Brisbane & Womens Hospital, Herston,

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QLD; Su Ann Ding, Blacktown Hospital Clinical Trials Centre, University of Western Sydney, Blacktown, NSW; Christopher Gilfillan, Eastern Health Clinical School, Monash University, Melbourne, VIC; Tim Greenaway, Diabetes Centre, Royal Hobart Hospital, Hobart, TAS; Florence Gunawan, Eastern Health Clinical School, Monash University, Melbourne, VIC; Jui Ho, South Australian Endocrine Research Pty Ltd, Keswick, SA; Richard Jackson, Logan Hospital, Griffith University, Griffith University, Meadowbrook, QLD; Balvinder Kalra, Eastern Health Clinical School, Monash University, Melbourne, VIC; Sue-Lynn Lau, Blacktown Hospital Clinical Trials Centre, University of Western Sydney, Blacktown, NSW; Jaime Lin, Blacktown Hospital Clinical Trials Centre, University of Western Sydney, Blacktown, NSW; Richard MacIsaac, St. Vincent's Hospital, Fitzroy, VIC; Ashley Makepeace, University of Western Australia, School of Medicine and Pharmacology, Fremantle Hospital, Fremantle, WA; Usman Malabu, Townsville Hospital, Douglas, QLD; Joanne Marjason, Royal Brisbane & Women's Hospital, Herston, QLD; Roland McCallum, Diabetes Centre, Royal Hobart Hospital, Hobart, TAS; Mark McLean, Blacktown Hospital Clinical Trials Centre, University of Western Sydney, Blacktown, NSW; Naswrin Moin, Blacktown Hospital Clinical Trials Centre, University of Western Sydney, Blacktown, NSW; Carolyn Petersons, Southern Adelaide Diabetes & Endocrine Services, Repatriation General Hospital, Adelaide, SA; Sarah Price, Eastern Health Clinical School, Monash University, Melbourne, VIC; Anthony Roberts, South Australian Endocrine Research Pty Ltd, Keswick, SA; David Roberts, Logan Hospital, Meadowbrook, QLD; Kunwarjit Sangla, Townsville Hospital, Douglas, QLD; Richard Simpson, Eastern Health Clinical School, Monash University, Melbourne, VIC; Stephen Stranks, Southern Adelaide Diabetes & Endocrine Services, Repatriation General Hospital, Adelaide, SA; Yong Tan, Townsville

SUPPLEMENTARY DATA

Hospital, Douglas, QLD; Tilenka Thynne, Southern Adelaide Diabetes & Endocrine Services, Repatriation General Hospital, Adelaide, SA; Jacqueline Walters, St. Vincent's Hospital, Fitzroy, VIC; Glenn Ward, St. Vincent's Hospital, Fitzroy, VIC; Wanling Wen, Eastern Health Clinical School, Monash University, Melbourne, VIC; Jane Zhang, Blacktown Hospital Clinical Trials Centre, University of Western Sydney, Blacktown, NSW.

Austria: Johanna Brix, Rudolfstiftung Hospital, Vienna; Astrid Feder, Rudolfstiftung Hospital, Vienna; Clemens Höbaus, Medical University of Vienna, Vienna; Florian Höllerl, Rudolfstiftung Hospital, Vienna; Vera Höller, Medical University of Graz, Graz; Torsten Kotter, Hanusch Hospital, Vienna; Eva Kratz, Rudolfstiftung Hospital, Vienna; Eva-Christina Krzizek, Rudolfstiftung Hospital, Vienna; Ulrike Leb-Stoeger, Medical University of Graz, Graz; Julia Mader, Medical University of Graz, Graz; Nikolaus Mras, Hanusch Hospital, Vienna; Eva Novak, Medical University of Graz, Graz; Florian Obendorf, Medical University of Vienna, Vienna; Slobodan Peric, Hietzing Hospital, Vienna; Gerfried Pesau, Medical University of Vienna, Vienna; Thomas Pieber, Medical University of Graz, Graz; Rudolf Prager, Hietzing Hospital, Vienna; Anja Ribitsch, Medical University of Graz, Graz; Christoph Schnack, Rudolfstiftung Hospital, Vienna; Guntram Schernthaner, Rudolfstiftung Hospital, Vienna; Gerit Schernthaner, Medical University of Vienna, Vienna; Thomas Wascher, Hanusch Hospital, Vienna.

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SUPPLEMENTARY DATA

Lapauw, Ghent University Hospital, De Pintelaan, Ghent; Michel Letiexhe, CHU de Liège, Liège; Chantal Mathieu, University Hospital Leuven, Leuven; Sophie Neven, University Hospital Leuven, Leuven; Frida Peiffer, Faculty of Medicine, Antwerp University Hospital, Edegem, Antwerp; Johannes Ruige, Ghent University Hospital, De Pintelaan, Ghent; André Scheen, CHU de Liège, Liège; Youri Taes, Ghent University Hospital, De Pintelaan, Ghent; Inge Van Boxelaer, University Hospital Leuven, Leuven; Greet Vandistel, University Hospital Leuven, Leuven; Yannick Van Durme, Ghent University Hospital, De Pintelaan, Ghent; Luc Van Gaal, Faculty of Medicine, Antwerp University Hospital, Edegem, Antwerp; Ann Verhaegen, Faculty of Medicine, Antwerp University Hospital, Edegem, Antwerp.

Brazil: Eveline Alencar, Centro de Pesquisas em Diabetes e Doenças Endócrino-metabólicas, Fortaleza, CE; Renata Alencar, Instituto Cearense de Endocrinologia, Fortaleza, CE; Ana Cristina Almeida, Irmandade da Santa Casa de Misericórdia de Curitiba, Unidade de Pesquisa Clínica, Curitiba, PR; Breno Alves, Hospital das Clínicas da Faculdade de Medicina de Universidade de Sao Paulo, São Paulo, SP; Erica Alves, Centro de Pesquisas Clínicas Ltda, São Paulo, SP; Graciella Alves, Hospital Geral de Goiânia Dr. Alberto Rassi, RDM Pesquisas Clínicas, Goiânia, GO; Jacy Alves, Hospital de Clínicas/UFPR, Curitiba, PR; Leticia Araujo, Hospital Geral de Goiânia Dr. Alberto Rassi, RDM Pesquisas Clínicas, Goiânia, GO; Vivian Arruda, Clínica de Endocrinologia Prof. Dr. Fadlo Fraige Filho, São Paulo, SP; Gustavo Akerman Augusto, CPQuali Pesquisa Clínica Ltda, São Paulo, SP; Rejane Baggentoss, Instituto de Endocrinologia e Diabetes de Joinville, Joinville, SC; Luíza Balestrassi, Hospital São Joaquim, Beneficência Portuguesa de São Paulo, São Paulo, SP; Marcus Barbosa, Instituto de Endocrinologia e Diabetes de Joinville, Joinville, SC; Igor Barcelos, Hospital Geral de Goiânia Dr. Alberto Rassi, RDM

SUPPLEMENTARY DATA

Pesquisas Clínicas, Goiânia, GO; Lucia Belem, Instituto Cearense de Endocrinologia, Fortaleza, CE; Anke de Bem, Hospital de Clinicas, Curitiba, PR; Roberto Tadeu Betti, Instituto do Coração do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo,, São Paulo, SP; Renata Bona, Centro de Pesquisas Clínicas Ltda, São Paulo, SP; Adriana Bosco, Centro de Estudos e Pesquisa da Clinica de Endocrinologia e Metabologia, Belo Horizonte, MG; Julia Branda, Hospital São Joaquim, Beneficência Portuguesa, São Paulo, SP; Marcello Bronstein, CPQuali Pesquisa Clínica Ltda., São Paulo, SP; Thiago Bueno, Clínica de Endocrinologia Prof. Dr. Fadlo Fraige Filho, São Paulo, SP; Tania Bulcão, Instituto de Estudos e Pesquisas Clínicas do Ceará, Fortaleza, CE; Fátima Caiado, Instituto de Ciências Farmacêuticas de Estudos e Pesquisas, Aparecida de Goiânia, GO; Fabio Camazzola, Instituto de Pesquisas Clínicas para Estudos Multicêntricos, Universidade de Caxias do Sul, Caxias do Sul, RS; Maria Fernanda Cambréa, Clínica de Endocrinologia Prof Dr Fadlo Fraige Filho, São Paulo, SP; Simone Campos, Centro de Estudos e Pesquisa da Clinica de Endocrinologia e Metabologia, Belo Horizonte, MG; Stela Campos, Instituto Estadual de Diabetes e Endocrinologia, Rio de Janeiro, RJ; Luis Canani, Centro de Pesquisas em Diabetes, Porto Alegre, RS; Mario Kehdi Carra, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP; Salvador Caruso, Hospital São Joaquim, Beneficência Portuguesa de São Paulo, São Paulo, SP; Nara Carvalho, Centro de Pesquisas Medicas Básica e Clínica Ltda., Recife, PE; Angela Casillo, Instituto de Ensino e Pesquisa do Hospital da Cruz Vermelha Brasileira, Curitiba, PR; Denise Castro, Centro de Pesquisas Clínicas Ltda., São Paulo, SP; Taciana Cavalcanti, Centro de Pesquisas Medicas Básica e Clínica Ltda., Recife, PE; Vinicius Cavichioli, Centro de Endocrinologia Geloneze, Campinas, SP; Cintia

SUPPLEMENTARY DATA

Cercato, Hospital das Clínicas da Faculdade de Medicina de Universidade de São Paulo, São Paulo, SP; Antonio Chacra, Centro de Pesquisa Clínica em Diabetes, Hospital São Paulo UNIFESP, São Paulo, SP; William Challela, Instituto do Coração do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo,, São Paulo, SP; Helaine Silva Charchar, Hospital Universitário João de Barros Barreto, Belém, PA; Camila Chaves, Núcleo de Medicina Integrada, Mogi das Cruzes, SP; Carlos Chrisman, Núcleo de Medicina Integrada, Mogi das Cruzes, SP; Carolina Chrisman, Núcleo de Medicina Integrada, Mogi das Cruzes, SP; Joya Correia-Deur, Centro de Pesquisas Clínicas Ltda., São Paulo, SP; Augusto da Costa Junior, CPQuali Pesquisa Clínica Ltda,São Paulo, SP; Midiã Costa, Pontifícia Universidade Católica de Campinas, Campinas, SP; Bruna Costi, Centro de Pesquisas Médicas Básica e Clínica Ltda., Recife, PE; Priscilla Coutinho, Centro de Diabetes Curitiba, Curitiba, PR; Walmir Coutinho, Instituto Estadual de Diabetes e Endocrinologia, Rio de Janeiro, RJ; Maria Rosaria Cunha, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP; Jorge Daher Junior, Hospital Geral de Goiânia Dr. Alberto Rassi, RDM Pesquisas Clínicas, Goiânia, GO; Elaine Davini, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP; Dimas Democh Junior, Centro de Pesquisa Clínica em Diabetes, Hospital São Paulo UNIFESP, São Paulo, SP; Freddy Eliaschewitz, Centro de Pesquisas Clínicas Ltda., São Paulo, SP; Giuseppe Esmanhoto Facin, Instituto de Ensino e Pesquisa do Hospital da Cruz Vermelha Brasileira, Curitiba, PR; Francisco Farias, Centro de Pesquisas Médicas Básica e Clínica Ltda., Recife, PE; João Felício, Hospital Universitário João de Barros Barreto, Belém, PA; Virgínia Fernandes, Instituto Cearense de Endocrinologia, Fortaleza, CE; Celso Sallum Filho, Centro de Pesquisa Clínica em Diabetes,

SUPPLEMENTARY DATA

Hospital São Paulo UNIFESP, São Paulo, SP; Fadlo Fraige Filho, Clínica de Endocrinologia Prof. Dr. Fadlo Fraige Filho, São Paulo, SP; Manoel Filho, Centro de Pesquisas Medicas Básica e Clínica Ltda., Recife, PE; Daniele Fontan, Centro de Pesquisas Medicas Básica e Clínica Ltda., Recife, PE; Ana Paula Fontenele, Centro de Pesquisas em Diabetes e Doenças Endócrino-metabólicas, Fortaleza, CE; Adriana Forti, Centro de Estudos em Diabetes e Hipertensão, Fortaleza, CE; Denise Franco, Centro de Pesquisas Clínicas Ltda., São Paulo, SP; Kyara Freire, Centro de Pesquisas Medicas Básica e Clínica Ltda., Recife, PE; Annunziata Fusaro, Centro de Pesquisa Clínica em Diabetes, Hospital São Paulo UNIFESP, São Paulo, SP; Paulo Genestreti, Centro de Pesquisas Clínicas Ltda., São Paulo, SP; Fernando Gerchman, Hospital Moinhos de Vento, Porto Alegre, RS; Ana Godi, Hospital de Clinicas da Faculdade de Medicina de Marília, Marília, SP; Karla Fabiana Gomes, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP; Pedro Gonçalves, Instituto Estadual de Diabetes e Endocrinologia, Rio de Janeiro, RJ; Rodrigo Gonçalves, Centro de Pesquisas Clínicas Ltda, São Paulo, SP; Luiz Griz, Centro de Pesquisas Medicas Básica e Clínica Ltda., Recife, PE; Jorge Gross, Centro de Pesquisas em Diabetes, Porto Alegre, RS; Michelle Grossman, Centro de Pesquisas Clínicas Ltda, São Paulo, SP; Maria Helane Gurgel, Instituto Cearense de Endocrinologia, Fortaleza, CE; Amine Wiener Vasconcellos Haddad, Clínica de Endocrinologia Prof. Dr. Fadlo Fraige Filho, São Paulo, SP; Alfredo Halpern, Hospital das Clinicas da Faculdade de Medicina de Universidade de Sao Paulo, São Paulo, SP; Miguel Hissa, Centro de Pesquisas em Diabetes e Doenças Endócrinometabólicas, Fortaleza, CE; Alinne Inuy, Clínica de Endocrinologia Prof. Dr. Fadlo Fraige Filho, São Paulo, SP; Juliana Jaime, Hospital Geral de Goiânia Dr. Alberto Rassi, RDM Pesquisas Clínicas, Goiânia, GO; Thaisa

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Jonasson, Hospital de Clínicas/UFPR, Curitiba, PR; José Carlos Jorge, Irmandade da Santa Casa de Misericórdia de Curitiba, Unidade de Pesquisa Clínica, Curitiba, PR; Fernanda Justus Malucelli, Hospital de Clinicas, Curitiba, PR; Suely Kohara, Instituto de Endocrinologia e Diabetes de Joinville, Joinville, SC; Caroline Kramer, Centro de Pesquisas em Diabetes, Porto Alegre, RS; Claudio Lacerda, Centro de Diabetes Curitiba, Curitiba, PR; Suzanny Ladeira, Hospital Universitário João de Barros Barreto, Belém, PA; Janaína Lana, Centro de Pesquisas Clínicas Ltda., São Paulo, SP; Flavio Lastebasse, Centro de Pesquisas Clínicas Ltda, São Paulo, SP; Andressa Leitão, Centro de Diabetes Curitiba, Curitiba, PR; Silmara Leite, Instituto de Ensino e Pesquisa do Hospital da Cruz Vermelha Brasileira, Curitiba, PR; Antonio Carlos Lerário, Instituto do Coração do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP; Denise Lima, Centro de Pesquisas Medicas Básica e Clínica Ltda., Recife, PE; Marcelo Lima, Centro de Endocrinologia Geloneze, Campinas, SP; Vinicius Lippi, Hospital São Joaquim, Beneficência Portuguesa de São Paulo, São Paulo, SP; Maria Lunardi, Núcleo de Medicina Integrada, Mogi das Cruzes, SP; Evelyn Machado, Centro de Diabetes de Sergipe, Aracaju, SE; Frederico Maia, CPQuali Pesquisa Clínica Ltda., São Paulo, SP; Juliana Maia, Centro de Pesquisas Medicas Básica e Clínica Ltda., Recife, PE; Kleisson Pontes Maia, Centro de Estudos e Pesquisa da Clinica de Endocrinologia e Metabologia, Belo Horizonte, MG; Nadila Mañas, Hospital de Clinicas, Curitiba, PR; Frederico Marchisotti, CPQuali Pesquisa Clínica Ltda., São Paulo, SP; Carlos Marinho, Centro de Pesquisas Medicas Básica e Clínica Ltda., Recife, PE; Carliane Martins, Hospital Universitário João de Barros Barreto, Belém, PA; Fabrícia Figueiredo de Medeiros, Hospital Geral de Goiânia Dr. Alberto Rassi, RDM Pesquisas Clínicas, Goiânia, GO; Amanda Melo, Centro de Pesquisas Medicas

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Básica e Clínica Ltda., Recife, PE; Franciane Melo, Hospital Universitário João de Barros Barreto, Belém, PA; Eurico Mendonca, Centro de Pesquisa Clínica em Diabetes, Hospital São Paulo UNIFESP, São Paulo, SP; Paulo Mendonça, Hospital Geral de Goiânia Dr. Alberto Rassi, RDM Pesquisas Clínicas, Goiânia, GO; Raimundo Menezes Filho, Centro de Diabetes de Sergipe, Aracaju, SE; Marianna Miguel, Hospital Geral de Goiânia Dr. Alberto Rassi, RDM Pesquisas Clínicas, Goiânia, GO; Karem Miléo, Hospital Universitário João de Barros Barreto, Belém, PA; Margareth Miyahara, Hospital Universitário João de Barros Barreto, Belém, PA; Ana Paula Montenegro, Instituto Cearense de Endocrinologia, Fortaleza, CE; Aline Moraes, Instituto Estadual de Diabetes e Endocrinologia, Rio de Janeiro, RJ; Alessandro Moreira, Instituto de Ciências Farmacêuticas de Estudos e Pesquisas, Aparecida de Goiânia, GO; José Ítalo Mota, Instituto de Estudos e Pesquisas Clínicas do Ceará, Fortaleza, CE; Flávia Silvia Mothe, Pontifícia Universidade Católica de Campinas, Campinas, SP; Ada Murro, Universidade Estadual de Campinas, Campinas, SP; Viviane Nakatani, Hospital de Clinicas, Curitiba, PR; Thiago Fraga Napoli, Instituto de Pesquisa Clínica, São Paulo, SP; Bruno Geloneze Neto, Centro de Endocrinologia Geloneze, Campinas, SP; Oscar Queiroz Neto, Instituto de Estudos e Pesquisas Clínicas do Ceará, Fortaleza, CE; Edgard Niclewicz, Centro de Diabetes Curitiba, Curitiba, PR; Louis Nakayama Ohe, Centro de Pesquisa Clínica em Diabetes, Hospital São Paulo UNIFESP, São Paulo, SP; Francisco Oliveira, Hospital São Joaquim, Beneficência Portuguesa de São Paulo, São Paulo, SP; Marcela Oliveira, Centro de Pesquisas Medicas Básica e Clínica Ltda., Recife, PE; Daniel Panarotto, Instituto de Pesquisas Clínicas para Estudos Multicêntricos, Universidade de Caxias do Sul, Caxias do Sul, RS; Erika Parente, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São

SUPPLEMENTARY DATA

Paulo, SP; Salma Parolin, Irmandade da Santa Casa de Misericórdia de Curitiba, Unidade de Pesquisa Clínica, Curitiba, PR; Luciana Pechmann, Centro de Diabetes Curitiba, Curitiba, PR; Paula Costa da Penha, Hospital Universitário João de Barros Barreto, Belém, PA; Lidiane Perlamagna, Centro de Pesquisas Clínicas Ltda., São Paulo, SP; Bruno Perotta, Clínica de Endocrinologia Prof. Dr. Fadlo Fraige Filho, São Paulo, SP; Larissa Pimentel, Centro de Pesquisas Medicas Básica e Clínica Ltda., Recife, PE; Mauro Pinto, Centro de Diabetes Curitiba, Curitiba, PR; Christiani Poço, Instituto de Pesquisa Clínica, São Paulo, SP; Clarisse Ponte, Instituto Cearense de Endocrinologia Fortaleza, CE; Paula Prazeres, Centro de Pesquisas Medicas Básica e Clínica Ltda., Recife, PE; Eder Quintao, CPQuali Pesquisa Clínica Ltda., São Paulo, SP; Roberto Raduan, Hospital São Joaquim, Beneficência Portuguesa de São Paulo, São Paulo, SP; Danilo Teixeira Rassi, Hospital Geral de Goiânia Dr. Alberto Rassi, RDM Pesquisas Clínicas, Goiânia, GO; Nelson Rassi, Hospital Geral de Goiânia Dr. Alberto Rassi, RDM Pesquisas Clínicas, Goiânia, GO; Rosangela Rea, Universidade Federal do Parana, Curitiba, PR; Luciana Reck, Centro de Pesquisas em Diabetes, Porto Alegre, RS; Renan Montenegro Jr., Instituto Cearense de Endocrinologia, Fortaleza, CE; Rochele Ribeiro, Instituto Cearense de Endocrinologia, Fortaleza, CE; Sylka Rodovalho, Centro de Endocrinologia Geloneze, Campinas, SP; Goretti Silveira Rodrigues, Instituto de Endocrinologia e Diabetes de Joinville, Joinville, SC; Guilherme Rollin, Hospital Moinhos de Vento, Porto Alegre, RS; Sarah Rossi, Clínica de Endocrinologia Prof. Dr. Fadlo Fraige Filho, São Paulo, SP; Cleide Sabino, Centro de Pesquisas Clínicas Ltda., São Paulo, SP; Ana Paula Sales, Instituto Cearense de Endocrinologia, Fortaleza, CE; João Salles, Instituto de Pesquisa Clínica, São Paulo, SP; Celia Regina Sampaio, Centro de Pesquisas Clínicas Ltda., São Paulo, SP; Lidiana

SUPPLEMENTARY DATA

Santana, Hospital Universitário João de Barros Barreto, Belém, PA; Victor Sato, Centro de Pesquisas Clínicas Ltda., São Paulo, SP; Mariana da Silva Santos, Hospital Geral de Goiânia Dr. Alberto Rassi, RDM Pesquisas Clínicas, Goiânia, GO; Norma Lúcia Santos, Centro de Diabetes de Sergipe, Aracaju, SE; Rosa Santos, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP; José Saraiva, Pontifícia Universidade Católica de Campinas, Campinas, SP; Carla Sartori, Centro de Pesquisas em Diabetes, Porto Alegre, RS; Rita Sena, Centro de Estudos em Diabetes e Hipertensão, Fortaleza, CE; Marcela Sevilha, Hospital São Joaquim, Beneficência Portuguesa de São Paulo, São Paulo, SP; José Sgarbi, Hospital de Clínicas da Faculdade de Medicina de Marília, Marília, SP; Dalisbor Silva, Instituto de Endocrinologia e Diabetes de Joinville, Joinville, SC; Daniel Silva, Centro de Estudos e Pesquisa da Clínica de Endocrinologia e Metabologia, Belo Horizonte, MG; Lilian D'albuquerque Silva, Hospital Universitário João de Barros Barreto, Belém, PA; Maria Elizabeth Silva, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP; Kátia Siqueira, Centro de Pesquisas Clínicas Ltda, São Paulo, SP; Samuel Soares, Hospital Geral de Goiânia Dr. Alberto Rassi, RDM Pesquisas Clínicas, Goiânia, GO; Wladia Sobreira, Instituto de Estudos e Pesquisas Clínicas do Ceará, Fortaleza, CE; Bruno Sousa, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP; Ana Carolina Souza, Hospital Universitário João de Barros Barreto, Belém, PA; Barbara Souza, Instituto de Endocrinologia e Diabetes de Joinville, Joinville, SC; Marcos Tambascia, Universidade Estadual de Campinas, Campinas, SP; Roberta Tarantino, Instituto Estadual de Diabetes e Endocrinologia, Rio de Janeiro, RJ; Fernanda Tenor, CPQuali Pesquisa Clínica Ltda., São Paulo, SP; Maithe Tomarchio, Clínica de Endocrinologia Prof. Dr. Fadlo Fraige Filho, São

SUPPLEMENTARY DATA

Paulo, SP; Cristina Triches, Instituto de Pesquisas Clínicas para Estudos Multicêntricos, Universidade de Caxias do Sul, Caxias do Sul, RS; Livia Justen Tristão, Instituto de Ensino e Pesquisa do Hospital da Cruz Vermelha Brasileira, Curitiba, PR; Adriana Valenti, Centro de Pesquisas em Diabetes, Porto Alegre, RS; Enio Vasques, Núcleo de Medicina Integrada, Mogi das Cruzes, SP; Sergio Vencio, Instituto de Ciências Farmacêuticas de Estudos e Pesquisas, Aparecida de Goiânia, GO; André Vianna, Centro de Diabetes Curitiba, Curitiba, PR; Thiago Munhoz Vidotto, Centro de Pesquisa Clínica em Diabetes, Hospital São Paulo UNIFESP, São Paulo, SP; Suélen Vieira, Instituto de Ensino e Pesquisa do Hospital da Cruz Vermelha Brasileira, Curitiba, PR; Heloisa Villar, Hospital de Clinicas da Faculdade de Medicina de Marília, Marília, SP; Guilherme Visconti, Centro de Pesquisas Clínicas Ltda, São Paulo, SP; Alexei Volaco, Irmandade da Santa Casa de Misericórdia de Curitiba, Unidade de Pesquisa Clínica, Curitiba, PR; Bernardo Wajchenberg, Instituto do Coração do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP; Leila Zanatta, Hospital de Clinicas, Curitiba, PR; Leila Zimmerman, Instituto de Pesquisa Clínica, São Paulo, SP.

Canada: E. Carl Abbott, Nova Scotia Health Authority, Halifax, Nova Scotia; Asiru Abu-Bakare, Port Arthur, Ontario; Andrew Advani, St. Michael's Health Centre, Toronto, Ontario; Roy Allison, Canadian Centre for Research on Diabetes, Smith Falls, Ontario; Phoebe Bishara, Medicine Professional Corporation, Cambridge, Ontario; C. Keith Bowering, Baker Clinic, Edmonton, Alberta; Alice Cheng, Credit Valley Hospital, Mississauga, Ontario; Sylvain Chouinard, Institut Universitaire de Cardiologie et de Pneumologie de Quebec, Quebec; Dale Clayton, Nova Scotia Health Authority, Halifax, Nova Scotia; James Conway, Canadian Centre for

SUPPLEMENTARY DATA

Research on Diabetes, Smith Falls, Ontario; Martin D'Amours, CHUL Research Center, Québec; Barna de Tugwell, Nova Scotia Health Authority, Halifax, Nova Scotia; Paul DeYoung, McConnell Medical Centre, Cornwall; Giuseppe D'Ignazio, Canadian Centre for Research on Diabetes, Smith Falls, Ontario; Francois Dube, Institut Universitaire de Cardiologie et de Pneumologie de Quebec, Quebec; Jean-Marie Ekoe, Institut de Recherches Cliniques de Montréal, Montréal, Québec; Susan Fagan, St. John's, Newfoundland; Claude Garceau, Institut Universitaire de Cardiologie et de Pneumologie de Quebec, Quebec; Irving Gottesman, Credit Valley Hospital, Mississauga, Ontario; Amir Hanna, St. Michael's Health Centre, Toronto, Ontario; Stewart Harris, The Western Centre for Public Health and Family Medicine, London, Ontario; Irene M. Hramiak, St. Joseph's Health Care, London, Ontario; Carmen Hurd, Health Sciences Centre, Winnipeg, Manitoba; S. Imran, Nova Scotia Health Authority, Halifax, Nova Scotia; Robert Josse, St. Michael's Health Centre, Toronto, Ontario; Carol Joyce, Memorial University of Newfoundland, St. John's, Newfoundland; Stephanie Kaiser, Nova Scotia Health Authority, Halifax, Nova Scotia; Farrukh Khan, Rouge Valley Metabolic Research Centre, Scarborough, Ontario; Isabelle Kirouac, Institut Universitaire de Cardiologie et de Pneumologie de Quebec, Quebec; Christopher Kovacs, Memorial University of Newfoundland, St. John's, Newfoundland; Isabelle Labonte, Institut Universitaire de Cardiologie et de Pneumologie de Quebec, Quebec; W. John Langlois, Credit Valley Hospital, Mississauga, Ontario; Lawrence Leiter, St. Michael's Health Centre, Toronto, Ontario; Marie-France Levac, McConnell Medical Centre, Cornwall, Canada; Joanne Liutkus, Medicine Professional Corporation, Cambridge, Ontario; Charlotte McDonald, St. Joseph's Health Care, London, Ontario; Vladimir Milosevic, Credit Valley Hospital, Mississauga, Ontario; Bulangu Lukuki Nyomba, Health Sciences

SUPPLEMENTARY DATA

Centre, Winnipeg, Manitoba; Terri Paul, St. Joseph's Health Care, London, Ontario; Kathleen Raby, Institut Universitaire de Cardiologie et de Pneumologie de Quebec, Quebec; Thomas Ransom, Nova Scotia Health Authority, Halifax, Nova Scotia; Sonja M. Reichert, The Western Centre for Public Health and Family Medicine, London, Ontario; Ravi Retnakaran, Mount Sinai Hospital, Toronto, Canada; Remi Rabasa-Lhoret, Institut de Recherches Cliniques de Montréal, Montréal, Québec; Errol Raff, Baker Clinic Edmonton, Alberta; Roya Shaikholeslami, Cambridge, Ontario; John Sigalas, Rouge Valley Metabolic Research Centre, Scarborough, Ontario; Churn-Ern Yip, Nova Scotia Health Authority, Halifax, Nova Scotia; S. John Weisnagel, CHUL Research Center, Québec, Canada; Vincent Woo, Health Sciences Centre, Winnipeg, Manitoba; Bernard Zinman, Mount Sinai Hospital, Toronto, Canada.

China: Yi Bao, Shanghai Changzheng Hospital, Shanghai; Xiaoling Cai, Peking University People's Hospital, Beijing; Jiangtian Chen, Peking University People's Hospital, Beijing; Kang Chen, Chinese PLA General Hospital, Beijing; Meiling Chen, Chinese PLA General Hospital, Beijing; Xia Chen, the Affiliated Hospital of Jiangsu University, Jiangsu; Yingli Chen, Peking University People's Hospital, Beijing; Linong Ji, Peking University People's Hospital, Beijing; Yang Ji, The affiliated hospital of Qingdao University, Shandong Province; Juan Lei, Sun Yat-sen memorial Hospital, Sun Yat-sen University, Guangzhou; Hongbing Li, Beijing Tongren Hospital, Beijing; Peijing Liu, the Affiliated Hospital of Jiangsu University, Jiangsu; Yiming Mu, Chinese PLA General Hospital, Beijing; Changyu Pan, Chinese PLA General Hospital, Beijing; Meng Ren, Sun Yat-sen memorial Hospital, Sun Yat-sen University, Guangzhou; Yusheng Ren, Shanghai Changzheng Hospital, Shanghai; Yongquan Shi, Shanghai Changzheng Hospital, Shanghai; Dong Wang, the Affiliated Hospital

SUPPLEMENTARY DATA

of Jiangsu University, Jiangsu; Fang Wang, The affiliated hospital of Qingdao University, Shandong Province; Jingjing Wang, Chinese PLA General Hospital, Beijing; Yangang Wang, The affiliated hospital of Qingdao University, Shandong Province; Li Yan, Sun Yat-sen memorial Hospital, Sun Yat-sen University, Guangzhou; Guoqing Yang, Chinese PLA General Hospital, Beijing; Jinkui Yang, Beijing Tongren Hospital, Beijing; Xiaolong Yu, The affiliated hospital of Qingdao University, Shandong Province; Guoyue Yuan, the Affiliated Hospital of Jiangsu University, Jiangsu; Mingtong Xu, Sun Yat-sen memorial Hospital, Sun Yat-sen University, Guangzhou; Xiuli Zhao, Beijing Tongren Hospital, Beijing; Jiaoyang Zheng, Shanghai Changzheng Hospital, Shanghai; Lingli Zhou, Peking University People's Hospital, Beijing.

Czech Republic: Kateřina Anderlová, III. Interní klinika VFN v Praze, U Nemocnice 1, Prague; Jitka Brožová, Diabetologické centrum I. interní kliniky FN Plzeň, Alej Svobody 80, Plzeň; Martin Haluzík, III. Interní klinika VFN a 1. LF UK v Praze, U Nemocnice 1, Prague; Věra Hanušová, III. Interní klinika VFN v Praze, U Nemocnice 1, Praha; Mikuláš Kosák, III. Interní klinika VFN v Praze, U Nemocnice 1, Prague; Jarmila Křížová, III. Interní klinika VFN v Praze, U Nemocnice 1, Prague; Miloš Mráz, III. Interní klinika VFN v Praze, U Nemocnice 1, Prague; Klára Owen, III. Interní klinika VFN v Praze, U Nemocnice 1, Prague; Zdenek Rušavý, Diabetologické centrum I. interní kliniky FN Plzeň, Alej Svobody 80, Plzeň; Jitka Tomešová, Diabetologické centrum I. interní kliniky FN Plzeň, Alej Svobody 80, Plzeň; Pavel Trachta, III. Interní klinika VFN v Praze, U Nemocnice 1, Prague; Michal Žourek, Diabetologické centrum I. interní kliniky FN Plzeň, Alej Svobody 80, Plzeň.

Denmark: Per Heden Andersen, Endokrinologisk Ambulatorium, Sydvestjysk Sygehus, Esbjerg; Trine Boesgaard, Steno Diabetes Centre, Gentofte; Sidsel

SUPPLEMENTARY DATA

Christensen, Steno Diabetes Centre, Gentofte; Jeppe Gram, Endokrinologisk Ambulatorium, Sydvestjysk Sygehus, Esbjerg; Søren Gregersen, Endokrinologisk Afdeling Medicinsk, MEA, Århus Universitetshospital THG, Århus; Jan Erik Henriksen, Endokrinologisk afdeling M, Odense Universitets Hospital, Odense; Kjeld Hermansen, Endokrinologisk Afdeling Medicinsk, MEA, Århus Universitetshospital THG, Århus; Poul Erik Jakobsen, Endokrinologisk Afdeling , Aalborg Sygehus, Aalborg; Jens Jensen, Endokrinologisk Afdeling Medicinsk, MEA, Århus Universitetshospital THG, Århus; Peter Kristensen, Steno Diabetes Centre, Gentofte; Annesofie Krogsaa, Steno Diabetes Centre, Gentofte; Mette Larsen, Endokrinologisk Afdeling Medicinsk, MEA, Århus Universitetshospital THG, Århus; Hans Henrik Lervang, Endokrinologisk Afdeling, Aalborg Sygehus Aalborg; Sten Madsbad, Medicinsk endokrinologisk amubalatorium, Hvidovre Hospital, Hvidovre; Lene Mortensen, Endokrinologisk Afdeling Medicinsk, MEA, Århus Universitetshospital THG, Århus; Thomas Olesen, Endokrinologisk afdeling M, Odense Universitets Hospital, Odense; Anna Pietraszek, Endokrinologisk Afdeling, Aalborg Sygehus, Aalborg; Martin Ridderstråle, Steno Diabetes Centre, Gentofte; Narges Safai, Steno Diabetes Centre, Gentofte; Anne Grethe Schioldan, Endokrinologisk Afdeling Medicinsk, MEA, Århus Universitetshospital THG, Århus; Christina Schmidt, Endokrinologisk afdeling M, Odense Universitets Hospital, Odense; Ole Snorgaard, Medicinsk endokrinologisk amubalatorium, Hvidovre Hospital, Hvidovre; Jacob Stidsen, Endokrinologisk afdeling M, Odense Universitets Hospital, Odense; Lise Tarnow, Steno Diabetes Center, Gentofte.

Finland: Henna Cederberg, Kuopio University Hospital, Kuopio; Hannu Haapamäki, Mehiläinen, Lahti; Janne Hukkanen, Oulu Sisätautien tutkimusyksikkö, Oulu; Raimo Jauhiainen, Kuopio University Hospital, Kuopio; Mona-Lisa Kujari, Oulu Sisätautien

SUPPLEMENTARY DATA

tutkimusyksikkö, Oulu; Markku Laakso, Kuopio University Hospital, Kuopio; Jorma Lahtela, Finn-Medi Research Ltd., Tampere; Merja Laine, Myyrmäki Health Centre, Vantaa; Jyrki Mäkelä, Mehiläinen, Lahti; Manna Miilunpohja, Kuopio University Hospital, Kuopio; Markku Savolainen, Oulu Sisätautien tutkimusyksikkö, Oulu; Jyrki Taurio, Finn-Medi Research Ltd., Tampere; Markku Vääntinen, Kuopio University Hospital, Kuopio.

France: Christine Creton, Nancy; Valeria Cosma, Hôpital Caremeau, Nîmes; Jean Dillinger, Mondelange; Jean-Luc Jacques, Mars-la-Tour; AnneMarie Guedj, Hôpital Caremeau, Nîmes; Michel Marre, Hôpital Bichat, Paris; Mustapha Moulla, Pont-à-Mousson; Catherine Petit, Centre Hospitalier Général Sud Francilien, Corbeil-Essonnes; Victor Ratsianoharana, Bousse; Dominique Richter, Jarny; Michel Rodier, Hôpital Caremeau, Nîmes; Ronan Roussel, Service de Diabétologie, Hôpital Bichat, Paris; Florence Travert, Service de Diabétologie, Hôpital Bichat, Paris.

Germany: Andrea Hinz, Diabetologische Schwerpunktpraxis, Gifhorn; Eberhard Politz, Diabetologische Schwerpunktpraxis, Gifhorn; Michael Esser, Praxis Esser, Essen; Ulrich Deuse, Praxis Esser, Essen; Dirk Mittag, Zentrum für Klinische Studien Südbrandenburg GmbH, Elsterwerda; Andreas Hagenow, Zentrum für Klinische Studien Südbrandenburg GmbH, Elsterwerda; Frohmut Jacob, Praxis für Prävention und Therapie, Villingen-Schwenningen; Stephan Jacob, Praxis für Prävention und Therapie, Villingen-Schwenningen; Ralf Jordan, Clintrial Berlin Praxis für Medizinische Studien, Berlin; Dominique Gantke, Clintrial Berlin Praxis für Medizinische Studien, Berlin; Ulrike Venschott-Jordan, ClinTrial Berlin c/o Diabetologie Steglitz, Berlin; Carmen Löhr, Studienzentrum, Aschaffenburg; Gerhard Klausmann, Studienzentrum, Aschaffenburg; Karin Eschenbrücher, Studienzentrum, Aschaffenburg; Mahir Karakas, Universitätsklinikum Ulm Innere Medizin II, Ulm;

SUPPLEMENTARY DATA

Bernd Jahrsdörfer, Universitätsklinikum Ulm Innere Medizin II, Ulm; Markus Rolf Kunze, Universitätsklinikum Ulm Innere Medizin II, Ulm; Jochen Wöhrle, Universitätsklinikum Ulm Innere Medizin II, Ulm; Wolfgang König, Universitätsklinikum Ulm Innere Medizin II, Ulm; Heike Spielhagen, Praxis Dr. med. J Lüdemann, Falkensee; Adam Kilimnik, Praxis Dr. med. J Lüdemann, Falkensee; Hans-Peter Lüdemann, Praxis Dr. med. J Lüdemann, Falkensee; Jörg Lüdemann, Praxis Dr. med. J Lüdemann, Falkensee; Andrea Mölle, Diabetologicum Dresden, Dresden; Matthias Mölle, Diabetologicum Dresden, Dresden; Joachim Müller, Ambulanzzentrum, Schweinfurt; Steffi Appelt, Ambulanzzentrum, Schweinfurt; Anke Sauter, Praxis Sauter & Sauter & Hartmann, Wangen; Joachim Sauter, Praxis Sauter & Sauter & Hartmann, Wangen; Ulrike Hartmann, Praxis Sauter & Sauter & Hartmann, Wangen; Anja Löw, Medizinische Klinik LMU Präventive Kardiologie, München; Florian Krötz, Medizinische Klinik LMU Präventive Kardiologie, München; Hae-Young Sohn, Medizinische Klinik LMU Präventive Kardiologie, München; Clemens von Schacky, Medizinische Klinik LMU Präventive Kardiologie, München; Volker Klauss, Medizinische Klinik LMU Präventive Kardiologie, München; Desiree Braun, Gemeinschaftspraxis Segner & Braun, St. Ingbert; Alexander Segner, Gemeinschaftspraxis Segner & Braun, St. Ingbert; Elizaveta Degtyareva, Synexus Clinical Research GmbH, Leipzig; Kristin Kreutzmann, GWT-TUD GmbH, Zentrum für Klinische Studien Forschungsbereich Endokrinologie und Stoffwechsel, Dresden; Rita Paschmionka, Synexus Clinical Research GmbH, Leipzig; Nora Hauck, Synexus Clinical Research GmbH, Leipzig; Olena Sihal, Synexus Clinical Research GmbH, Leipzig; Anne-Kathrin Busch, Synexus Clinical Research GmbH, Leipzig; Olga Maus, Synexus Clinical Research GmbH, Leipzig; Petra Stübler, Landteilstr 24, 68163 Mannheim; Sabine Füllgraf-Horst, Landteilstr 24, 68163 Mannheim; Angelika

SUPPLEMENTARY DATA

Vietzke, Studienzentrum in Berlin, Berlin; Christine Müller, Studienzentrum in Berlin, Berlin; Regina Tosch-Sisting, Studienzentrum in Berlin, Berlin; Bianca Lengsfeld, RED-Institut für medizinische Studien und Fortbildung GmbH, Oldenburg; Julia Thaler, RED-Institut für medizinische Studien und Fortbildung GmbH, Oldenburg; Thomas Schaum, RED-Institut für medizinische Studien und Fortbildung GmbH, Oldenburg; Joerg Steindorf, Diabetes-Schwerpunktpraxis, Schkeuditz; Sandra Steindorf, Diabetes-Schwerpunktpraxis, Schkeuditz; Alexander König, Klemens-Mengele Str. 10, 89407 Dillingen; Stefan Reitschuster, Klemens-Mengele Str. 10, 89407 Dillingen; Daniel Schlott, Blankeneser Bahnhofstr 23, 22587 Hamburg; Hans-Ulrich Clever, Blankeneser Bahnhofstr 23, 22587 Hamburg; Peter Witzel, Blankeneser Bahnhofstr 23, 22587 Hamburg; Hans-Peter Kempe, Gemeinschaftspraxis Dr. med. Kempe Dr. med. Stemler, Ludwigshafen; Lutz Stemler, Gemeinschaftspraxis Dr. med. Kempe Dr. med. Stemler, Ludwigshafen.

Greece: Apostolos Benis, “Thermi” Private Hospital, Thessaloniki; Marian Benroubi, Athens Polyclinic General Hospital, Athens; Evanthia Diakoumopoulou, Diabetes Centre, Laiko General Hospital of Athens, Athens; Kyriakos Kazakos, “Thermi” Private Hospital, Thessaloniki; Nikolaos Kypraios, Athens Polyclinic General Hospital, Athens; Stavros Liatis, Diabetes Centre, Laiko General Hospital of Athens, Athens; Emmanouil Pagkalos, “Thermi” Private Hospital, Thessaloniki; Evangelia Siami, Laiko General Hospital of Athens, Athens; Nikolaos Tentolouris, Diabetes Centre, Laiko General Hospital of Athens, Athens.

India: Varun Chandra Alur, Department of Endocrinology and Diabetes, Amrita Institute of Medical Sciences, Kerala; Megha Agrawal, TOTALL Diabetes Hormone Institute, Indore; Mazher Ali, CARE Outpatient Centre, Babu Khan Chambers, Hyderabad; Arthur Asirvatham, Kuruvikaran Salai, Madurai, Tamil Nadu; Evelyn

SUPPLEMENTARY DATA

Asirvatham, Kuruvikaran Salai, Madurai, Tamil Nadu; Tushar R Bandgar, Seth GS Medical College & KEM Hospital, Parel, Mumbai; Madhuri Balaji, Diabetes Research Institute, Chennai; Neil Bardoloi, Excel Care Hospitals, Ulubari, Guwahati; Manash Baruah, Excel Care Hospitals, Ulubari, Guwahati; Ragini Bekur, Kasturba Hospital, Manipal, Karnataka; Anil Bhansali, Postgraduate Institute of Medical Education and Research, Chandigarh; Sumith Bhatia, Kasturba Hospital, Manipal, Karnataka; Suchitra Bhonsley, Bangalore Clinisearch, Kalyan Nagar, Bangalore, Karnataka; Sonali Bhuyan, Excel Care Hospitals, Ulubari, Guwahati; Bidyut Borah, Christian Medical College, Vellore, Tamil Nadu; Nancy Bright, Bangalore Clinisearch, Kalyan Nagar, Bangalore, Karnataka; Ambrish C, Bangalore Clinisearch, Kalyan Nagar, Bangalore, Karnataka; Tirthankar Chaudhury, Apollo Gleneagles Hospital, Kolkata, West Bengal; Sapna Choudhury, TOTALL Diabetes Hormone Institute, Indore; Gopi Chellan, Department of Endocrinology and Diabetes, Amrita Institute of Medical Sciences, Kerala; Mrinal Das, Apollo Gleneagles Hospital, Kolkata, West Bengal; Mala Dharmalingam, Bangalore Endocrinology & Diabetes Research Centre, Malleshwaram, Bangalore, Karnataka; Pinaki Dutta, Postgraduate Institute of Medical Education and Research, Chandigarh; Anil Erugu, Christian Medical College, Vellore, Tamil Nadu; Vinutha F P, Bangalore Endocrinology & Diabetes Research Centre, Malleshwaram, Bangalore, Karnataka; Prasad Gunasekaran, Christian Medical College, Vellore, Tamil Nadu; Riddhi Das Gupta, Christian Medical College, Vellore, Tamil Nadu; Asif Iqbal, Kasturba Hospital, Manipal, Karnataka; Padoor Jagadish, Madras Diabetes Research Foundation, Chennai, Tamil Nadu; Sanjay Jain, TOTALL Diabetes Hormone Institute, Indore; Sunil Jain, TOTALL Diabetes Hormone Institute, Indore; Helen Jebasingh, Kuruvikaran Salai, Madurai, Tamil Nadu; Anulekha John, Christian Medical College, Vellore, Tamil Nadu; Maya

SUPPLEMENTARY DATA

John, Jothydev's Diabetes & Research Center, Kerala; Bharti Kalra, Bharti Research Institute of Diabetes & Endocrinology, Karnal, Haryana; Sanjay Kalra, Bharti Research Institute of Diabetes & Endocrinology, Karnal, Haryana; Prakash Kasaragod, Department of Endocrinology and Diabetes, Amrita Institute of Medical Sciences, Kerala; Jothydev Kesavadev, Jothydev's Diabetes & Research Center, Kerala; Harish Kumar, Department of Endocrinology and Diabetes, Amrita Institute of Medical Sciences, Kerala; Prasanna Kumar, Bangalore Diabetes Hospital, Vasanth Nagar Bangalore, Karnataka; Vivek Lakshmanan, Department of Endocrinology and Diabetes, Amrita Institute of Medical Sciences, Kerala; Anurag Ranjan Lila, Seth GS Medical College & KEM Hospital, Parel, Mumbai; Tom Mathew, Jothydev's Diabetes & Research Center, Kerala; Hameed Miya, Bangalore Clinisearch, Kalyan Nagar, Bangalore, Karnataka; Tara Mohan, Jothydev's Diabetes & Research Center, Kerala; Ashwin Motha, Christian Medical College, Vellore, Tamil Nadu; Chaithanya Murthy, Christian Medical College, Vellore, Tamil Nadu; Shivashankara N, Kasturba Hospital, Manipal, Karnataka; Amrit Nanaiah, Christian Medical College, Vellore, Tamil Nadu; Tittu Oommen, Department of Endocrinology and Diabetes, Amrita Institute of Medical Sciences, Kerala; Keshava Pani, Bangalore Clinisearch, Kalyan Nagar Bangalore, Karnataka; Kirnesh Pandey, TOTALL Diabetes Hormone Institute, Indore; Shamanna Paramesh, Bangalore Clinisearch, Kalyan Nagar, Bangalore, Karnataka; Vijayalakshmi Paramesh, Bangalore Diabetes Centre, Kalyan Nagar Bangalore, Karnataka; Binu Pillai, Department of Endocrinology and Diabetes, Amrita Institute of Medical Sciences, Kerala; Mukhyaprana Prabhu, Kasturba Hospital, Manipal, Karnataka; Kalki R.C, Christian Medical College, Vellore, Tamil Nadu; Saritha Ramachandran, Bangalore Diabetes Hospital, Vasanth Nagar Bangalore, Karnataka; Muthu Ramu, Madras Diabetes Research Foundation, Chennai, Tamil Nadu;

SUPPLEMENTARY DATA

Yashwanth Rao, Kasturba Hospital, Manipal, Karnataka; Sanjay Reddy, Bangalore Diabetes Hospital, Bangalore Vasanth Nagar, Bangalore, Karnataka; Padma Saikia, Bangalore Clinisearch, Kalyan Nagar, Bangalore, Karnataka; Kavitha Saravu, Kasturba Hospital, Manipal, Karnataka; Kasthuri Selvam, Madras Diabetes Research Foundation, Chennai, Tamil Nadu; Bipin Sethi, CARE Outpatient Centre, Babu Khan Chambers, Hyderabad; Arun Shankar, Jothydev's Diabetes & Research Center, Karala; Amit Sharma, Bharti Research Institute of Diabetes & Endocrinology, Karnal, Haryana ; Nalini Shah, Seth GS Medical College & KEM Hospital, Parel, Mumbai; Priti Shankar, Bangalore Endocrinology & Diabetes Research Centre, Malleshwaram, Bangalore, Karnataka; Ranjan Shetty, Kasturba Hospital, Manipal, Karnataka; Vyankatesh Shivane, Seth GS Medical College & KEM Hospital, Parel, Mumbai; Sudha Srivalli, Bangalore Clinisearch, Kalyan Nagar, Bangalore, Karnataka; Sufiya Thaseen, Christian Medical College, Vellore, Tamil Nadu; Nihal Thomas, Christian Medical College, Vellore, Tamil Nadu; Sarada S, Christian Medical College, Vellore, Tamil Nadu; Amanchi Shirisha, Christian Medical College, Vellore, Tamil Nadu; Manvizhi Subramani, Christian Medical College, Vellore, Tamil Nadu; Balaji V, Diabetes Research Institute, Chennai; Mohan V, Madras Diabetes Research Foundation, Chennai, Tamil Nadu; Padmanaban V, Christian Medical College, Vellore, Tamil Nadu; Muralidhar Verma, Kasturba Hospital, Manipal, Karnataka; Sudha Vidyasagar, Kasturba Hospital, Manipal, Karnataka; Vidya Walinjkar, Madras Diabetes Research Foundation, Chennai, Tamil Nadu; Rama Walia, Postgraduate Institute of Medical Education and Research, Chandigarh.

Ireland: Colin Davenport, Beaumont Hospital, Dublin; Hannah Forde, Beaumont Hospital, Dublin; Gaoatswe Gadintshware, Diabetes Day Centre, St Vincent's University Hospital, Dublin; KJ Gan, St Vincent's University Hospital, Dublin; Frances

SUPPLEMENTARY DATA

Hayes, St Vincent's University Hospital, Dublin; Aftab Khattak, St Vincent's University Hospital, Dublin; Jean O'Connell, St Vincent's University Hospital, Dublin; Donal O'Shea, St Vincent's University Hospital, Dublin; Diarmuid Smith, Beaumont Hospital, Dublin.

Israel: Victorya Beilin, Rabin Medical Center, Hasharon Hospital, Petah Tikva; Avivit Cahn, Diabetes Unit, Hadassah Ein Karem Medical Center, Jerusalem; Ohad Cohen, Institute of Endocrinology Sheba Medical Center, Tel HaShomer; Tali Cukierman-Yaffe, Institute of Endocrinology, Sheba Medical Center, Tel HaShomer; Deeb Daoud, Rambam Medical Center, Haifa; Mahmud Darawsha, Lin Medical Center, Haifa; Dror Dicker, Rabin Medical Center, Hasharon Hospital, Petah Tikva; Alex Gavish, Diabetes Unit, Hadassah Ein Karem Medical Center, Jerusalem; Irit Hochberg, Rambam Medical Center, Haifa; Jacob Ilany, Institute of Endocrinology Sheba Medical Center, Tel HaShomer; Uri Inbal, Institute of Endocrinology, Sheba Medical Center, Tel HaShomer; Baruch Itzhak, Lin Medical Center, Haifa; Avraham Karasik, Institute of Endocrinology, Sheba Medical Center, Tel HaShomer; Eddy Karnieli, Rambam Medical Center, Haifa; Nader Khader, Lin Medical Center, Haifa; Mogher Khamaisi, Rambam Medical Center, Haifa; Dan Lender, Diabetes Unit, Hadassah Ein Karem Medical Center, Jerusalem; Gabriella Segal Lieberman, Institute of Endocrinology, Sheba Medical Center, Tel HaShomer; Riad Mahamid, Rambam Medical Center, Haifa; Dana Marcoviciu, Rabin Medical Center - Hasharon Hospital, Petah Tikva; Leonid Michael, Institute of Endocrinology, Sheba Medical Center, Tel HaShomer; Oscar Minuchin, Lin Medical Center, Haifa; Ofri Mosenzon, Diabetes Unit, Hadassah Ein Karem Medical Center, Jerusalem; Feige Narevichius, Rambam Medical Center, Haifa; Ruth Percik, Institute of Endocrinology, Sheba Medical Center, Tel HaShomer; Marina Potekhin, Diabetes Unit, Hadassah Ein

SUPPLEMENTARY DATA

Karem Medical Center, Jerusalem; Itamar Raz, Diabetes Unit, Hadassah Ein Karem Medical Center, Jerusalem; Muhammad Sabbah, Lin Medical Center, Haifa; Said Sawaed, Lin Medical Center, Haifa; Daniel Schurr, Diabetes Unit, Hadassah Ein Karem Medical Center, Jerusalem; Elena Segal, Rambam Medical Center, Haifa; Ladislav Slezak, Lin Medical Center, Haifa; Ira Vollach, Institute of Endocrinology, Sheba Medical Center, Tel HaShomer; Adnan Zaina, Rambam Medical Center, Haifa; Moshe Zloczower, Rambam Medical Center, Haifa; Sagit Zolotov, Rambam Medical Center, Haifa.

Italy: Alessandro Antenore, Azienda Ospedaliero Universitaria Careggi, Firenze; Mariangela Arnone, Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone, Palermo; Franco Arturi, Policlinico Mater Domini Università di Catanzaro Campus Germaneto, Catanzaro; Valeria Barbaro, Azienda Ospedaliero Universitaria Careggi, Firenze; Milena Barone, Policlinico Mater Domini Università di Catanzaro Campus Germaneto, Catanzaro; Rosamaria Di Biagio, Università degli Studi Gabriele d'Annunzio, Chieti; Chiara Buscemi, Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone, Palermo; Silvio Buscemi, Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone, Palermo; Raffaella Buzzetti, Ospedale Santa Maria Goretti, Latina; Alberto Di Carlo, Ospedale Civile Campo di Marte, Lucca; Angela Carlone, Ospedale Santa Maria Goretti, Latina; Vittoria Caruso, Policlinico Mater Domini Università di Catanzaro Campus Germaneto, Catanzaro; Ilaria Casadidio, Ospedale Civile Campo di Marte, Lucca; Fernanda Cerrelli, Policlinico Sant Orsola-Malpighi, Bologna; Adolfo Ciavarella, Policlinico Sant Orsola-Malpighi, Bologna; Laura Cipolloni, Ospedale Santa Maria Goretti, Latina; Alessandra Colella, Umberto I - Policlinico di Roma, Roma; Marco Colotto, Umberto I - Policlinico di Roma, Roma; Agostino Consoli, Università degli Studi Gabriele d'Annunzio, Chieti; Valentina Giulia

SUPPLEMENTARY DATA

Crippa, Ospedale San Raffaele, Milano; Ilaria Cuccuru, Ospedale Civile Campo di Marte, Lucca; Sabrina Cufone, Policlinico Mater Domini Università di Catanzaro Campus Germaneto, Catanzaro; Carla Desideri, Azienda Ospedaliero Universitaria Careggi, Firenze; Mara Fallarino, Umberto I - Policlinico di Roma, Roma; Fabrizio Febo, Università degli Studi Gabriele d'Annunzio, Chieti; Sebastiano Filetti, Umberto I - Policlinico di Roma, Roma; Chiara Foffi, Ospedale Santa Maria Goretti, Latina; Gloria Formoso, Università degli Studi Gabriele d'Annunzio, Chieti; Laura Frosio, Ospedale San Raffaele, Milano; Patrizia Di Fulvio, Università degli Studi Gabriele d'Annunzio, Chieti; Alessandra Gambineri, Università di Bologna, Azienda Ospedaliera S. Orsola Malpighi, Bologna; Federica Ginestra, Università degli Studi Gabriele d'Annunzio, Chieti; Michele Salvatore Grimaldi, Policlinico Sant Orsola-Malpighi, Bologna; Caterina Lamanna, Azienda Ospedaliero Universitaria Careggi, Firenze; Gaetano Leto, Ospedale Santa Maria Goretti, Latina; Pietro Lucotti, Ospedale San Raffaele, Milano; Marina Lugarà, Policlinico Mater Domini Università di Catanzaro Campus Germaneto, Catanzaro; Gabriella Lumera, Ospedale San Raffaele, Milano; Andrea Magistro, Ospedale San Raffaele, Milano; Edoardo Mannucci, Azienda Ospedaliero Universitaria Careggi, Firenze; Marianna Maranghi, Umberto I - Policlinico di Roma, Roma; Daniele Martelli, Azienda Ospedaliero Universitaria Careggi, Firenze; Alessandro Mattina, Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone, Palermo; Lucilla D. Monti, Ospedale San Raffaele, Milano; Martina Parise, Policlinico Mater Domini Università di Catanzaro Campus Germaneto, Catanzaro; Elisabetta Pedace, Policlinico Mater Domini Università di Catanzaro Campus Germaneto, Catanzaro; Francesca Perticone, Ospedale San Raffaele, Milano; PierMarco Piatti, Ospedale San Raffaele, Milano; Maria Pompea Antonia Baldassarre, Università degli Studi Gabriele d'Annunzio,

SUPPLEMENTARY DATA

Chieti; Benedetta Ragghianti, Azienda Ospedaliero Universitaria Careggi, Firenze; Andrea Repaci, Università di Bologna, Azienda Ospedaliera S. Orsola Malpighi, Bologna; Danilo Ribichini, Università di Bologna, Azienda Ospedaliera S. Orsola Malpighi, Bologna; Silvia Da Ros, Umberto I - Policlinico di Roma, Roma; Margherita Rossi, Ospedale San Raffaele, Milano; Marcella Santilli, Umberto I - Policlinico di Roma, Roma; Giorgio Sesti, Policlinico Mater Domini Università di Catanzaro Campus Germaneto, Catanzaro; Emanuela Setola, Ospedale San Raffaele, Milano; Ermal Shehaj, Ospedale San Raffaele, Milano; Elena Succurro, Policlinico Mater Domini Università di Catanzaro Campus Germaneto, Catanzaro; Elodia Sussolano, Umberto I - Policlinico di Roma, Roma; Giovanna Tarquini, Umberto I - Policlinico di Roma, Roma; Salvatore Verga, Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone, Palermo; Valentina Vitale, Azienda Ospedaliero Universitaria Careggi, Firenze.

Mexico: Ricardo Rodríguez Alanís, Hospital Universitario Dr. José Eleuterio González, Monterrey; María del Rosario Arechavaleta-Granell, Unidad de Patología Clínica, Guadalajara; Teresita de Jesús Beltrán Jaramillo, Unidad de Patología Clínica, Guadalajara; David Amador de Jesús Rodríguez Berrones, Hospital Universitario Dr. José Eleuterio González, Monterrey; Ignacio Rodríguez Briones, Cardioarritmias e Investigación, S.C., San Luis Potosí; Rocio Rodríguez Briones, Cardioarritmias e Investigación, S.C., San Luis Potosí; Eduardo Saúl Acevedo Castañeda, Instituto Jalisciense de Investigación en Diabetes y Obesidad, S.C., Guadalajara; Jesus Benito Chapa Grimaldo, Hospital Universitario Dr. José Eleuterio González, Monterrey; Claudia Aida Flores-Moreno, Hospital Universitario Dr. José Eleuterio González, Monterrey; Sandra Garza Felix, Hospital Universitario Dr. José Eleuterio González, Monterrey; Jesus Nieto Flores, Instituto Jalisciense de

SUPPLEMENTARY DATA

Investigación en Diabetes y Obesidad, Guadalajara; Guadalupe Morales Franco, Centro de Diabetes Durango, Durango; Ricardo Aarón Garza Morán, Hospital Universitario Dr. José Eleuterio Gonzalez, Monterrey; Sandra Ofelia Hernández González, Investigación Clínica Especializada, Guadalajara; Guillermo González-Gálvez, Instituto Jalisciense de Investigación en Diabetes y Obesidad, S.C., Guadalajara; José Gerardo González González, Hospital Universitario Dr. José Eleuterio González, Monterrey; Eduardo Hernández Salazar, Unidad de Patología Clínica, Guadalajara; Pedro Alberto García Hernández, Hospital Universitario Dr. José Eleuterio González, Monterrey; Sandra Campos Hurtado, Centro de Diabetes Durango, Durango; Martha Leticia López-Velázco, Instituto Jalisciense de Investigación en Diabetes y Obesidad, S.C., Guadalajara; Ernesto Germán Cardona Muñóz, Investigación Clínica Especializada, Guadalajara; Ricardo Nuñez Márquez, Unidad de Patología Clínica, Guadalajara; Oscar Vladimir Campos Moreno, Centro de Diabetes Durango, Durango; Francisco Javier Cavazos Oliveros, Hospital Universitario Dr. José Eleuterio González, Monterrey; Jose Alfredo Haro Ortiz, Cardioarritmias e Investigación, S.C., San Luis Potosí; Emilia Susana Pelayo-Orozco, Instituto Jalisciense de Investigación en Diabetes y Obesidad, S.C., Guadalajara; Paulina Sida Perez, CardioPrevent S.C., Durango; Roxana Vazquez Ramírez, Hospital Universitario Dr. José Eleuterio González, Monterrey; Maritza A. Uribe Rios, CardioPrevent S.C., Durango; Julio César López Rodríguez, Hospital Universitario Dr. José Eleuterio González, Monterrey; Mónica Rodríguez Rosales, Hospital Universitario Dr. José Eleuterio Gonzalez, Monterrey; Israel Robledo Durón, Unidad de Patología Clínica, Guadalajara; Ricardo Alvarado Ruíz, CardioPrevent S.C., Durango; Gerardo González Saldivar, Hospital Universitario Dr. José Eleuterio González, Monterrey; Roxana Reyes Sánchez, CardioPrevent S.C., Durango;

SUPPLEMENTARY DATA

Blanca Leticia Sánchez-Michel, Instituto Jalisciense de Investigación en Diabetes y Obesidad, S.C, Guadalajara; Aleida Yael Contreras Sandoval, Unidad de Patología Clínica, Guadalajara; Arturo Velasco Gutiérrez, Instituto Jalisciense de Investigación en Diabetes y Obesidad, S.C., Guadalajara; Ana Elena Perez Verdín, Instituto Jalisciense de Investigación en Diabetes y Obesidad, S.C., Guadalajara; María Guadalupe Ramos Zavala, Investigación Clínica Especializada, Guadalajara.

Netherlands: Evertine Abbink-Zandbergen, Radboud University Medical Centre, Nijmegen; Mohamed Ahdi, Slotervaart Ziekenhuis, Amsterdam; Annemiek Bugter, SHL-Groep, Etten-Leur; Marcel van Dijk, University Medical Center Utrecht, Utrecht; Geert Eisma, SHL-Groep, Etten-Leur; Ronald Erdtsieck, Máxima Medisch Centrum, Eindhoven; Maaike Gerards, Slotervaart Ziekenhuis, Amsterdam; Victor Gerdes, Slotervaart Ziekenhuis, Amsterdam; Harm Haak, Máxima Medisch Centrum, Eindhoven; Veroniek Harbers, Radboud University Medical Centre, Nijmegen; Klaas Hoogenberg, Martini Ziekenhuis, Groningen; Frank Huvers, Bethesda Diabetes Research Center, Hoogeveen; Wilbert Janssen, Martini Ziekenhuis, Groningen; Marleen Kars, Academic Hospital Maastricht, Maastricht; Adriaan Kooy, Bethesda Diabetes Research Center, Hoogeveen; M. Lafeber, University Medical Center Utrecht, Utrecht; Sabine Landewé-Cleuren, Academic Hospital Maastricht, Maastricht; Aloysius Lieveerse, Máxima Medisch Centrum, Eindhoven; Eelco Meesters, Slotervaart Ziekenhuis, Amsterdam; Sharon Moerman, Divisie Julius Centrum, University Medical Center Utrecht, Utrecht; Dirk van Moorsel, Academic Hospital Maastricht, Maastricht; Jeroen Nijhuis, Academic Hospital Maastricht, Maastricht; Guy Rutten, University Medical Center Utrecht, Utrecht; C.J Smit, Martini Ziekenhuis, Groningen; Cornelius Tack, Radboud University Medical Centre, Nijmegen; Kristof Thevissen, Máxima Medisch Centrum, Eindhoven; Dirk Meijer

SUPPLEMENTARY DATA

Timmerman Thijssen, SHL-Groep, Etten-Leur; Annelieke Willemsen, Máxima Medisch Centrum, Eindhoven.

Norway: Kåre Birkeland, Endokrinologisk Avdeling, Oslo Universitetssykehus, Oslo; John Cooper, Stavanger Helseforskning, Stavanger; Hanne Gulseth, Oslo Universitetssykehus, Oslo; Jøran Hjelmæsæth, Senter for Sykelig Overvekt, Tønsberg; Pål Jørgensen, Endokrinologisk Seksjon, Medisinsk avdeling, Trondheim; Bente K. Kilhovd, Oslo Universitetssykehus, Oslo; Bård Kulseng, Endokrinologisk Seksjon, Medisinsk Avdeling, Trondheim; Bjørn Nicolaisen, Endokrinologisk Seksjon, Medisinsk Avdeling, Trondheim; Øivind Skadberg, Stavanger Helseforskning, Stavanger, Njord Nordstrand, Senter for sykelig overvekt, Tønsberg; Cecilie Wium, Endokrinologisk Avdeling, Oslo Universitetssykehus, Oslo.

Poland: Karolina Antkowiak-Piatyszek, Synexus Polska Sp, Warszawa; Malgorzata Arciszewska, NZOZ Specjalistyczny Ośrodek InternistycznoDiabetologiczny, Białystok; Agnieszka Bajkowska-Fiedziukiewicz, Centrum Medyczne OmniMed, Lodz; Pawel Bogdanski, Oddział Nadciśnienia Tętniczego i Zaburzeń Metabolicznych, Katedra i Klinika Chorób Wewnętrznych, Zaburzeń Metabolicznych i Nadciśnienia Tętniczego Uniwersytetu Medycznego im. K. Marcinkowskiego w Poznaniu, Poznan; Urszula Czubek, UNICARDIA Specjalistyczne Centrum Leczenia Chorob Serca i Naczyn & UNIMEDICA Specjalistyczne Centrum Medyczne, Kraków; Katarzyna Cypryk, Centrum Medyczne OmniMed, Lodz; Jan Dabrowski, Centrum Medyczne OmniMed, Lodz; Magda Dabrowska, Synexus Polska Sp, Warszawa; Marek Dwojak, Synexus Polska Sp, Wrocław; Szymon Dziedzic, Śląskie Centrum Osteoporozy, Katowice; Tomasz Dziewit, Śląskie Centrum Osteoporozy, Katowice; Magdalena Faligowska, Synexus Polska Sp, Warszawa; Grazyna Fedor-Plenkowska, Medyczne Centrum Diabetologiczno-Endokrynologiczno-Metaboliczne

SUPPLEMENTARY DATA

“Diab-EndoMet”, Kraków; Edward Franek, Centralny Szpital Kliniczny MSW w Warszawie, Warszawa; Grzegorz Gajos, UNICARDIA Specjalistyczne Centrum Leczenia Chorob Serca i Naczyn & UNIMEDICA Specjalistyczne Centrum Medyczne, Kraków; Danuta Galicka-Latala, SPZOZ Uniwersytecki Szpital w Krakowie, Kraków; Alicja Galuszka-Bilinska, Samodzielny Publiczny Zakład Opieki Zdrowotnej, Ruda Śląska; Izabella Gladysz, Synexus Polska Sp, Warszawa; Joanna Grycewicz, Centrum Medyczne OmniMed, Lodz; Grzegorz Hachula, Śląskie Centrum Osteoporozy, Katowice; Izabela Janas, SPZOZ Uniwersytecki Szpital w Krakowie, Kraków; Ewa Jazwinska-Tarnawska, Synexus Polska Sp, Wrocław; Krystyna Jedyndasty, Centralny Szpital Kliniczny MSW w Warszawie, Warszawa; Malgorzata Jozefowska, Centrum Medyczne OmniMed, Lodz; Anna Kaminska, Bydgoskie Centrum Diabetologii i Endokrynologii, Bydgoszcz; Beata Kutra, SPZOZ Uniwersytecki Szpital w Krakowie, Kraków; Jolanta Kitowska-Koterla, Śląskie Centrum Osteoporozy, Katowice; Tomasz Klupa, SPZOZ Uniwersytecki Szpital w Krakowie, Kraków; Teresa Koblik, SPZOZ Uniwersytecki Szpital w Krakowie, Kraków; Ewa Konduracka, UNICARDIA Specjalistyczne Centrum Leczenia Chorob Serca i Naczyn & UNIMEDICA Specjalistyczne Centrum Medyczne, Kraków; Jan Konieczny, KO-MED Marek Konieczny Centrum Wielospecjalistycznej Opieki Ambulatoryjnej z Ambulatoryjnym Osrodkiem Zabiegowym, Pulawy; Marek Konieczny, KO-MED Marek Konieczny Centrum Wielospecjalistycznej Opieki Ambulatoryjnej z Ambulatoryjnym Osrodkiem Zabiegowym, Pulawy; Marcin Kosinski, Centrum Medyczne OmniMed, Lodz; Grzegorz Kulkowski, Samodzielny Publiczny Zakład Opieki Zdrowotnej, Ruda Śląska; Marcin Kunecki, Śląskie Centrum Osteoporozy, Katowice; Malgorzata Kurmaniak, Samodzielny Publiczny Zakład Opieki Zdrowotnej, Ruda Śląska; Robert Lesniewski, Centralny Szpital Kliniczny

SUPPLEMENTARY DATA

MSW w Warszawie, Warszawa; Teresa Lominska, Centralny Szpital Kliniczny MSW w Warszawie, Warszawa; Beata Losa, Samodzielny Publiczny Zakład Opieki Zdrowotnej, Ruda Śląska; Danuta Majkowska, Medyczne Centrum Diabetologiczno-Endokrynologiczno-Metaboliczne “Diab-Endo-Met”, Kraków; Maciej Malecki, SPZOZ Uniwersytecki Szpital w Krakowie, Kraków; Joanna Mirocka, Medyczne Centrum Diabetologiczno-Endokrynologiczno-Metaboliczne “Diab-EndoMet”, Kraków; Marcin Misztal, UNICARDIA Specjalistyczne Centrum Leczenia Chorob Serca i Naczyn & UNIMEDICA Specjalistyczne Centrum Medyczne, Kraków; Krzysztof Mruk, Medyczne Centrum Diabetologiczno-Endokrynologiczno-Metaboliczne “Diab-Endo-Met”, Kraków; Katarzyna Musialik, Oddział Nadciśnienia Tętniczego i Zaburzeń Metabolicznych, Katedra i Klinika Chorób Wewnętrznych, Zaburzeń Metabolicznych i Nadciśnienia Tętniczego Uniwersytetu Medycznego im. K. Marcinkowskiego w Poznaniu, Poznan; Henryka Olejniczak, Bydgoskie Centrum Diabetologii i Endokrynologii, Bydgoszcz; Piotr Opadczuk, Synexus Polska Sp, Warszawa; Jadwiga Peczyńska, NZOZ Specjalistyczny Ośrodek Internistyczno-Diabetologiczny, Białystok; Maria Plinta, Medyczne Centrum Diabetologiczno-Endokrynologiczno-Metaboliczne “Diab-Endo-Met”, Kraków; Mirosława Polaszewska-Muszynska, Bydgoskie Centrum Diabetologii i Endokrynologii, Bydgoszcz; Elżbieta Przech, Centrum Medyczne OmniMed, Łódź; Danuta Pupek-Musialik, Oddział Nadciśnienia Tętniczego i Zaburzeń Metabolicznych, Katedra i Klinika Chorób Wewnętrznych, Zaburzeń Metabolicznych i Nadciśnienia Tętniczego Uniwersytetu Medycznego im. K. Marcinkowskiego w Poznaniu, Poznan; Zofia Ruzga, Synexus Polska Sp, Wrocław; Zdzisława Scibor, Centrum Medyczne OmniMed, Łódź; Anna Sidorowicz-Bialynicka, Synexus Polska Sp, Wrocław; Anna Siegel, Śląskie Centrum Osteoporozy, Katowice; Andrzej Stankiewicz, Medyczne Centrum Diabetologiczno-

SUPPLEMENTARY DATA

Endokrynologiczno-Metaboliczne “Diab-Endo-Met”, Kraków; Agnieszka Strzelecka-Sosik, KO-MED Marek Konieczny Centrum Wielospecjalistycznej Opieki Ambulatoryjnej z Ambulatoryjnym Osrodkiem Zabiegowym, Pulawy; Teresa Swierszcz, NZOZ Specjalistyczny Ośrodek Internistyczno-Diabetologiczny, Białystok; Monika Szulinska, Oddział Nadciśnienia Tętniczego i Zaburzeń Metabolicznych, Katedra i Klinika Chorób Wewnętrznych, Zaburzeń Metabolicznych i Nadciśnienia Tętniczego Uniwersytetu Medycznego im. K. Marcinkowskiego w Poznaniu, Poznan; Katarzyna Szymkowiak, Synexus Polska Sp, Wrocław; Iwona Trybul, SPZOZ Uniwersytecki Szpital w Krakowie, Kraków; Przemyslaw Witek, SPZOZ Uniwersytecki Szpital w Krakowie, Kraków; Iwona Wozniak, KO-MED Marek Konieczny Centrum Wielospecjalistycznej Opieki Ambulatoryjnej z Ambulatoryjnym Osrodkiem Zabiegowym, Pulawy; Jan Zambrzycki, Synexus Polska Sp, Warszawa; Grazyna Zarzycka-Lindner, Bydgoskie Centrum Diabetologii i Endokrynologii, Bydgoszcz; Dorota Zuradzka-Wajda, Medyczne Centrum Diabetologiczno-Endokrynologiczno-Metaboliczne “Diab-Endo-Met”, Kraków; Monika Zurawska-Klis, Centrum Medyczne OmniMed, Lodz.

Republic of Korea: Hwa Young Ahn, Seoul National University Bundang Hospital, Seongnam; Sang Ouk Chin, Kyung-hee University Medical Center, Seoul; Sung Hee Choi, Seoul National University Bundang Hospital, Seongnam; Suk Chon, Kyung-hee University Medical Center, Seoul; Kyung Ah Han, Eulji General Hospital, Seoul; Hak Chul Jang, Seoul National University Bundang Hospital, Seongnam; Ki Cheon Jeong, National Health Insurance Corporation Ilsan Hospital, Goyang; Seon Mee Kang, Seoul National University Bundang Hospital, Seongnam; Jin Woo Kim, Kyung-hee University Medical Center, Seoul; Hun-Sung Kim, The Catholic University of Korea, Seoul St. Mary's Hospital, Seoul; Soo Joong Kim, Kyung-hee University

SUPPLEMENTARY DATA

Medical Center, Seoul; Sung Woon Kim, Kyung-hee University Medical Center, Seoul; Young Seol Kim, Kyung-hee University Medical Center, Seoul; Eun Young Lee, National Health Insurance Corporation Ilsan Hospital, Goyang; Soo Lim, Seoul National University Bundang Hospital, Seongnam; Kyung Wan Min, Eulji General Hospital, Seoul; Joo Young Nam, National Health Insurance Corporation Ilsan Hospital, Goyang; Seung Joon Oh, Kyung-hee University Medical Center, Seoul; So Young Park, Kyung-hee University Medical Center, Seoul; Sang Youl Rhee, Kyung-hee University Medical Center, Seoul; Jung Ah Shin, The Catholic University of Korea, Seoul St. Mary's Hospital, Seoul; Jung Il Son, Kyung-hee University Medical Center, Seoul; Young Duk Song, National Health Insurance Corporation Ilsan Hospital, Goyang; Jeong Taek Woo, Kyung-hee University Medical Center, Seoul; Hae Kyung Yang, The Catholic University of Korea, Seoul St. Mary's Hospital, Seoul; Jeong Seon Yoo, National Health Insurance Corporation Ilsan Hospital, Goyang; Ji Won Yoon, Seoul National University Bundang Hospital, Seongnam; Kun-Ho Yoon, The Catholic University of Korea, Seoul St. Mary's Hospital, Seoul.

Romania: Rodica Avram, County Hospital Deva, Deva; Marioara Daniela Braicu, Clinical County Emergency Hospital, Craiova; Luminita Carlan, Bacau County Emergency Hospital, Bacau; Doina Catrinoiu, Emergency County Hospital, Constanta; Daniela Ciomos, Centrul Medical PULS, Târgu Mureş; Alina Ciorba, County Emergency Hospital Satu Mare, Satu Mare; Gheorghe Ghise, Clinical County Hospital Sibiu, Sibiu; Sigina Girgavu, Clinical County Emergency Hospital, Craiova; Cristian Guja, Institute of Diabetes, Nutrition and Metabolic Diseases, Bucharest; Doina Mihai, Institute of Diabetes, Nutrition and Metabolic Diseases, Bucharest; Maria Mota, Clinical County Emergency Hospital, Craiova; Simona Nicodim, Emergency County Hospital, Constanta; Laura Nistor, SC Consultmed SRL, Iasi;

SUPPLEMENTARY DATA

Delia Reurean Pintilei, SC Consultmed SRL, Iasi; Ella Pintilei, SC Consultmed SRL, Iasi; Noemi Pletea, Bacau County Emergency Hospital, Bacau; Alina Pop, County Emergency Hospital Satu Mare, Satu Mare; Mihaela Rosu, Clinical County Hospital, Timisoara; Octavian Savu, Institute of Diabetes, Nutrition and Metabolic Diseases, Bucharest; Viorel Serban, Clinical County Hospital, Timisoara; Alexandra Sima, Clinical County Hospital, Timisoara; Carmen Sitterli-Natea, Clinical County Hospital Sibiu, Sibiu; Gina Suci, Centrul Medical PULS, Târgu Mureş; Monica Szabo, Centrul Medical PULS, Târgu Mureş; Iosif Szilagyi, County Emergency Hospital Satu Mare, Satu Mare; Bogdan Timar, Spitalul Clinic Judetean de Urgenta Timisoara, Timisoara; Adrian Vlad, Clinical County Hospital, Timisoara; Ionela Mihaela Vladu, Clinical County Emergency Hospital, Craiova.

Russian Federation: Anas Alfaraj, Central Clinical, Moscow; Veronika Dubova, Yaroslavl Regional Clinical Hospital, Yaroslavl; Irina Dvoryashina, First City Hospital Of Arkhangelsk, Arkhangelsk; Leylya Gaysina, Republic Clinical Hospital, GUZ, Tatarstan; Svetlana Gromova, GUZ Regional Clinical Hospital, Saratov; Ksenia Gudkova, Smolensk State Medical Institute, Smolensk; Svetlana Ivanova, Regional Clinical Hospital, Arkhangelsk; Irina Ivashkina, Penza Regional Clinical Hospital, Penza; Marina Kalashnikova, Propaedeutics of Internal Diseases Clinic, Moscow; Tatyana Kazankova, City Clinical Hospital №5, Barnaul; Elena Khaykina, Smolensk State Medical Institute, Smolensk; Olga Khaykina, Smolensk State Medical Institute, Smolensk; Tatiana Kiseleva, Republic Clinical Hospital, GUZ, Tatarstan; Ekaterina Komissarova, Penza Regional Clinical Hospital, Penza; Irina Kononenko, Institute Of Endocrinology, Moscow; Valeria Koreneva, Central Clinical, Moscow; Olga Koshcheeva, Central Clinical, Moscow; Larisa Koshel, Propaedeutics of internal diseases clinic, Moscow; Dina Kozachuk, Regional Clinical Hospital, Arkhangelsk;

SUPPLEMENTARY DATA

Tatiana Kufelkina, Republic Clinical Hospital, GUZ, Tatarstan; Marina Kunitsyna, GUZ Regional Clinical Hospital, Saratov; Natalia Likhodey, Propaedeutics of Internal Diseases Clinic, Moscow; Tatyana Lysenko, City Clinical Hospital №5, Barnaul; Olga Makarova, Tyumen Medical Academy, Tyumen Region; Anna Malceva, City Clinical Hospital №5, Barnaul; Svetlana Mikhailova, Regional Clinical Hospital, Arkhangelsk; Evgeniya Ogorodnikova, City Clinical Hospital №5, Barnaul; Irina Pavlikova, City Clinical Hospital №5, Barnaul; Elena Pekareva, Institute Of Endocrinology, Moscow; Anna Postoeva, First City Hospital Of Arkhangelsk, Arkhangelsk; Dmitry Reshedko, Smolensk State Medical Institute, Smolensk; Galina Reshedko, Smolensk State Medical Institute, Smolensk; Leonid Reshedko, Smolensk State Medical Institute, Smolensk; Angelika Rogaleva, Regional Clinical Hospital, Arkhangelsk; Larisa Rogova, Central Clinical, Moscow; Denis Rozanov, Yaroslavl Regional Clinical Hospital, Yaroslavl; Georgiy Runov, Hospital Of Semashko, Nizhny Novgorod; Irina Samylina, Penza Regional Clinical Hospital, Penza; Tatiana Semikina, GUZ Regional Clinical Hospital, Saratov; Marina Sergeeva-Kondrachenko, Penza Regional Clinical Hospital, Penza; Olga Shatskaya, Institute Of Endocrinology, Moscow; Marina Shestakova, Institute Of Endocrinology, Moscow; Olga Shimokhina, Penza Regional Clinical Hospital, Penza; Svetlana Smetanina, Tyumen Medical Academy, Tyumen Region; Maria Startseva, Regional Clinical Hospital, Arkhangelsk; Alexandra Strelkova, First City Hospital Of Arkhangelsk, Arkhangelsk; Lyudmila Suplotova, Tyumen Medical Academy, Tyumen Region; Larisa Suvorova, GUZ Regional Clinical Hospital, Saratov; Yulia Sych, Propaedeutics of internal diseases clinic, Moscow; Alfiya Valeeva, Kazan State Medical University (KSMU), Kazan; Farida Valeeva, Kazan State Medical University (KSMU), Kazan; Tatiana Venjkova, GUZ Regional Clinical Hospital, Saratov; Valentina Vinokurova, GUZ Regional

SUPPLEMENTARY DATA

Clinical Hospital, Saratov; Emma Voychik, Central Clinical, Moscow; Elena Yanovskaya, Yaroslavl Regional Clinical Hospital, Yaroslavl; Maria Yanovskaya, Yaroslavl Regional Clinical Hospital, Yaroslavl; Natalia Yarkova, Hospital Of Semashko, Nizhny Novgorod; Ekaterina Yarygina, Regional Clinical Hospital, Arkhangelsk; Natalia Yuzhakova, Tyumen Medical Academy, Tyumen Region; Tatiana Zakharova, Yaroslavl Regional Clinical Hospital, Yaroslavl; Olga Zanozina, Hospital Of Semashko, Nizhny Novgorod; Anatoly Zenovko, Central Clinical, Moscow; Svetlana Zhuk, Hospital Of Semashko, Nizhny Novgorod; Elena Zhukova, GUZ Regional Clinical Hospital, Saratov.

Serbia: Sandra Aleksic, Clinical Center of Serbia, Belgrade; Ana Bulatovic, Clinical Hospital Centre Zvezdara, Belgrade; Bogdan Buric, Clinical Hospital Centre Zvezdara, Belgrade; Goran Cvijovic, Clinical Center of Serbia, Belgrade; Marina Andjelic Jelic, Clinical Hospital Centre Zvezdara, Belgrade; Biljana Jojic, Clinical Hospital Centre Zvezdara, Belgrade; Aleksandra Jotic, Clinical Center of Serbia, Belgrade; Aleksandra Kendereski, Clinical Center of Serbia, Belgrade; Katarina Lalic, Clinical Center of Serbia, Belgrade; Nebojsa Lalic, Clinical Center of Serbia, Belgrade; Ljiljana Lukic, Clinical Center of Serbia, Belgrade; Marija Macesic, Clinical Center of Serbia, Belgrade; Milica Marjanovic Petkovic, Clinical Hospital Centre Zvezdara, Belgrade; Dragan Micic, Clinical Center of Serbia, Belgrade; Tanja Milicic, Clinical Center of Serbia, Belgrade; Ljiljana Popovic, Clinical Center of Serbia, Belgrade; Milica Prostran, Clinical Center of Serbia, Belgrade; Natasa Rajkovic, Clinical Center of Serbia, Belgrade; Jelena Seferovic, Clinical Center of Serbia, Belgrade; Sandra Singh, Clinical Center of Serbia, Belgrade; Radan Stojanovic, Clinical Hospital Centre Zvezdara, Belgrade; Ljubica Stosic, Clinical Center of Serbia, Belgrade; Miljanka Vuksanovic, Clinical Hospital Centre Zvezdara, Belgrade;

SUPPLEMENTARY DATA

Miroslava Zamaklar, Clinical Center of Serbia, Belgrade; Teodora Beljic Zivkovic, Clinical Hospital Centre Zvezdara, Belgrade; Svetlana Zoric, Clinical Center of Serbia, Belgrade.

South Africa: Nazimuddin Aboo, Centre for Diabetes and Endocrinology, Durban; Hendrik Willem Albertse, Rosepark Hospital, Fichardtpark; Aysha Badat, The Wits Donald Gordon Medical Centre, Johannesburg; Matthys Basson, Tiervlei Trial Centre, Cape Town; Ebrahim Bawa, Dr Lakha's Rooms, Lenasia South; Frederick Bester, Rosepark Hospital, Fichardtpark; Suzanne Blignaut, Tread Research, Cape Town; Susan Booyesen, Tread Research, Cape Town; Fredricka Johanna Bosch, Rosepark Hospital, Fichardtpark; Lesley Burgess, Tread Research, Cape Town; Soraya Cassimjee, The Wits Donald Gordon Medical Centre, Johannesburg; Kathleen Coetzee, Tread Research, Cape Town; Jeannine Du Bois, Tiervlei Trial Centre, Cape Town; Johannes Engelbrecht, Mediclinic Vergelegen, Western Cape; Kathleen Finegan, Midrand Medical Centre, Midrand; Gilbert John Gibson, Rosepark Hospital, Fichardtpark; Somaya Hansa, The Wits Donald Gordon Medical Centre, Johannesburg; Alana Hemus, The Wits Donald Gordon Medical Centre, Johannesburg; Ignatius Petrus Immink, Rosepark Hospital, Fichardtpark; Andrew Jacovides, Midrand Medical Centre, Midrand; Pankaj Joshi, Louis Pasteur Medical Center, Pretoria; Shaifali Joshi, Suite 5 Diabetes Care Centre, Benoni; Cornelia Kapp, Union Hospital, Alberton; Setswakae Khoele-Machobane, Midrand Medical Centre, Midrand; Hendrik Johannes Uys Knox, Rosepark Hospital, Fichardtpark; Johanna Kok, Union Hospital, Alberton; Stephanus Komati, Louis Pasteur Medical Center, Pretoria; Evelyn Lai, The Wits Donald Gordon Medical Centre, Johannesburg; Deepak Lakha, Dr Lakha's Rooms, Lenasia South; Kenneilwe Lehloenyane, Tread Research, Cape Town; Akhter Goolam Mahomed, Louis

SUPPLEMENTARY DATA

Pasteur Medical Center, Pretoria; Ronel Meeding, The Wits Donald Gordon Medical Centre, Johannesburg; Rajendran Moodley, Netcare Umhlanga Medical Centre, Durban; Naeem Moosa, Moosa N, Lenasia; Jeanne Nel, Tiervlei Trial Centre, Cape Town; Haylene Nell, Tiervlei Trial Centre, Cape Town; Frederick Johannes Van Niekerk, Mediclinic Heart Hospital, Pretoria; Mahommed Omar, Suite 1 Parklands Medical Centre, Durban; Nagassree Pillay, Seadoone Medical Centre, Durban; Maria Pretorius, Tiervlei Trial Centre, Cape Town; Hans Prozesky, Tread Research, Cape Town; Shantakumari Ramduth, Midrand Medical Centre, Midrand; Johannes Roos, Mediclinic Vergelegen, Western Cape; Mahomed Sarvan, Netcare Umhlanga Medical Centre, Durban; Mary Seeber, Mediclinic Heart Hospital, Pretoria; Mirna Siebert, Tiervlei Trial Centre, Cape Town; Pillay Somasundram, Seadoone Medical Centre, Durban; Andreas Stavrides, Union Hospital, Alberton; Frederick Johannes Van Niekerk, Mediclinic Heart Hospital, Pretoria; Nadia Venter, Tiervlei Trial Centre, Cape Town; Shahid Wadvalla, Moosa N, Lenasia.

Spain: Josefina Olivares Alcolea, Hospital Son Llätzer, Palma de Mallorca; Aránztazu Álvarez de Arcaya Vicente, Hospital Universitario Clínico San Carlos, Madrid; M^a Beatriz Pérez Arroyo, Quirónsalud Madrid University Hospital, Madrid; Enrique Romero Bobillo, Hospital Clínico Universitario de Valladolid, Castilla y Leon; M^a Manuela Buño, Hospital de A Coruña, La Coruña; José N. Carreira Arias, Hospital de A Coruña, La Coruña; Miguel Camafort Babkowski, Hospital Clínic de Barcelona, Barcelona; Daniel Cepero García, Clinica San Pedro, Almería; Luis Masmiquel Comas, Hospital Son Llätzer, Palma de Mallorca; María José Coves Figueras, Hospital Clínic de Barcelona, Barcelona; Carmen de la Cuesta Mayor, Nuevas Tecnologías en Diabetes y Endocrinología S.L, Sevilla; Mónica Domenech Feria-Carot, Hospital Clínic de Barcelona, Barcelona; Ana M^a Frade Fernández,

SUPPLEMENTARY DATA

Hospital de A Coruña, La Coruña; Manuel Ferreiro Gómez, Hospital de A Coruña, La Coruña; Clara García García, Nuevas Tecnologías en Diabetes y Endocrinología S.L, Sevilla; Emilio García Delgado, Hospital Universitario de Móstoles, Móstoles; Santiago Durán García, University Hospital Nuestra Señora de Valme, Sevilla; Luis A. Gómez Gómez, Hospital Son Llätzer, Palma de Mallorca; Alfonso Soto González, Hospital de A Coruña, La Coruña; Cristina Hernán García, Hospital Clínico Universitario de Valladolid, Castilla y Leon Valladolid; M^a Ángeles Tapia Herrero, Hospital Universitario de Móstoles, Móstoles; Esteban Jodar Gimeno, Quirónsalud Madrid University Hospital, Madrid; Julia Quevedo Juanals, Hospital Son Llätzer, Palma de Mallorca; Manuel López Jiménez, Hospital Universitario de Móstoles, Móstoles; Ferrán Masanes , Hospital Clínic de Barcelona, Barcelona; Ángel L. Marco Mur, Hospital Universitario de Móstoles, Móstoles; Margarita Navarro López, Hospital Clínic de Barcelona, Barcelona; Joana Nicolau Ramis, Hospital Son Llätzer, Palma de Mallorca; Apolonia Gil Palmer, Hospital Son Llätzer, Islas Baleares; Alfonso Calle Pascual, Hospital Universitario Clínico San Carlos, Madrid; Laura G. Romero Pérez, Hospital Universitario Clínico San Carlos, Madrid; Cristobal Morales Portillo, Nuevas Tecnologías en Diabetes y Endocrinología S.L, Sevilla; Sergio Prieto González, Hospital Clínic de Barcelona, Barcelona; Pedro Mezquita Raya, Clinica San Pedro, Almería; Rebeca Reyes García, Clinica San Pedro, Almería; Tomás Ripoll Vera, Hospital Son Llätzer, Palma de Mallorca; Carmen Rodríguez Castro, Hospital Universitario de Móstoles, Móstoles; Irene Rodríguez Rodríguez, Hospital Son Llätzer, Palma de Mallorca; Emilio Sacanella Meseguer, Hospital Clínic de Barcelona, Barcelona; Isabel Serrano Olmedo, Nuevas Tecnologías en Diabetes y Endocrinología S.L, Sevilla; Alfonso Lopez Soto, Hospital Clínic de Barcelona, Barcelona; Fernando Toba Alonso, Hospital de A Coruña, 22 La Coruña; Alberto

SUPPLEMENTARY DATA

Aliaga Verdugo, Nuevas Tecnologías en Diabetes y Endocrinología S.L, Sevilla;
Josep Vidal Cortada, Hospital Clínic de Barcelona, Barcelona; Luis Vigil Medina,
Hospital Universitario de Móstoles, Móstoles.

Sweden: Eva Ackefelt-Frick, Universitetssjukhuset Örebro, Örebro; Helena
Alfredsson, Karolinska Trial Alliance, Stockholm; Erik Beling, Karolinska Trial
Alliance, Stockholm; Peter Benedek, Karolinska Universitetssjukhuset, Stockholm;
Milica Crisby, Karolinska Trial Alliance, Stockholm; Mozgan Dorkhan,
Endokrinologiska kliniken, Malmö; Tomasz Drescik, Universitetssjukhuset Örebro,
Örebro; Katarina Eeg-Olofsson, Lundberglaboratoriet för diabetesforskning,
Sahlgrenska Universitetssjukhuset, Göteborg; Björn Eliasson, Lundberglaboratoriet
för diabetesforskning, Sahlgrenska Universitetssjukhuset, Göteborg; Ken Eliasson,
Universitetssjukhuset Örebro, Örebro; Mats Eriksson, Karolinska
Universitetssjukhuset, Stockholm; Peter Fardelin, Universitetssjukhuset Örebro,
Örebro; Anna Fredholm, Karolinska Trial Alliance, Stockholm; Anders Frid,
Endokrinologiska kliniken, Malmö; Kurt Gerok-Andersson, Karolinska
Universitetssjukhuset, Stockholm; Lars Hjelmæus, Citydiabetes, Stockholm;
Andreas Hufnagl, Karolinska Trial Alliance, Stockholm; Ewa Jasinska,
Universitetssjukhuset Örebro, Örebro; Ewa Kowalska, Universitetssjukhuset Örebro,
Örebro; Pierre Lafolie, Karolinska Trial Alliance, Stockholm; Otto Lindquist,
Karolinska Trial Alliance, Stockholm; Martin Lundvall, Universitetssjukhuset Örebro,
Örebro; Eva Melander, Universitetssjukhuset Örebro, Örebro; Camilla Nicander,
Universitetssjukhuset Örebro, Örebro; Linda Moris, Karolinska Trial Alliance,
Stockholm; Bengt-Olov Tengmark, Citydiabetes, Stockholm; Martin Ridderstråle,
Endokrinologiska kliniken, Malmö; Ulrika Saphir, Karolinska Trial Alliance,
Stockholm; Pia Skagerberg, Karolinska Trial Alliance, Stockholm; Christian Steczko-

SUPPLEMENTARY DATA

Nilsson, Universitetssjukhuset Örebro, Örebro; Björn Strandell, Universitetssjukhuset Örebro, Örebro; Ylva Tomson, Karolinska Trial Alliance, Stockholm.

Taiwan: Jeng-Yeou Chen, Chung Gung Medical Foundation-Linkou Branch 5, Gueishan, Taoyuan; Yu-Cheng Chen, Changhua Christian Hospital, Changhua; Chun-Yen Chiang, Chi Mei Medical Center, Tainan Tsuei-Yuan Huang, Chi Mei Medical Center, Tainan; Chien-Wen Chou, Chi Mei Medical Center, Tainan; Chun-Wei Ho, Kaohsiung Medical University Hospital, Kaohsiung; Pi-Jung Hsiao, Kaohsiung Medical University Hospital, Kaohsiung; Ming-Chia Hsieh, Changhua Christian Hospital, Changhua; Ray-Sea Hsu, Chung Gung Medical Foundation-Linkou Branch 5, Gueishan, Taoyuan; Shang Ren Hsu, Changhua Christian Hospital, Changhua; Chung-Huei Huang, Chung Gung Medical Foundation-Linkou Branch 5, Gueishan, Taoyuan; Yu-Yao Huang, Chung Gung Medical Foundation-Linkou Branch 5, Gueishan, Taoyuan; Wei-Wen Hung, Kaohsiung Medical University Hospital, Kaohsiung; Mei-Yueh Lee, Kaohsiung Medical University Hospital, Kaohsiung; Yang-Ming Lee, Changhua Christian Hospital, Changhua; Chen-Wei Lin, Chung Gung Medical Foundation-Linkou Branch 5, Gueishan, Taoyuan; Chia-Hung Lin, Chung Gung Medical Foundation-Linkou Branch 5, Gueishan, Taoyuan; Kun-Der Lin, Kaohsiung Medical University Hospital, Kaohsiung; Shi-Dou Lin, Changhua Christian Hospital, Changhua; Shu-Fu Lin, Chung Gung Medical Foundation-Linkou Branch 5, Gueishan, Taoyuan; Miaw-Jene Liou, Chung Gung Medical Foundation-Linkou Branch 5, Gueishan, Taoyuan; Wen-Tsung Lu, Chung Gung Medical Foundation-Linkou Branch 5, Gueishan, Taoyuan; Shyi-Jang Shin, Kaohsiung Medical University Hospital, Kaohsiung; Hon-Ke Sia, Changhua Christian Hospital, Changhua; Mu-Hsuan Su, Kaohsiung Medical University Hospital, Kaohsiung; Shih-Li Su, Changhua Christian Hospital, Changhua; Jui-Hung Sun, Chung Gung Medical

SUPPLEMENTARY DATA

Foundation Linkou Branch 5, Gueishan, Taoyuan; Kai-Jen Tien, Chi Mei Medical Center, Tainan; Dong Hwa Tsai, Changhua Christian Hospital, Changhua; Sung-Sheng Tsai, Chung Gung Medical Foundation-Linkou Branch 5, Gueishan, Taoyuan; Shih-Te Tu, Changhua Christian Hospital, Changhua; Chih-Ching Wang, Chung Gung Medical Foundation-Linkou Branch 5, Gueishan, Taoyuan; Shu Yi Wang, Changhua Christian Hospital, Changhua; Chwen-Yi Yang, Chi Mei Medical Center, Tainan; Feng Chieh Yen, Chi Mei Medical Center, Tainan.

Turkey: Abdurrahman Acikgoz, Haseki Training and Research Hospital, Istanbul; Sema Akalin, Marmara University Medical Faculty, Istanbul; Safak Akin, Hacettepe University Medical School, Ankara; Baris Akinci, Dokuz Eylul University Medical Faculty, Izmir; Aysen Akkurt, School of Medicine, Uludag University, Bursa; Mujde Akturk, Gazi University Faculty of Medicine, Ankara; Nihan Alkis, School of Medicine, Uludag University, Bursa; Ilker Altun, Ege University Medical School, Izmir; Hasan Ali Altunbas, Akdeniz University Medical Faculty, Antalya; Yuksel Altuntas, Sisli Etfal Training and Research Hospital, Istanbul; Mustafa Araz, Gaziantep University Medical Faculty, Gaziantep; Sulbiye Aribas, Erciyes University Medical Faculty, Kayseri; Emre Arslan, Gazi University Faculty of Medicine, Ankara; Gulgun Arslan, Dr. Lutfi Kırdar Kartal Training and Research Hospital, Istanbul; Metin Arslan, Gazi University Faculty of Medicine, Ankara; Esra Hayriye Ataoglu, Haseki Training and Research Hospital, Istanbul; Faruk Ayan, Cerrahpasa Medical School, Istanbul University, Istanbul; Kadriye Aydin, Hacettepe University School of Medicine, Ankara; Berna Imge Aydogan, Ankara University School of Medicine, Ankara; Goksun Ayvaz, Gazi University Faculty of Medicine, Ankara; Muzeyyen Arslan Bahadir, Goztepe Training and Research Hospital, Istanbul Medeniyet University, Istanbul; Mustafa Kemal Balci, Akdeniz University Medical Faculty, Antalya; Mehtap

SUPPLEMENTARY DATA

Navdar Basaran, Ankara Numune Training and Research Hospital, Ankara; Nilgun Baskal, Ankara University School of Medicine, Ankara; Melike Zehra Bugra, Istanbul Faculty of Medicine, Istanbul University, Istanbul; Mehmet Calan, Dokuz Eylul University Medical Faculty, İzmir; Umit Cavdar, Dokuz Eylul University Medical Faculty, İzmir; Faik Cetin, Haseki Training and Research Hospital, Istanbul; Nese Cinar, Hacettepe University School of Medicine, Ankara; Mehmet Colbay, Gazi University Faculty of Medicine, Ankara; Abdurrahman Comlekci, Dokuz Eylul University Medical Faculty, İzmir; Selcuk Dagdelen, Hacettepe University School of Medicine, Ankara; Taner Damci, Cerrahpasa Medical School, Istanbul University, Istanbul; Vedat Davutoglu, Gaziantep University Medical Faculty, Gaziantep; Mustafa Demir, Dr. Lutfi Kırdar Kartal Training and Research Hospital, Istanbul; Tevfik Demir, Dokuz Eylul University Medical Faculty, İzmir; Oguzhan Deyneli, Marmara University Medical Faculty, Istanbul; Irem Dincer, Ankara University School of Medicine, Ankara; Burcu Dogan, Goztepe Training and Research Hospital, Istanbul Medeniyet University, Istanbul; Kadriye Yesim Kanipek Doker, Haseki Training and Research Hospital, Istanbul; Ismail Engin, Haseki Training and Research Hospital, Istanbul; Ayten Eraydin, Gaziantep University Medical Faculty, Gaziantep; Tomris Erbas, Hacettepe University School of Medicine, Ankara; Murat Faik Erdogan, Ankara University School of Medicine, Ankara; Canan Ersoy, School of Medicine, Uludag University, Bursa; Arzu Gedik, Dokuz Eylul University Medical Faculty, İzmir; Ferhat Gokay, Ankara Numune Training and Research Hospital, Ankara; Ozen Oz Gul, School of Medicine, Uludag University, Bursa; Serdar Guler, Ankara Numune Training and Research Hospital, Ankara; Tugba Gumus, Dokuz Eylul University Medical Faculty, Izmir; Elif Gunes, School of Medicine, Uludag University, Bursa; Mehmet Yavuz Gurler, Sisli Etfal Training and Research Hospital,

SUPPLEMENTARY DATA

Istanbul; Esra Hatipoglu, Cerrahpasa Medical School, Istanbul University, Istanbul; Hasan Ilkova, Florence Nightingale Hospital, Istanbul; Ozlem Turhan Iyidir, Gazi University Faculty of Medicine, Ankara; Giray Kabakci, Hacettepe University Medical School, Ankara; Berrin Karadag, Sisli Etfal Training and Research Hospital, Istanbul; Guzin Karatemiz, Sisli Etfal Training and Research Hospital, Istanbul; Alper Cagri Karci, Ankara Numune Training and Research Hospital, Ankara; Emine Kartal, Ege University Medical School, Izmir; Ergun Baris Kaya, Hacettepe University Medical School, Ankara; Caglar Keskin, Ankara University School of Medicine, Ankara; Ela Fatma Keskin, Cerrahpasa Medical School, Istanbul University, Istanbul; Gokcen Kocabas, Ege University Medical School, Izmir; Feride Kocak, Goztepe Training and Research Hospital, Istanbul Medeniyet University, Istanbul; Aylin Kamut Kol, Sisli Etfal Training and Research Hospital, Istanbul; Hakan Korkmaz, Gaziantep University Faculty of Medicine, Gaziantep; Ferit Kerim Kucukler, Ankara Numune Training and Research Hospital, Ankara; Banu Alpaslan Mesci, Goztepe Training and Research Hospital, Istanbul Medeniyet University, Istanbul; Aytekin Oguz, Istanbul Medeniyet University, Goztepe Training and Research Hospital, Istanbul; Ekrem Orbay, Dr. Lutfi Kirdar Kartal Training and Research Hospital, Istanbul; Hasan Oz, Dr. Lutfi Kirdar Kartal Training and Research Hospital, Istanbul; Nazan Demir Ozcan, Sisli Etfal Training and Research Hospital, Istanbul; Sadi Ozdem, Akdeniz University Medical Faculty, Antalya; Secil Ozisik, Dokuz Eylul University Medical Faculty, Izmir; Cigdem Ozkan, Gazi University Faculty of Medicine, Ankara; Muge Ozsan, Gaziantep University Medical Faculty, Gaziantep; Mucahit Ozyazar, Cerrahpasa Medical School, Istanbul University, Istanbul; Hayri Parlar, Florence Nightingale Hospital, Istanbul; Haluk Sargin, Dr. Lutfi Kirdar Kartal Training and Research Hospital, Istanbul; Mehmet Sargin, Dr. Lutfi Kirdar Kartal Training and

SUPPLEMENTARY DATA

Research Hospital, Istanbul; Ilhan Satman, Istanbul Faculty of Medicine, Istanbul University, Istanbul; Fusun Saygili, Ege University Medical School, Izmir; Alev Selek, Marmara University Faculty of Medicine, Istanbul; Yasin Simsek, Erciyes University Medical Faculty, Kayseri; Pinar Sisman, School of Medicine, Uludag University, Bursa; Kubra Solmaz, Haseki Training and Research Hospital, Istanbul; Cahide Soydas, Ege University Medical School, Izmir; Serkan Tatliagac, Florence Nightingale Hospital, Istanbul; Ismet Tamer, Dr. Lutfi Kirdar Kartal Training and Research Hospital, Istanbul; Sule Temizkan, Marmara University Medical Faculty, Istanbul; Cansin Tulunay, Ankara University School of Medicine, Ankara; Ercan Tuncel, School of Medicine, Uludag University, Bursa; Fulya Turker, Istanbul Faculty of Medicine, Istanbul University, Istanbul; Kursat Unluhizarci, Erciyes University Medical Faculty, Kayseri; Ugur Unluturk, Ankara University School of Medicine, Ankara; Meliha Melin Uygur, Marmara University Medical Faculty, Istanbul; Buket Vatansever, Dr. Lutfi Kirdar Kartal Training and Research Hospital, Istanbul; Dilek Yazici, Marmara University Medical Faculty, Istanbul; Dilek Gogas Yavuz, School of Medicine, Marmara University, Istanbul; Serkan Yener, Dokuz Eylul University Medical Faculty, Izmir; Mustafa Yenigun, Haseki Training and Research Hospital, Istanbul; Merve Yilmaz, Dokuz Eylul University Medical Faculty, Izmir.

United Arab Emirates: Saira Abbas, Diabetology Unit, Rashid Hospital, Dubai; Fatheya Alawadi, Dubai Hospital, Dubai; Azza Abdul Aziz, Dubai Hospital, Dubai; Alaaeldin Bashier, Dubai Hospital, Dubai; Khadija Hafidh, Rashid Hospital, Dubai; Ghaida Kaddaha, Rashid Hospital, Dubai; Fauzia Rashid, Dubai Hospital, Dubai.

United Kingdom: Prakash Abraham, Aberdeen Royal Infirmary, Aberdeen; Karen Adamson, St John's Hospital, Livingston; Steve Atkin, Michael White Centre for Diabetes & Endocrinology, Hull Royal Infirmary, Hull; Myint Aye, Michael White

SUPPLEMENTARY DATA

Centre for Diabetes & Endocrinology, Hull Royal Infirmary, Hull; Mohammad Azam, Diabetes Centre, Birmingham Heartlands Hospital, Birmingham; S Bain, Clinical Trials Unit, Morriston Hospital, Morriston; AH Barnett, Diabetes Centre, Birmingham Heartlands Hospital, Birmingham; Srikanth Bellary, Diabetes Centre, Birmingham Heartlands Hospital, Birmingham; Ketan Dhatariya, University of East Anglia, Norwich; Mike Eaton, Diabetes Clinical Research Unit, Plymouth Science Park, Plymouth; Patrick English, Derriford Hospital, Plymouth; Jane Ewing, University of East Anglia, Norwich; Niall Furlong, Diabetes & Endocrinology Centre, Whiston Hospital, Preston; Martin Gibson, Clinical Science Building, Salford Royal Hospital Foundation Trust, Salford; Darren Green, Salford Royal NHS Foundation Trust, Salford; Roselle Herring, Cedar Centre, Royal Surrey County Hospital, Guildford; Victoria Hordern, The Royal Surrey County Hospital, Guildford; Alan Jaap, Royal Infirmary of Edinburgh, Edinburgh; Zeesham Javed, Michael White Centre for Diabetes & Endocrinology, Hull Royal Infirmary, Hull; Andrew Johnson, Southmead Hospital, Westbury on Trym; Judit Konya, Michael White Centre for Diabetes & Endocrinology, Hull Royal Infirmary, Hull; Sudesh Kumar, Diabetes and Metabolism Unit, Coventry & Warwick Hospital, Coventry; Robert Lindsay, BHF Glasgow Cardiovascular Research Centre, University of Glasgow, Glasgow; Alasdair Mackie, Diabetes Support Unit, Ninewells Hospital, Dundee; Stephen McGlynn, Salford Royal Hospital Foundation Trust, Salford; Joyce McKenzie, Diabetes Centre, The New Stobhill Hospital, Glasgow; Ann Millward, Derriford Hospital, Plymouth; N. Murthy, Warwickshire Institute for Diabetes, Endocrinology and Metabolism Centre, University Hospital Coventry & Warwickshire NHS Trust, Coventry; Richard Paisey, Torbay Hospital, Torquay; Ewan Pearson, Ninewells Hospital and Medical School, Dundee; Milan Piya, University Hospitals Coventry and Warwickshire NHS Trust,

SUPPLEMENTARY DATA

Coventry; Mike Ramell, Royal Devon & Exeter Hospital, Exeter; Doug Robertson, Diabetes Centre, Sandwell General Hospital, West Bromwich; David Russell-Jones, The Cedar Centre, Royal Surrey County Hospital, Guildford; Ponnusamy Saravanan, Diabetes and Endocrinology Centre, George Eliot Hospital NHS Trust, Nuneaton; Thozhukat Sathyapalan, Michael White Centre for Diabetes & Endocrinology, Hull Royal Infirmary, Hull; Jayadave Shakher, Diabetes Centre, Birmingham Heartlands Hospital, Birmingham; Hannah Shiels, Torbay Hospital, Torquay; Subash Sivaraman, University Hospitals Coventry and Warwickshire NHS Trust, Coventry; Jamie Smith, Torbay Hospital, Torquay; Upendram Srinivas-Shankar, Diabetes Centre, St. Helens Hospital, Merseyside; J Stokes, Derriford Hospital, Plymouth; Inessa Tracey, Diabetes Centre, Sandwell General Hospital, West Bromwich; Bijay Vaidya, Royal Devon & Exeter Hospital, Wonford; Michael Yee, Metabolic Medicine, St Mary's Hospital, London; Prasad Yemparala, Diabetes Centre, Birmingham Heartlands Hospital, Birmingham; James Walker, St John's Hospital, Livingston; Peter Wiggins, Castlemilk Health Centre, Glasgow; Jane Williams, Diabetes Centre, Hospital of St Cross, Rugby; John Wright, Cedar Centre, Royal Surrey County Hospital, Guildford; Carol Mackinnon, Castlemilk Group Practice, Glasgow; Janet Inkster, Aberdeen Royal Infirmary, Aberdeen; Javeed Zeeshan, Michael White Centre for Diabetes and Endocrinology, Hull Royal Infirmary, Hull; Christina Bejnariu, Michael White Centre for Diabetes and Endocrinology, Hull Royal Infirmary, Hull; Nagaraj Malipatil, Salford Royal NHS Foundation Trust, Salford; Sumithra Giritharan, Salford Royal NHS Foundation Trust, Salford; Kathryn Lonnen, Southmead Hospital, Bristol; Ioannis Kyrou, Diabetes and Metabolism Unit, Coventry & Warwick Hospital, Coventry.

SUPPLEMENTARY DATA

United States of America: Sayed Aamir, University Specialty Clinics, Columbia; Michelle Ababa, Anaheim Clinical Trials, Anaheim; Marconi Abreu, UT Southwestern Medical Center, Dallas; Derick Adams, Lexington VA Medical Center, Lexington; Penny Adams, Station Medical Center, Altoona; Joy Aden, Northeast Clinical Research Center, Bethlehem; Diana Aguilar, Catalina Research Institute, Chino; Ana Aguilon, Facey Medical Group, Mission Hills; Afiya Ahmed, Apex Medical Research Inc, Chicago; Azazuddin Ahmed, Apex Medical Research Inc, Chicago; Bilal Ahmed, Central Florida Medical Associates, Orange City; Intekhab Ahmed, Thomas Jefferson University Hospitals, Philadelphia; Atif Akhtar, Northwest Heart Center, Tomball; Bruce Akright, Northeast Clinical Research Center, Bethlehem; Laura Akright, Northeast Clinical Research Center, Bethlehem; Cesar Albarracin, Corpus Christi Memorial Hospital, Corpus Christi; Sara Albert, FPA Clinical Research, Kissimmee; Shamasa Ali, Tulane University School of Medicine, New Orleans; Bushra Aliuddin, Apex Medical Research Inc, Chicago; Afrah Almasmary, Alzohaili Medical Consultants, Dearborn; Abdulmalek Al-Maweri, Alzohaili Medical Consultants, Dearborn; Opada Alzohaili, Medical Consultants, Dearborn; William Amador, University Specialty Clinics, Columbia; Maged Amine, Northwest Heart Center, Tomball; Sami Amini, Narbonne Medical, Lomite; Marshall Anderson, Kernodle Clinic Inc, Burlington; Linda Anderson, The Christ Hospital Lindner Research Center, Cincinnati; Robert Anderson, Veterans Affairs Medical Center, Omaha; Maria Andrews, Covenant Clinical Research, San Antonio; Jose Angel, Iowa Diabetes & Endocrinology Center, Des Moines; Wissam Anteer, Alzohaili Medical Consultants, Dearborn; Vincent Anthony, American Institute of Research, Los Angeles; Arturo Antillon, American Institute of Research, Los Angeles; Penny Anzures, Veterans Affairs Medical Center, Omaha; Sirlys Arcon-Rios, OUHSC:

SUPPLEMENTARY DATA

Diabetes and Endocrinology, Oklahoma City; David Arkin, Physicians Research Associates LLC, Lawrenceville; Bassam Arodak, OUHSC: Diabetes and Endocrinology, Oklahoma City; Louis Aronne, Comprehensive Weight Control Center, New York; Stephen Aronoff, Research Institute of Dallas, Dallas; Guadalupe Arreola, Facey Medical Group, Mission Hills; Sonia Arroyo, 400 North Medical Center, Michigan City; Sunil Asnani, Jersey Shore University Medical Center, Neptune; Gwendolyn Astudillo-Tee, Dignity Health - Chandler Regional Medical Center, Chandler; Susan Ault, Awasty Research Network, Marion; Barry Austin, Preferred Primary Care Physicians, Pittsburgh; Veronica Avila, Orange County Senior Care Clinical Trials, Tustin; Nicholas Avitabile, Tulane University School of Medicine, New Orleans; Vivek Awasty, Awasty Research Network, Marion; Vivek Awasty, OhioHealth Marion Area Physicians, Marion; Madona Azar, University of Oklahoma College of Medicine Internal Medicine, Oklahoma City; Ammara Aziz, OUHSC: Diabetes and Endocrinology, Oklahoma City; Pouya Bahrami, American Institute of Research, Los Angeles; Mirza Baig, Paramount Medical Research & Consulting, Cleveland; Kimberly Bailey, Christ Hospital Lindner Research Center, Cincinnati; Timothy Bailey, AMCR Institute Inc, Escondido; Mary Baker, University Of Oklahoma College Of Medicine, Oklahoma City; Narinder S. Bala, Bala and Khaira Medical Center, Fresno; Idelisse Balbes-Reyes, Eastern Consulting Group Inc, Humacao; David Baldwin, Rush University Medical Center, Chicago; Elisa Baldwin, Awasty Research Network, Marion; Tracy Balentine, Meridien Research, Tampa; Thomas Ballard, Mountain View Clinical Research, Greer; Kemal Baloch, Northwest Houston Cardiology, Houston; Salomon Banarar, Dallas Diabetes & Endocrine Center, Dallas; Cheryl Baney, Blair Medical Associates Inc, Station Medical Center, Altoona; Ajaz Banka, Tulane University School of Medicine, New Orleans; Linda

SUPPLEMENTARY DATA

Barber, Lexington VA Medical Center, Lexington; Mark Barber, Professional Clinical Research, Interlochen; Timothy Barker, Research Institute of the Carolinas, Mooresville; Kristie Barnes, Physicians East Endocrinology, Greenville; Otis Barnum, Natchitoches Medical Specialists, Natchitoches; Joel Barra, American Institute of Research, Los Angeles; Anthony Bartkowiak, Blair Medical Associates Inc, Altoona; Giovanni Baula, Westcoast Primary Care, St. Petersburg; Angela Bautista, AMCR Institute Inc, Escondido; Robert Bayliss, Internal Medicine Associates of Greenville, Greenville; Melissa Beaman, Facey Medical Group, Mission Hills; Karen Beatty, University of Louisville Physicians, Louisville; Judith Becker, Paramount Medical Research & Consulting, Cleveland; Laura Bedolla, AMCR Institute Inc, Escondido; Gulshan Begum, Medex Healthcare Research Inc., New York; Paula Belejchak, Preferred Primary Care Physicians, Pittsburgh; Amy Bell, University of Tennessee Health Science Center, Memphis; Magali Beltran, Radiant Research Inc, Chicago; Christine Belucher, Blair Medical Associates Inc, Altoona; Erin Bensfield, Orange County Senior Care Clinic Tustin; Julia Benton, Blair Medical Associates Inc, Altoona; Katherine Bergamo, UNC Diabetes Care Center, Chapel Hill; Richard Bergenstal, International Diabetes Center, Minneapolis; Bradford Bergman, Benefis Medical Group, Great Falls; Martha Berry, Arthritis & Diabetes Clinic, Monroe; Kirsten Bettino, Narbonne Medical, Lomita; Matthew Beyea, Clinical Study Center of Asheville, Asheville; Anuj Bhargava, Iowa Diabetes & Endocrinology Center, Des Moines; Arjun Bhattacharya, Medex HealthCare Research, St. Louis; Alistaire Bilas, Anaheim Clinical Trials, Anaheim; Lindsay Bischoff, Thomas Jefferson University Hospitals, Philadelphia; Lacey Bixler, OUHSC: Diabetes and Endocrinology, Oklahoma City; Susan Bizjack, Paramount Medical Research & Consulting, Cleveland; Roy Blank, Novant Health Southern Peidmont, Monroe; Robert

SUPPLEMENTARY DATA

Blankfield, Paramount Medical Research & Consulting, Cleveland; Louba Block, Thomas Jefferson University Hospitals, Philadelphia; James Bloodworth, Internal Medicine Associates of Greenville, Ann Arbor; Kerri Bloomberg, Dignity Health - Chandler Regional Medical Center, Chandler; Robert Bloomberg, Dignity Health - Chandler Regional Medical Center, Chandler; Joy Blustin, Facey Medical Group, Mission Hills; Ivica Boban, Thomas Jefferson University Hospitals, Philadelphia; Alicia Bolden, Maxine Hamilton PA, Fort Lauderdale; Otilia Boncu, Midwest Endocrinology, Crystal Lake; Patricia Bookless, Southern New Hampshire Diabetes and Endocrinology, Nashua; Christina Brassie, Internist Associates of Central New York Crouse Medical Practice, Manlius; Donald Brautigam, Great Lakes Medical Research, Westfield; Peter Bressler, North Texas Endocrine Center, Dallas; Rose Brewster, Innovative Research of West Florida, Clearwater; Christina Brown, Heritage Valley Medical Group, Beaver; Cynthia Brown, Southeastern Endocrine & Diabetes, Roswell; Debra Brown, Endocrine and Psychiatry Center, Houston; Flossine Brown, Union Memorial Hospital, Baltimore; Mary Bruskevitz, University of Wisconsin School of Medicine and Public Health, Madison; Dawn Bryant, Endocrine and Psychiatry Center, Houston; Cyndi Buchanan, Medex HealthCare Research, St. Louis; Nicole Buchanan, Blair Medical Associates Inc, Altoona; Genena Buck, Physicians East Endocrinology, Greenville; Sharon Buckley, OUHSC: Diabetes and Endocrinology, Oklahoma City; Jacqueline Bueno, Midwest Endocrinology, Crystal Lake; Deborah Burke, Innovative Research of West Florida, Clearwater; Kathryn Burton, Cincinnati VA Medical Center, Cincinnati; John Buse, UNC Diabetes Care Center, Chapel Hill; Sherry Buske, Iowa Diabetes & Endocrinology Center, Des Moines; William Byars, Mountain View Clinical Research, Greer; Robin Bye, Tulane University School of Medicine, New Orleans; Ronald Caldwell, Clinical Study Center

SUPPLEMENTARY DATA

of Asheville, Asheville; Krystle Calvin, 400 North Medical Center, Michigan City; Rolando Camacho, Monterey Bay Family Physicians, Watsonville; Edward Campbell, Research Institute of the Carolinas, Mooresville; Daniel Cannon, Clinical Study Center of Asheville, Asheville; Janette Cantrell, Tampa Clinical Research, Tampa; Jonathan Caplan, Florida Diabetes/Endocrine Center, Orlando; Carlos Cardenas, Northeast Clinical Research Center, Bethlehem; Jamie Carlton, Alzohaili Medical Consultants, Dearborn; Gandahari Carpio, Tulane University School of Medicine, New Orleans; Anne Carrol, Paramount Medical Research & Consulting, Cleveland; Laurie Cartwright, Orange County Senior Care Clinic, Tustin; Gerardo Casanova, Apex Medical Research Inc, Chicago; Lorena Castaneda, Martin Diagnostic Clinic, Tomball; Martha Castle, Internist Associates of Central New York Crouse Medical Practice, Manlius; LouAnn Castro, Northeast Clinical Research Center, Bethlehem; Jennifer Catangay, Linda Vista Health Care Center, San Diego; Sushela Chaidarun, Dartmouth-Hitchcock Medical Center, Lebanon; Joseph Chambers, Facey Medical Group, Mission Hills; Thomas Chambliss, Internal Medicine Associates of Greenville, Ann Arbor; Lokesh Chandra, Apex Medical Research Inc, Chicago; Alvin Chang, Orange County Senior Care Clinic, Tustin; Simon Chang, Orange County Senior Care Clinic, Tustin; Jordan Chappel, FPA Clinical Research, Kissimmee; Christopher Chappel, FPA Clinical Research, Kissimmee; Tierra Chappell, Maxine Hamilton PA, Fort Lauderdale; Carmina Charles, Medical University of South Carolina, Charleston; Alberto Chavira, AMCR Institute Inc, Escondido; Louis Chaykin, Meridien Research, St. Petersburg; Ellen Check, Louis Stokes Cleveland VA Medical Center, Cleveland; Lambert Chee, Diablo Clinical Research, Walnut Creek; Junping Chen, University of Oklahoma College of Medicine, Oklahoma City; Amanda Cherry, Physicians East, Greenville,

SUPPLEMENTARY DATA

NC; Aaron Chestnut, University Specialty Clinics, Columbia; June Chiarot, Great Lakes Medical Research, Westfield; Niyati Chiniwala, Thomas Jefferson University Hospitals, Philadelphia; Kristen Chionh, Baylor Research Institute, Dallas, TX; James Choe, OUHSC: Diabetes and Endocrinology, Oklahoma City; Mark Christiansen, Diablo Clinical Research, Walnut Creek; Steven Chrzanowski, Benefis Med Spa, Great Falls; Ellie Chuang, Southern New Hampshire Diabetes and Endocrinology, Nashua; Leonard Chuck, Diablo Clinical Research, Walnut Creek; Julie Clyatt, Florida Diabetes/Endocrine Center, Orlando; Barry Cohan, Great Falls Clinic, Great Falls; Barry Cohan, Benefis Med Spa, Great Falls; Robert Cohen, University of Cincinnati College of Medicine, Cincinnati; Richard Comi, Dartmouth-Hitchcock Medical Center, Lebanon; Angel Comulada-Rivera, Instituto De Endocrinologia Diabetes, Levittown; Kathi Conner, Harrison Community Hospital, Cadiz; Gordon Connor, Radiant Research Inc, Birmingham; Rosa Contreras, Anaheim Clinical Trials, Anaheim; Karen Cook, Physicians Research Associates LLC, Lawrenceville; Robin Cook, Novant Health Southern Piedmont, Monroe; Richard Cook, Preferred Primary Care Physicians, Uniontown; Clinton Corder, COR Clinical Research, Oklahoma City; Brenda Cornejo Sr., Catalina Research Institute, Chino; Lisa Cornette, Southern New Hampshire Diabetes and Endocrinology, Nashua; Guadalupe Cortes, Facey Medical Group, Mission Hills; Lenore Cortez, Southern New Hampshire Diabetes and Endocrinology, Nashua; Carole Cox, Crescent City Clinical Research, Metairie; Gabriela Cox, Louis Stokes Cleveland VA Medical Center, Cleveland; William Craig, Internal Medicine Associates of Greenville, Ann Arbor; Bethany Cramer, Louis Stokes Cleveland VA Medical Center, Cleveland; Carol Cromer, Tampa Clinical Research, Tampa; Michael Cromer, Tampa Clinical Research, Tampa; Robert Cuddihy, International Diabetes Center,

SUPPLEMENTARY DATA

Minneapolis; Dawn Culmer, UNC Diabetes Care Center, Chapel Hill; Dawn Culmer, UNC Diabetes Care Center, Chapel Hill; Hope Curran, Radiant Research Inc, Chicago; Miriam Curran, Suncoast Medical Center, St. Petersburg; Catherine Dadis, Benefis Med Spa, Great Falls; Samuel Dagogo-Jack, University of Tennessee Health Science Center, Memphis; Ismail Dairywala, Northwest Heart Center, Tomball; David D'Alessio, University of Cincinnati College of Medicine, Cincinnati; Gregory Damberg, International Diabetes Center, Minneapolis; Andy Dang, Facey Medical Group, Mission Hills; Karen Daniel, Endocrine and Psychiatry Center, Houston; Michael Davidson, Radiant Research Inc, Chicago; Trent Davis, AMCR Institute Inc, Escondido; John Dean, Clinical Study Center of Asheville, Asheville; Rowan DeBold, International Diabetes Center, Minneapolis; Peggy Deitz, Clinical Study Center of Asheville, Asheville; Maria Del, Pilar Solano Diabetes Research Institute University of Miami, Miami; David Delaney, Great Falls Clinic, Great Falls; Elizabeth Delgado, Anaheim Clinical Trials, Anaheim; Michael DeMicco, Anaheim Clinical Trials, Anaheim; Mary Ann DeMuro, University of Louisville Hospital, Louisville; Dina DeSalle, Heritage Valley Medical Group, Beaver; Cyrus Desouza, Veterans Affairs Medical Center, Omaha; Karthikeya Devireddy, KD Medical Group Inc, Columbia; Benjamin DeVries, Innovative Research of West Florida, Clearwater; Milana Dezube, UNC Diabetes Care Center, Chapel Hill; Isam Diab, Paramount Medical Research & Consulting, Cleveland; Amy Diesburg-Stanwood, Denver VA Medical Center, Denver; Julia Dilliard, North Texas Endocrine Center, Dallas; Jessica Dilling, Blair Medical Associates Inc, Altoona; Jaime Diner, UNC Diabetes Care Center, Chapel Hill; Katherine Dishongh, John L. McClellan Memorial Veterans Hospital, Little Rock; Regina Dodis, Norwalk Medical Group, Norwalk; Christina Doing, Mercy Medical Research Institute, Springfield; Warren Doll, Union Memorial

SUPPLEMENTARY DATA

Hospital, Baltimore; Amanda Donoho, Holston Medical Group, Kingsport; Daniel Donovan, Mount Sinai Hospital, New York; Nathan Doremus, American Institute of Research, Los Angeles; Steven Dorfman, Research Institute Of Dallas, Dallas; Pinal Doshi, Pioneer Medical Group, Cerritos; Jean Dostou, UNC Diabetes Care Center, Chapel Hill; Jean Dostou, Highgate Specialty Center, Durham; Delaine Douglas, Grunberger Diabetes Institute, Bloomfield Hills; Sara Douglass, University of Colorado School of Medicine, Denver; Desiree Douglas, Meridien Research, St. Petersburg; Michelle Dowell, Meridien Research, St. Petersburg; Emily Drazich, Great Falls Clinic, Great Falls; Erika Driver, Radiant Research Inc, Chicago; Haiming Du, University of Tennessee Health Science Center, Memphis; Robert DuBose III, Internal Medicine Associates of Greenville Ann Arbor; Michelle Duclos, UNC Diabetes Care Center, Chapel Hill; Michelle Duclos, UNC Diabetes Care Center, Chapel Hill; Kelly Dunn, Tampa Clinical Research, Tampa; Terry Dunnam, Research Institute Of Dallas, Dallas; Nancy Durham, Mountain View Clinical Research, Greer; Lyndsey Dye, Lexington VA Medical Center, Lexington; Donald Eagerton, Carolina Health Specialists, Myrtle Beach; Sotonte Ebenibo, University of Tennessee Health Science Center, Memphis; Chimaroke Edeoga, University of Tennessee Health Science Center, Memphis; Gina Edwards, Panacea Clinical Research, San Antonio; James Ekwensi, University of Tennessee Health Science Center, Memphis; Imad El Asmar, American Institute of Research, Los Angeles; Nabil El Sayad, Narbonne Medical, Lomita; Christopher Eliopoulos, UK HealthCare Kentucky Clinic, Lexington; Myriam Elkosseifi, OUHSC: Diabetes and Endocrinology, Oklahoma City; Ryanne Elmer, OUHSC: Diabetes and Endocrinology, Oklahoma City; Miles Elmore, Clinical Study Center of Asheville, Asheville; Diane Elson, University of Wisconsin School of Medicine and Public Health, Madison; Louna El-Zein, University Specialty Clinics,

SUPPLEMENTARY DATA

Columbia; Laurie Emmert, Meridien Research, St. Petersburg; Lee Erbe, Medical University of South Carolina, Charleston; Susie Estes, Endocrine and Psychiatry Center, Houston; Lorie Estrada, Baylor Research Institute, Dallas, TX; Aristides Estrada, Internal Medicine of Morris County, Dover; Tricia Eveleigh, Crouse Medical Practice, Syracuse; Brian Everhart, Heritage Valley Medical Group, Beaver; Fred Faas, John L. McClellan Memorial Veterans Hospital, Little Rock; Carri Faircloth, Research Institute of the Carolinas, Mooresville; Mildred Farmer, Meridien Research, Brooksville; Karen Fehr, Suncoast Medical Center, St. Petersburg; Tanya Ferguson, Orange County Senior Care Clinic, Tustin; Joytika Fernandes, Medical University of South Carolina, Charleston; Kristin Ferree, Diabetes & Endocrinology Consultants, Morehead; Beth Ferrington, Arthritis & Diabetes Clinic, Monroe; Stacey Fitzgibbons, Crouse Medical Practice, Syracuse; Margeret Fitzhugh, Natchitoches Medical Specialists, Natchitoches; Rosalie Fitzsimmons, Suncoast Medical Center, St. Petersburg; Donna Flanders, North Texas Endocrine Center, Dallas; Maryalice Flores, Northeast Clinical Research Center, Bethlehem; Edith Flores, Facey Medical Group, Mission Hills; John Flores, Facey Medical Group, Mission Hills; Maryalice Flores, Northeast OB/GYN Associates Schertz; Christine Florida, Anaheim Clinical Trials, Anaheim; Jacob Flynn, Professional Clinical Research, Interlochen; Pink Folmar, Radiant Research Inc, Birmingham; Ray Forbes, Crouse Medical Practice, Syracuse; Wanissa Ford, Rush University Medical Center, Chicago; Michael Fowler, Vanderbilt University Medical Center, Nashville; Ann Fraker, Greater Baltimore Medical Center, Baltimore; Spencer Francis, Physicians Group, Little Rock; Edgardo Franco-Cotto, Eastern Consulting Group Inc, Humacao; Corina Fratila, Greater Baltimore Medical Center, Baltimore; Martiza Fuentes, Suncoast Medical Center, St. Petersburg; Robert Galagan, Tulane University School of Medicine, New Orleans;

SUPPLEMENTARY DATA

Allison Galloway, OUHSC: Diabetes and Endocrinology, Oklahoma City; Michelle Garcia, American Institute of Research, Los Angeles; Ronald Garcia, Covenant Clinical Research, San Antonio; Martha Garriott, University of Tennessee Health Science Center, Memphis; Joseph Garza, Northeast Clinical Research Center, Bethlehem; Nicole Gass, Apex Medical Research Inc, Chicago; Sabrena Gates, Emory Clinic at Emory Saint Joseph's, Atlanta; Sarah Gates, Louis Stokes Cleveland VA Medical Center, Cleveland; Mary Geary, Innovative Research of West Florida, Clearwater; Katharine Geiger, Blair Medical Associates Inc, Altoona; Jennifer Geishauser, Blair Medical Associates Inc, Altoona; Anthony Giglio, Mercy Medical Research Institute, Springfield; Matthew Gilbert, University of Vermont Medical Center, Burlington; Sarah Godwin, Physicians East Endocrinology, Greenville; Bebe Goetter, Eastern Shore Medical Specialists, Fairhope; April Goley, UNC Diabetes Care Center, Chapel Hill; Laura Golici, UT Southwestern Medical Center, Dallas; Elisabeth Gomori, Medex Healthcare Research, New York; Jody Gonzales, Benefis Med Spa, Great Falls; Ashwini Gore, Medical University of South Carolina, Charleston; Timothy Gorman, Great Lakes Medical Research, Westfield; Albina Gosmanova, University of Oklahoma College of Medicine, Oklahoma City; Ketan Goswami, Physicians Research Associates LLC, Lawrenceville; Ann Gotham, University of Vermont Medical Center, Burlington; James Govoni, Panacea Clinical Research, San Antonio; Steven Graddick, Internal Medicine Associates of Greenville, Ann Arbor; Tiffany Grant, Radiant Research Inc, Chicago; Amanda Greca, OUHSC: Diabetes and Endocrinology, Oklahoma City; Carrie Green, DCOL Center for Clinical Research, Longview; Kathleen Greenbaum, Christiana Medical Aid Unit, Newark; James Greenwald, Medex Healthcare Research, New York; Daniel Grover, Internal Medicine Associates of Greenville, Ann Arbor; George Grunberger,

SUPPLEMENTARY DATA

Grunberger Diabetes Institute, Bloomfield Hills; Michael Guice, American Institute of Research, Los Angeles; David Guirao, Internal Medicine Associates of Greenville, Ann Arbor; Vijayasudha Gunna, Southeastern Endocrine & Diabetes, Roswell; Nina Guseva, Southern New Hampshire Diabetes and Endocrinology, Nashua; Thu Ha, Linda Vista Health Care Center, San Diego; Anjani Hagan, Louis Stokes Cleveland VA Medical Center, Cleveland; Shelton Hager, Holston Medical Group, Kingsport; Amina Haggag, Anaheim Clinical Trials, Anaheim; Michelle Haggar, Tulane University School of Medicine, New Orleans; Maxine Hamilton, Maxine Hamilton PA, Fort Lauderdale; Melinda Hamilton, Medex HealthCare Research, St. Louis; Pearlena Hamlet, St Johns Health System Inc, Springfield; Judy Hammond, Carolina Health Specialists, Myrtle Beach; Ashley Hansen, Optimum Clinical Research, Salt Lake City; Wendy Harrell, Mountain View Clinical Research, Greer; Elizabeth Harris, UNC Diabetes Care Center, Chapel Hill; Kathi Harris, OhioHealth Marion Area Physicians, Marion; Mary Harris, Naidu Clinic, Odessa; Lindsay Harrison, University of Texas Southwestern Medical Center, Dallas; Israel Hartman, Dr. Israel A. Hartman MD Clinical Practice, Dallas; Adrienne Hatch, Meridien Research, Brooksville; Daniel Hayes, University of Michigan Comprehensive Cancer Center, Ann Arbor; Michael Hayes, Awasty Research Network, Marion; Judy Heath, Internal Medicine Associates of Greenville, Ann Arbor; Rob Heineman, University of Nebraska Medical Center, Omaha, NE; April Heinzman, Facey Medical Group, Mission Hills; Mary Hendrick, Meridien Research, St. Petersburg; Roberta Herbst, Professional Clinical Research, Interlochen; Kathie Hermayer, Medical University of South Carolina, Charleston; Janet Hibbard, Lexington VA Medical Center, Lexington; WD Hill, Northeast Clinical Research Center, Bethlehem; Belinda Hilliard, AM Diabetes & Endocrinology Center, Bartlett; Matthew Hix, University Specialty Clinics,

SUPPLEMENTARY DATA

Columbia; Brian Hoch, Medex Healthcare Research, New York; Priscilla Hollander, Baylor Endocrine Center, Dallas; Zella Holmes, Mercy Medical Research Institute, Springfield; Catherine Horobetz, University of Tennessee Health Science Center, Memphis; Rivkah Horowitz, Greater Baltimore Medical Center, Baltimore; Paul Hsieh, Orange County Senior Care Clinic, Tustin; Sue Hsieh, Dignity Health - Chandler Regional Medical Center, Chandler; Wynn Htun, Tulane University School of Medicine, New Orleans; Jimmy Huang, American Institute of Research, Los Angeles; Christine Huber, Christ Hospital Lindner Research Center, Cincinnati; Tina Hudson, DCOL Center for Clinical Research, Longview; Sulmarur Huizar, Facey Medical Group, Mission Hills; Beatrice Hull, Medical University of South Carolina, Charleston; Jenny Hull, Preferred Primary Care Physicians, Pittsburgh; Kimberly Hummer, OUHSC: Diabetes and Endocrinology, Oklahoma City; Ripudaman Hundal, Christiana Medical Aid Unit, Newark; Gloria Hunt, Awasty Research Network, Marion; Vickie Hunt, Medical University of South Carolina, Charleston; Phillip Hutchinson, University Specialty Clinics, Columbia; Jai Hwang, Internal Medicine Associates of Greenville, Ann Arbor; Anthony Iannamorelli, Preferred Primary Care Physicians, Uniontown; Lisa Iannuzzi, Endocrine Associates of Long Island, Smithtown; Michelle Ingram, Veterans Affairs Medical Center, Omaha; Nazia Iram, Northwest Houston Cardiology, Houston; Faramarz Ismail-Beigi, University Hospitals Case Medical Center, Cleveland; Faramarz Ismail-Beigi, CWRU School of Medicine, Cleveland; Serge Jabbour, Thomas Jefferson University Hospitals, Philadelphia; Timothy Jackson, Heritage Valley Medical Group, Beaver; Luzmaria Jaen, Paramount Medical Research & Consulting, Cleveland; Vandana Jain, Radiant Research Inc, Chicago; Roya Jannesari, AMCR Institute Inc, Escondido; Victoria Januski, Physicians East Endocrinology, Greenville; Usha Japa, Tulane University

SUPPLEMENTARY DATA

School of Medicine, New Orleans; Kelly Jarvis, Louis Stokes Cleveland VA Medical Center, Cleveland; Lindsay Jayson, Research Institute of the Carolinas, Mooresville; Richard Jensen, Benefis Medical Group, Great Falls; Donni Jester, Southeastern Endocrine & Diabetes, Roswell; Christine Jocko, Crouse Medical Practice, Syracuse; Carol Johnson, Carol M Johnson MD LLC, Alabaster; Mandi Johnson, AM Diabetes & Endocrinology Center, Bartlett; Megan Johnson, Washington State University, Spokane; Kelly Johnston, 400 North Medical Center, Michigan City; Dan Jones, Harrison Community Hospital, Cadiz; Jocelyn Jones, Rush University Medical Center, Chicago; Terry Jordan, Blair Medical Associates Inc, Altoona; Mario Juarez, Panacea Clinical Research, San Antonio; Abhishake Kaapuraala, Iowa Diabetes & Endocrinology Center, Des Moines; Angela Kain, Robley Rex VAMC, Louisville; Valerie Kaiser, Awasty Research Network, Marion; Kent Kamradt, Radiant Research Inc, Chicago; Peggy Karatoprakli, Veterans Affairs Medical Center, Omaha; Marjan Karegar, Robley Rex VAMC, Louisville; Chrisi Karounos, Lexington VA Medical Center, Lexington; Dennis Karounos, Lexington VA Medical Center, Lexington; Harischandra Karunaratne, Florida Heart Group, Orlando; Bonnie Katalenich, Tulane University School of Medicine, New Orleans; Kristen Katic, Preferred Primary Care Physicians, Uniontown; Michelle Katz, North Texas Endocrine Center, Dallas; Gulsharn Kaur, Bala and Khaira Medical Center, Fresno; Ashley Kawa, Louis Stokes Cleveland VA Medical Center, Cleveland; Caroline Keib, Crouse Medical Practice, Syracuse; Gayle Keider, Oakland Medical Research Center, Troy; David Kem, University of Oklahoma College of Medicine, Oklahoma City; Ryan Kennedy, UK HealthCare Kentucky Clinic, Lexington; Barbara Kenney, Apex Medical Research Inc, Chicago; Dean Kereiakes, Christ Hospital Lindner Research Center, Cincinnati; Mohamed Ketana, American Institute of Research, Los Angeles; Lindsey Kettinger,

SUPPLEMENTARY DATA

Medical University of South Carolina, Charleston; Ajit Khaira, Bala and Khaira Medical Center, Fresno; Amna Khan, Tulane University School of Medicine, New Orleans; Khaleda Khan, American Institute of Research, Los Angeles; Meena Khan, Greater Baltimore Medical Center, Baltimore; Muneer Khan, OUHSC: Diabetes and Endocrinology, Oklahoma City; Teck Khoo, Mercy Medical Center, Des Moines; Narine Khrlobyan, Facey Medical Group, Mission Hills; James Kilgore, Clinical Research Consultants Inc, Hoover; Grace Kim, Facey Medical Group, Mission Hills; Sarah Kimble, Medical University of South Carolina, Charleston; Maureen Kinsley, Jersey Shore University Medical Center, Neptune; Timothy Kitchen, Great Lakes Medical Research, Westfield; Michelle Klick, Crouse Medical Practice, Syracuse; Wendy Kniffen, Dallas Diabetes & Endocrine Center, Dallas; Rebecca Knight, Pioneer Medical Group, Cerritos; Dorothy Kodzwa, Medical University of South Carolina, Charleston; Troy Koenig, FPA Clinical Research, Kissimmee; Kateryna Komarovskiy, Robley Rex VAMC, Louisville; Yuthana Kong, Anaheim Clinical Trials, Anaheim; David Koontz, Internal Medicine Associates of Greenville, Ann Arbor; Sathya Krishnasamy, Robley Rex VAMC, Louisville; Sathya Krishnasamy, Louisville VA Medical Center, Louisville; Elizabeth Krueger, Radiant Research Inc, Chicago; Lisa Kuechenmeister, Veterans Affairs Medical Center, Omaha; Ann Kuehl, Apex Medical Research Inc, Chicago; Kevin Kuettel, Anaheim Clinical Trials, Anaheim; David Kugler, Endocrine Associates of Long Island, Smithtown; Tanya Kulow, University Hospitals Case Medical Center, Cleveland; Tanya Kulow, Louis Stokes Cleveland VA Medical Center, Cleveland; Igor Kupriyanchik, Grunberger Diabetes Institute, Rochester, MI; Tulsidas Kuruvanka, Northwest Houston Cardiology, Houston; Donald Kushner, Preferred Primary Care Physicians, Pittsburgh; Elise Kwon, Facey Medical Group, Mission Hills; Sooho Kwon, Medical University of South

SUPPLEMENTARY DATA

Carolina, Charleston; Michael Kyle, Radiant Research Inc, Chicago; Lauren LaBryer, OUHSC: Diabetes and Endocrinology, Oklahoma City; Joseph Labuda, Preferred Primary Care Physicians, Uniontown; Julie Lafave, Oakland Medical Research Center, Troy; Jacques Laguerre, Novant Health Southern Piedmont, Monroe; Alison Laliberte, Southern New Hampshire Diabetes and Endocrinology, Nashua; James Lane, OUHSC: Diabetes and Endocrinology, Oklahoma City; Christine Langel, Mercy Medical Center, Des Moines; Danielle Lann, Jersey Shore University Medical Center, Neptune; Joseph Largay, UNC Diabetes Care Center, Chapel Hill; Kashif Latif, AM Diabetes & Endocrinology Center, Bartlett; Tammi Latus, DCOL Center for Clinical Research, Longview; Jereta Lawrence, Arthritis & Diabetes Clinic, Monroe; Gregory Ledger, Mercy Medical Research Institute, Springfield; Francis Gil Lee, Greater Baltimore Medical Center, Baltimore; Elizabeth Lee, Anaheim Clinical Trials, Anaheim; Jonathan Leffert, North Texas Endocrine Center, Dallas; Matthew Leinung, Albany Medical Center, Albany; M. James Lenhard, Christiana Medical Aid Unit, Newark; Joseph Lentino, Radiant Research Inc, Chicago; Julissa Leon, Baylor Endocrine Center, Dallas; Molly Leonard, University of Colorado School of Medicine, Denver; Nancy Letassy, OUHSC: Diabetes and Endocrinology, Oklahoma City; Kathryn Leuck, Research Institute of Dallas, Dallas; Philip Levin, Greater Baltimore Medical Center, Baltimore; Dennis Levinson, Apex Medical Research Inc, Chicago; Melissa Lewis, Physicians East Endocrinology, Greenville; Timothy Light, Innovative Research of West Florida, Clearwater; Jonea Lim, OUHSC: Diabetes and Endocrinology, Oklahoma City; Ronald Lindamood, Internal Medicine Associates of Greenville, Ann Arbor; Ildiko Lingvay, UT Southwestern Medical Center, Dallas; Janie Lipps, Vanderbilt University Medical Center, Nashville; Anna Lisa, Chavana Northeast Clinical Research Center, Bethlehem; Yolanda Livingston, Mountain View

SUPPLEMENTARY DATA

Clinical Research, Greer; Lee Llamas, Anaheim Clinical Trials, Anaheim; Ryan Loesch, University of Colorado School of Medicine, Denver; Tanya Long, Alzohaili Medical Consultants, Dearborn; Robert Looby, Harrison Community Hospital, Cadiz; Carlos Lopez, New York Presbyterian University Hospital of Columbia, New York; Timothy Lorenz, Oakland Medical Research Center, Troy; Dragana Lovre, Tulane University School of Medicine, New Orleans; Peter Lu, Physicians Research Associates LLC, Lawrenceville; Kathryn Lucas, Diabetes & Endocrinology Consultants, Morehead; Gabriela Luevano, Narbonne Medical, Lomita; Mary Luidens, Albany Medical Endocrinology Albany; Blanca Luna, Speedway Family Practice Stanley F Stockhammer Jr, Deland; Louis Luttrell, Medical University of South Carolina, Charleston; Timothy Lyons, OUHSC: Diabetes and Endocrinology, Oklahoma City; Maria MacAdams, Covenant Medical Center, Lubbock; Michael MacAdams, Covenant Medical Center, Lubbock; David Mack, Medex Healthcare Research, New York; Mellie Mack, Awasty Research Network, Marion; Marcia Madden, International Diabetes Center, Minneapolis; Robert Madder, Heritage Valley Medical Group, Beaver; Shiyanka Madireddy, Dynamed Clinical Research, Houston; Laura Mae, Pearlman Radiant Research Inc, Chicago; Aparna Mahakala, Physicians Research Associates LLC, Lawrenceville; Hiralal Maheshwari, Midwest Endocrinology, Crystal Lake; Hussain Malbari, Martin Diagnostic Clinic, Tomball; Norman Maldonado, American Institute of Research, Los Angeles; Michelle Mallitz, Meridien Research, St. Petersburg; Mustafa Mandviwala, Northwest Heart Center, Tomball; Kara Mann, Dallas Diabetes & Endocrine Center, Dallas; Milena Mardahay, Medex Healthcare Research, New York; Jaime Marino, Apex Medical Research Inc, Chicago; Annis Marney, University of Vermont Medical Center, Burlington; Lisa Marshall, Southern New Hampshire Diabetes and Endocrinology, Nashua; Adriana

SUPPLEMENTARY DATA

Martin, Medex HealthCare Research, St. Louis; Earl Martin, Martin Diagnostic Clinic, Tomball; Geraldine Martinez, Catalina Research Institute, Chino; Gilbert Martinez, Catalina Research Institute, Chino; Salomon Martinez-Miss, Catalina Research Institute, Chino; Phyllis Marx, Radiant Research Inc, Chicago; Leslie Massara, Thomas Jefferson University Hospitals, Philadelphia; Momina Mastoor, Union Memorial Hospital, Baltimore; Glenn Matfin, International Diabetes Center, Minneapolis; Amita Maturu, University of Colorado School of Medicine, Denver; Peter Maurides, Internal Medicine Associates of Greenville, Ann Arbor; Michael May, Vanderbilt University Medical Center, Nashville; Ronald Mayfield, Mountain View Clinical Research, Greer; Bobby Maynard, Great Falls Clinic, Great Falls; Angela Mazza, Florida Diabetes/Endocrine Center, Orlando; Kathy McCann, International Diabetes Center, Minneapolis; James McCoy, University Specialty Clinics, Columbia; Todd McCoy, FPA Clinical Research, Kissimmee; Mary Kate McCullen, Thomas Jefferson University Hospitals, Philadelphia; Clayton McDaniel, Monterey Bay Family Physicians, Watsonville; Anne-Marie McDaniel, Monterey Bay Family Physicians, Watsonville; Michael McDermott, University of Colorado Hospital - Anschutz Inpatient Pavilion, Aurora; Andrew McDonald, Internal Medicine Associates of Greenville, Ann Arbor; Camille McDonald, Novant Health Southern Piedmont, Monroe; Roberta McDuffie, Tulane University School of Medicine, New Orleans; Brandi McMasters, Naidu Clinic, Odessa; Corey McMurray, Awasty Research Network, Marion; Terri Medlin, Diabetes & Endocrinology Consultants, Morehead; Monya Meinel, Radiant Research Inc, Chicago; Iris Mendez, Covenant Medical Center, Lubbock; Judson Menefee, Eastern Shore Medical Specialists, Fairhope; Melissa Meredith, University of Wisconsin School of Medicine and Public Health, Madison; Marcus Merriweather, FPA Clinical Research, Kissimmee; James Mersey,

SUPPLEMENTARY DATA

Greater Baltimore Medical Center, Baltimore; Christine Messino, Clinical Study Center of Asheville, Asheville; Stephen Meyer, Tampa Clinical Research, Tampa; Linda Meyers, Medical University of South Carolina, Charleston; Donna Michael, Heritage Valley Medical Group, Beaver; Catherine Midyett, Arthritis & Diabetes Clinic, Monroe; Audrey Miklius, Research Institute of Dallas, Dallas; Emily Milford, Radiant Research Inc, Chicago; Bonnie Miller, Internal Medicine Associates of Greenville, Ann Arbor; Harold Miller, Crescent City Clinical Research, Metairie; Melissa Milligan, Awasty Research Network, Marion; Anita Minor, Medex HealthCare Research, St. Louis; Bresta Miranda-Palma, University of Miami Diabetes Treatment Center, Miami; Nicole Mirarchi, Thomas Jefferson University Hospitals, Philadelphia; Saritha Mittadodla, OUHSC: Diabetes and Endocrinology, Oklahoma City; Janette Mittle, Tampa Clinical Research, Tampa; Ann Moffat, Monterey Bay Family Physicians, Watsonville; Stephen Mohaupt, Catalina Research Institute, Chino; Kamran Mohiuddin, Northwest Heart Center, Tomball; Sri Mokshagundam, Robley Rex VAMC, Louisville; Susan Monaco, Anaheim Clinical Trials, Anaheim; Ronald Monsaert, Christiana Medical Aid Unit, Newark; Cynthia Montano-Pereira, Catalina Research Institute, Chino; Austin Montgomery, Medex HealthCare Research, St. Louis; Kelly Moody, Clinical Study Center of Asheville, Asheville; Mia Moon, Catalina Research Institute, Chino; Deborah Moore, Christiana Medical Aid Unit, Newark; Laura Moore, University Hospitals Case Medical Center, Cleveland; Laura Moore, Louis Stokes Cleveland VA Medical Center, Cleveland; Emily Morawski, Holston Medical Group, Kingsport; Cynthia Moreau, Tulane University School of Medicine, New Orleans; David Morin, Holston Medical Group, Kingsport; Carmen Moscoa, AMCR Institute Inc, Escondido; Chelsey Motzkin, Medex Healthcare Research, New York; Richard Mueller, Medex Healthcare Research, New York; Christina Munoz,

SUPPLEMENTARY DATA

Rush University Medical Center, Chicago; Miguel Munoz, Southeastern Endocrine & Diabetes, Roswell; Anjana Myneni, Grunberger Diabetes Institute, Bloomfield Hills; Bahar Naderi, Facey Medical Group, Mission Hills; Prathima Nagireddy, Grunberger Diabetes Institute, Bloomfield Hills; Jayaram Naidu, Naidu Clinic, Odessa; Raja Naidu, Naidu Clinic, Odessa; Savita Naik, Medex Healthcare Research, New York; Roberta Naimark, Clinical Study Center of Asheville, Asheville; Maria Nardicchi, Grunberger Diabetes Institute, Bloomfield Hills; Ikeadi Ndukwu, 400 North Medical Center, Michigan City; Christian Neller, Tampa Clinical Research, Tampa; Lisa Netten-Foster, Iowa Diabetes & Endocrinology Center, Des Moines; Joshua Neumiller, Washington State University, Spokane; Tirado New, York-Presbyterian University Hospital of Columbia, New York; Susan Newman, Great Lakes Medical Research, Westfield; Tabitha Newton, Instituto De Endocrinologia Diabetes, Levittown; BaoAn Nguyen, Veterans Affairs Medical Center, Omaha; Brent Nicol, The Diabetes Center, Murrells Inlet; Philip Nicol, The Diabetes Center, Murrells Inlet; Loretta Ninivaggi, Jersey Shore University Medical Center, Neptune; Kevin Niswender, Vanderbilt University Medical Center, Nashville; Lana Norman, Diablo Clinical Research, Walnut Creek; Gary Noworatzky, Dr. Israel A. Hartman MD Clinical Practice Dallas; Ebenzer Nyenwe, University of Tennessee Health Science Center, Memphis; Heather O'Brien, Physicians East, Greenville, NC; Thomas O'Connell, UNC Diabetes Care Center, Chapel Hill; Wendy Oden, DCOL Center for Clinical Research Longview; Adeniyi Odugbesan, Physicians Research Associates LLC, Lawrenceville; Michael Oliver, Heritage Valley Medical Group, Beaver; Tonya Oliver, 400 North Medical Center, Michigan City; Carly Olmeda, Tulane University School of Medicine, New Orleans; Christine O'Neil, Southern New Hampshire Diabetes and Endocrinology, Nashua; Ruth Oremus, Lexington VA Medical Center,

SUPPLEMENTARY DATA

Lexington; Tania Ortega, American Institute of Research, Los Angeles; Sonia Ortiz-Santos, Instituto De Endocrinologia Diabetes, Levittown; Tracey Osborn, Innovative Research of West Florida, Clearwater; Sailatha Padmanabhan, University of Oklahoma College of Medicine, Oklahoma City; Olivia Papacostea, UT Southwestern Medical Center, Dallas; Inna Park, Medex HealthCare Research, St. Louis; Anna Parker, Anaheim Clinical Trials, Anaheim; Kristine Parker, Medical University of South Carolina, Charleston; R. Parker, University Specialty Clinics, Columbia; Christine Patel, University Hospitals Case Medical Center, Cleveland; Christine Patel, Louis Stokes Cleveland VA Medical Center, Cleveland; Minesh Patel, 400 North Medical Center, Michigan City; Rakesh Patel, Endocrine and Psychiatry Center, Houston; Roshni Patel, Novant Health Southern Piedmont, Monroe; Marisol Patino, Wilshire Oncology Medical Group, Corona; Sara Patterson, Benefis Medical Group, Great Falls; Katrina Paulson, Benefis Medical Group, Great Falls; Alejandro Paz, AMCR Institute Inc, Escondido; Riga Pemba, Facey Medical Group, Mission Hills; Constance Pepe, Thomas Jefferson University Hospitals, Philadelphia; Jose Perez, FPA Clinical Research, Kissimmee; Tamra Perez, Robley Rex VAMC, Louisville; Debbie Perry, KD Medical Group Inc, Columbia; Bunny Phillips, Mountain View Clinical Research, Greer; Julie Phillips, Medical Group, Kingsport; Alicia Pickett, University Hospitals Case Medical Center, Cleveland; Alicia Pickett, Louis Stokes Cleveland VA Medical Center, Cleveland; Mark Pinson, Medex Healthcare Research, St. Louis; Robin Pitzer, Northeast Clinical Research Center, Bethlehem; Madhuri Poduri, UT Southwestern Medical Center, Dallas; Jennifer Poehls, University of Wisconsin School of Medicine and Public Health, Madison; Tony Poteat, Internal Medicine Associates of Greenville, Ann Arbor; Lisa Powell, Alzohaili Medical Consultants, Dearborn; Siripurapu Prasad, OhioHealth Marion Area

SUPPLEMENTARY DATA

Physicians, Marion; Richard Pratley, University of Vermont Medical Center, South Burlington; Richard Pratley, Florida Diabetes/Endocrine Center, Orlando; Jonathan Prevost, Medical Associates of New York, New York; Evelyn Price, Panacea Clinical Research, San Antonio; Diane Priest, OUHSC: Diabetes and Endocrinology, Oklahoma City; Luz Prieto, University of Miami, Miami; Tarlock Purewal, Awasty Research Network, Marion; Raman Purighalla, Preferred Primary Care Physicians, Pittsburgh; Uma Purighalla, Preferred Primary Care Physicians, Pittsburgh; Mark Quadrel, Internal Medicine of Morris County, Dover; Ambreen Qureshi, UK HealthCare Kentucky Clinic, Lexington; Rani Radhamma, Mercy Medical Research Institute, Springfield; Eman Rafla, Internal Medicine of Morris County, Dover; Hussein Rajab, Medical University of South Carolina Charleston; Ramesh Ramalingam, University of Nebraska Medical Center, Omaha, NE; Alexandra Ramirez, North Texas Endocrine Center, Dallas; Julie Ramirez, American Institute of Research, Los Angeles; Karina Ramirez, Anaheim Clinical Trials, Anaheim; Maria Ramirez, Medical University of South Carolina, Charleston; Martin Randall, Grunberger Diabetes Institute, Rochester, MI; Uma Rangaraj, Arthritis & Diabetes Clinic, Monroe; Veitla Rao, OUHSC: Diabetes and Endocrinology, Oklahoma City; Pat Rasmussen, Midwest Endocrinology, Crystal Lake; Neda Rasouli, University of Colorado Denver – Veterans Hospital, Aurora; Neda Rasouli, Denver VA Medical Center, Denver; Anita Ray, North Texas Endocrine Center, Dallas; Shannon Ray, Whiteville Medical Associates, Whiteville; John Reed, Southeastern Endocrine & Diabetes, Roswell; Lucy Rems, Anaheim Clinical Trials, Anaheim; Karen Renaud, Tampa Clinical Research, Tampa; Marie Reno, Medex HealthCare Research, St. Louis; Maria Resnick, Great Lakes Medical Research, Westfield; Jane Reusch, Denver VA Medical Center, Denver; L. Reynolds, University of Kentucky Medical

SUPPLEMENTARY DATA

Center, Lexington; Kimberly Rhoton, Medical University of South Carolina, Charleston; Jackson Rhudy, Optimum Clinical Research, Salt Lake City; Cassie Ricci, OUHSC: Diabetes and Endocrinology, Oklahoma City; Lucian Rice, Clinical Study Center of Asheville, Asheville; Antoinette Richardson, Vanderbilt University Medical Center, Nashville; Lynn Richardson, Louis Stokes Cleveland VA Medical Center, Cleveland; Lynn Richardson, Louis Stokes Cleveland VA Medical Center, Cleveland; Heather Rickard, Mountain View Clinical Research, Greer; Michael Rickels, Diabetes Endocrine, Spruce; Dennis Riff, Advanced Clinical Research Institute, Anaheim; Nancy Rightenour, Blair Medical Associates Inc, Altoona; Joseph Risser, Linda Vista Health Care Center, San Diego; Abid Rizvi, Mercury Pharma Services, Houston; Ali Rizvi, University Specialty Clinics, Columbia; Jennifer Robertson, Mercy Medical Research Institute, Springfield; Annette Robinson, University of Louisville Physicians, Louisville; Randall Robinson, Mercy Medical Research Institute, Springfield; Marion Rockwell, Blair Medical Associates Inc, Altoona; JuanPablo Rodriguez, The Diabetes Research Center, Fletcher Allen Health Care, South Burlington, VT; Mayra Rodriguez, FPA Clinical Research, Kissimmee; Martha Rojas, Anaheim Clinical Trials, Anaheim; Wendy Rojas, Pioneer Medical Group, Cerritos; Leslie Rooker-Morris, Dallas Diabetes & Endocrine Center, Dallas; Connie Root, Vanderbilt University Medical Center, Nashville; Muriel Rose, Monterey Bay Family Physicians, Watsonville; Richard Rosenberg, New York-Presbyterian University Hospital of Columbia, New York; Julio Rosenstock, Dallas Diabetes & Endocrine Center, Dallas; Marilyn Roth, University of Vermont Medical Center, South Burlington; Rachel Ruby, Monterey Bay Family Physicians, Watsonville; Richard Sachson, Endocrine Associates of Dallas, Dallas; Paul Sack, Union Memorial Hospital, Baltimore; R. Kent Sadler, Northeast Clinical Research

SUPPLEMENTARY DATA

Center, Bethlehem; Subhash Sahai, Iowa Diabetes & Endocrinology Center, Des Moines; Jennifer Salazar, OUHSC: Diabetes and Endocrinology, Oklahoma City; Manjula Salgam, Albany Medical Center, Albany; Aditya Samal, Northwest Houston Cardiology, Houston; Anil Samson, Apex Medical Research Inc, Chicago; Rebecca Sanagorski, Denver VA Medical Center, Denver; Angela Sanchez, Dr. Israel A. Hartman MD Clinical Practice, Dallas; Jay Sandberg, Oakland Medical Research Center, Troy; Marvin Sanderson, Physicians Group, Little Rock; Jaime Sandoval, Corpus Christi Memorial Hospital, Corpus Christi; Esther Santiago, FPA Clinical Research, Kissimmee; Tabby Sapp, Southeastern Endocrine & Diabetes, Roswell; Jacqueline Saunders, Mountain View Clinical Research, Greer; Joseph Schill, Research Institute of Dallas, Dallas; Charles Schott, AMCR Institute Inc, Escondido; Robert Schreiman, Orange County Senior Care Clinic, Tustin; Deborah Schu, Crouse Medical Practice, Syracuse; Kristy Schuh, Baylor Endocrine Center, Dallas; Mark Schutta, Diabetes Endocrine, Spruce; Jane Schwartz, Christ Hospital Lindner Research Center, Cincinnati; Laurie Schweppe, Meridien Research, St. Petersburg; Hal Scofield, University of Oklahoma College of Medicine, Oklahoma City; Anita Scribner, DCOL Center for Clinical Research, Longview; Jennifer Seal, 400 North Medical Center, Michigan City; John Sealock, Medex Healthcare Research, New York; Bruce Seaton, Research Institute of the Carolinas, Mooresville; Theresa Sedlak-Hanslik, Paramount Medical Research & Consulting, Cleveland; Kathleen Seekins, Panacea Clinical Research, San Antonio; Marianne Segal, Innovative Research of West Florida, Clearwater; Stacey Seggelke, University of Colorado Hospital - Anschutz Inpatient Pavilion, Aurora; Stephanie Semenza, Great Falls Clinic, Great Falls; Patricia Sentman, Meridien Research, Tampa; Marian Serra, Optimum Clinical Research, Salt Lake City; Prakash Seshadri, Christiana Medical

SUPPLEMENTARY DATA

Aid Unit, Newark; Eduardo Sevilla, Diablo Clinical Research, Walnut Creek; Shamik Shah, Grunberger Diabetes Institute, Bloomfield Hills; Kristen Shaheen, Physicians East Endocrinology, Greenville; Michael Shanik, Endocrine Associates of Long Island, Smithtown; Jessica Shaw, COR Clinical Research, Oklahoma City; Michelle Sheets, 400 North Medical Center, Michigan City; Carol Shellabarger, Southeastern Endocrine & Diabetes, Roswell; Jay Sher, Jersey Shore University Medical Center, Neptune; Jeanette Shippey, Southern New Hampshire Diabetes and Endocrinology, Nashua; Vijay Shivaswamy, Veterans Affairs Medical Center, Omaha; Mansur Shomali, Union Memorial Hospital, Baltimore; David Shore, Physicians Research Associates LLC, Lawrenceville; Pranavkumar Shroff, Apex Medical Research Inc, Chicago; Taha Siddiqui, Apex Medical Research Inc, Chicago; Angela Siegwald, University of Louisville Physicians, Louisville; Robert Silver, Southern New Hampshire Diabetes and Endocrinology, Nashua; Debra Simmons, Utah Diabetes Endocrinology Center, Salt Lake City; Robyn Simons, Internal Medicine Center, Mobile; Abdulhadi Sinan, Alzohaili Medical Consultants, Dearborn; Manmeet Singh, Tulane University School of Medicine, New Orleans; Sirinart Sirinvaravong, University Specialty Clinics, Columbia; Jennifer Skero, Covenant Medical Center, Lubbock; Judith Slover-Zipf, Jersey Shore University Medical Center, Neptune; Sarah Small, Novant Health Southern Piedmont, Monroe; Bridgette Smith, Kernodle Clinic Inc, Burlington; Kristy Smith, Mountain View Clinical Research, Greer; Megan Smith, Novant Health Southern Piedmont, Monroe; Jennifer Sohl, Crouse Medical Practice, Syracuse; Sarah-Helen Solarz, Louis Stokes Cleveland VA Medical Center, Cleveland; Sarah-Helen Solarz, University Hospitals Case Medical Center, Cleveland; Daniel Soler, Catalina Research Institute Chino; Ajay Sood, University Hospitals Case Medical Center, Cleveland; Nicoletta Sora, Medical University of

SUPPLEMENTARY DATA

South Carolina, Charleston; Annie Souchet, Apex Medical Research Inc, Chicago; Jeremy Soule, Medical University of South Carolina, Charleston; Jeffrey Sparks, Kernodle Clinic Inc, Burlington; Linda Spector, Southern New Hampshire Diabetes and Endocrinology, Nashua; Richard Speicher, Central Florida Medical Associates, Deland; Lori Spillers, Medical University of South Carolina, Charleston; Traci Spivey, Northeast Clinical Research Center, Bethlehem; Nina Springer, Preferred Primary Care Physicians, Uniontown; Heidi Sprouse, Blair Medical Associates Inc, Altoona; Jennifer St. John, OUHSC: Diabetes and Endocrinology, Oklahoma City; Amy Stacey, DCOL Center for Clinical Research, Longview; Helen Stacey, Diablo Clinical Research, Walnut Creek; Mollie Stafford, Clinical Study Center of Asheville, Asheville; Eva Stagner, DCOL Center for Clinical Research, Longview; Karen Staples, Carolina Health Specialists, Myrtle Beach; Emily Steadman, Radiant Research Inc, Chicago; Robert Steed, Southeastern Endocrine & Diabetes, Roswell; Gerald Steeves, Blair Medical Associates Inc, Altoona; Helmut Steinberg, University of Tennessee Health Science Center, Memphis; Carol Stell, Tulane University School of Medicine, New Orleans; Edward Stirman, Holston Medical Group, Kingsport; Karl Straub, John L. McClellan Memorial Veterans Hospital, Little Rock; Elinor Strock, International Diabetes Center, Minneapolis; Marian Sue, Kirkman UNC Diabetes Care Center, Chapel Hill; Orlando Suris, Northeast Clinical Research Center, Bethlehem; Terri Sutton, Diabetes & Endocrinology Consultants, Morehead; Isam Tabbah, OhioHealth Marion Area Physicians, Marion; Mitali Talsania, OUHSC: Diabetes and Endocrinology, Oklahoma City; Rocky Tang, New York Presbyterian University Hospital of Columbia, New York; Jessica Tapia, Southeastern Endocrine & Diabetes, Roswell; Kelly Taylor, Medical University of South Carolina, Charleston; Rebecca Taylor-Hancher, Preferred Primary Care Physicians, Uniontown; Rachel

SUPPLEMENTARY DATA

Teator, Baylor Endocrine Center, Dallas; Memello Tekateka, Radiant Research Inc, Chicago; Brian Temple, Medex Healthcare Research, New York; Karen Temple, Kernodle Clinic Inc, Burlington; Marsha Teodori, Rush University Medical Center, Chicago; Patricia Tharp, Tampa Clinical Research, Tampa; Tina Thethi, Tulane University School of Medicine, New Orleans; Pierre Theuma, Mercy Medical Center, Des Moines; Sarah Thomas, Radiant Research Inc, Chicago; Anna Thottan, University of Vermont Medical Center, South Burlington; James Thrasher, Physicians Group, Little Rock; Lesa Thrasher, Physicians Group, Little Rock; Monika Tiemeyer, Jersey Shore University Medical Center, Neptune; Margaret Tiktin, Louis Stokes Cleveland VA Medical Center, Cleveland; Margaret Tiktin, University Hospitals Case Medical Center, Cleveland; Irene Tinney, Naidu Clinic, Odessa; Timothy Tobin, Diagnostic Clinic of Longview, Longview; Shivani Toma, North Texas Endocrine Center, Dallas; Maritza Tovar, Suncoast Medical Center, St. Petersburg; Judith Townsend, Comprehensive Weight Control Center, New York; Constance Trantow, University of Wisconsin School of Medicine and Public Health, Madison; Henry Traylor, Whiteville Medical Associates, Whiteville; Miguel Trevino, Innovative Research of West Florida, Clearwater; Michael Troy, Northeast Clinical Research Center, Bethlehem; Darrell Trumper, Accurate Clinical Research, Houston; Jennifer Tryggestad, University of Colorado Hospital - Anschutz Inpatient Pavilion, Aurora; Carol Tucker, Grunberger Diabetes Institute, Bloomfield Hills; Juliana Turner, Clinical Study Center of Asheville, Asheville; Robert Turney, Kernodle Clinic Inc, Burlington; Cindy Tuten, Clinical Study Center of Asheville, Asheville; Joanna Tyzack, Greater Baltimore Medical Center, Baltimore; Lauren Ullo, Suncoast Medical Center, St. Petersburg; Chantal Underkofler, Denver VA Medical Center, Denver; Jeffrey Unger, Catalina Research Institute, Chino; Ramon Urdanetta, Florida Diabetes/Endocrine

SUPPLEMENTARY DATA

Center, Orlando; Vanessa Valdivia, Anaheim Clinical Trials, Anaheim; Sharon Valenti, Crouse Medical Practice, Syracuse; Anna Vanderheiden, UT Southwestern Medical Center, Dallas; Megan Vanderlinde-Wood, OUHSC: Diabetes and Endocrinology, Oklahoma City; Chandrasekhar Varma, AMCR Institute Inc, Escondido; Eloisa Vasquez, Anaheim Clinical Trials, Anaheim; Maripaz Vazquez, Rush University Medical Center, Chicago; David Vickery, Clinical Study Center of Asheville, Asheville; Betty Villafuerte, University of Louisville Physicians, Louisville; Claudia Villegas, Catalina Research Institute, Moreno; Jessica Vivar, Orange County Senior Care Clinic, Tustin; Krishnamoorthy Vivekananthan, Northwest Houston Cardiology, Houston; Glen Vo, Maxine Hamilton PA, Fort Lauderdale; Katarina Vukojcic, UNC Diabetes Care Center, Chapel Hill; Amy Wachter, Christiana Medical Aid Unit, Newark; Dain Wahl, Christ Hospital Lindner Research Center, Cincinnati; Jonathan Waitmann, Comprehensive Weight Control Center, New York; Debra Walker, Robley Rex VAMC, Louisville; John Walsh, AMCR Institute Inc, Escondido; Kimberly Walsh, Dartmouth-Hitchcock Medical Center, Lebanon; Anita Walton, Linda Vista Health Care Center, San Diego; Aileen Wang, Tulane University School of Medicine, New Orleans; Karla Wardell, Physicians Research Associates LLC, Lawrenceville; Mark Warren, Physicians East Endocrinology, Greenville; Michael Warren, Tampa Clinical Research, Tampa; Susan Watkins, North Texas Endocrine Center, Dallas; Jean Watkinson, Preferred Primary Care Physicians, Pittsburgh; Myra Watts, Medical Group, Kingsport; Veena Watwe, Endocrine and Psychiatry Center, Houston; Nancy Weaver, Blair Medical Associates Inc, Altoona; Robert Weber, Monterey Bay Family Physicians, Watsonville; Catherine Wedick, Comprehensive Weight Control Center, New York; Debra Weeks, Washington State University, Spokane; Larissa Weeks, Washington State University, Spokane;

SUPPLEMENTARY DATA

Kathleen Weindorff, DCOL Center for Clinical Research, Longview; Richard Weinstein, Diablo Clinical Research, Walnut Creek; Sarah Weiss, Meridien Research, Sarasota; Kelly Wenger, Naidu Clinic, Odessa; Marlene Wentworth, Radiant Research Inc, Chicago; Amanda Werner, Louis Stokes Cleveland VA Medical Center, Cleveland; Mary West, Naidu Clinic, Odessa; Sheila Whelan, Alzohaili Medical Consultants, Dearborn; Bee White, Catalina Research Institute, Chino; Judith White, Holston Medical Group, Kingsport; Melanie Whitmire, University Specialty Clinics, Columbia; Rochelle Whittington, Atlanta Diabetes Associates, Atlanta; Jessica Wical, Suncoast Medical Center, St. Petersburg; Christine Wigley, University of Tennessee Health Science Center, Memphis; Francesca Wilkins, Tulane University School of Medicine, New Orleans; Katharine Will, Blair Medical Associates Inc, Altoona; Aimee Williams, Diabetes & Endocrinology Consultants, Morehead; Lou Ellen Wilson, Facey Medical Group, Mission Hills; Meredith Wince, Medical University of South Carolina, Charleston; Sara Wine, Professional Clinical Research, Interlochen; Peter Winkle, Anaheim Clinical Trials, Anaheim; Connie Winner, Benefis Medical Group, Great Falls; Jonathan Wise, Crescent City Clinical Research, Metairie; Melanie Witte, University of Wisconsin School of Medicine and Public Health, Madison; Jackie Wittenmyer, Paramount Medical Research & Consulting, Cleveland; Cynthia Wood, Christ Hospital Lindner Research Center, Cincinnati; Ruth Wood, Mountain View Clinical Research, Greer; Chivers Woodruff, Radiant Research Inc, Birmingham; Bryan Worthington, Internal Medicine Associates of Greenville, Ann Arbor; Donny Wynn, OUHSC: Diabetes and Endocrinology, Oklahoma City; Carol Wysham, Washington State University, Spokane; Patricia Xavier, Martin Diagnostic Clinic, Tomball; Susana Yela, Catalina Research Institute, Chino; Lydia Yenoby, Tulane University School of Medicine, New

SUPPLEMENTARY DATA

Orleans; Laura Young, UNC Diabetes Care Center, Chapel Hill; Nadia Younus, Endocrine and Psychiatry Center, Houston; Veronica Yourell, Southern New Hampshire Diabetes and Endocrinology, Nashua; Musaab Zaid, Alzohaili Medical Consultants, Dearborn; Imran Zubair, Optimum Clinical Research, Salt Lake City.

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Definition of index events, first events and recurrent events

An 'index' event was the event selected among multiple events if these were assessed and confirmed to be one and the same event. If a patient had more than one confirmed event of the same event type, the event adjudication committee (EAC) Chair evaluated whether these constituted separate events or were related to the same event. If ≥ 2 confirmed events were determined to be one and the same event during this review, the EAC Chair grouped the relevant events and selected one as the 'index' event based on clinical importance, i.e., the event that led to the chain of events. Events were considered to be duplicates if the same index event was reported more than once in the same patient.

The term 'index event' refers to both events that were selected as 'index' within a group of combined events as well as EAC-confirmed events that were not part of a group. EAC-confirmed index events were categorized as 'first events' and 'recurrent events'. 'Recurrent events' were index events occurring in a patient who had already had a previous index event. Only 'first events' were included in the time-to-event analyses.

Sensitivity analyses of events captured by the sponsor's Medical Dictionary for Regulatory Activities (MedDRA) searches for malignant tumors

To support the analyses based on adjudicated data, neoplasm events were also identified through the systematic evaluation of investigator-reported events. MedDRA term searches for overall malignant tumors, malignant pancreatic, thyroid, colorectal, breast, prostate, or skin (non-melanoma) neoplasms, and malignant melanoma were performed *post hoc* among investigator-reported adverse events, to identify potential malignant neoplasm events. Case reviews of all investigator-reported adverse events of malignant neoplasms not confirmed by the EAC were performed by the sponsor.

These searches identified 59 investigator-reported adverse events that were not confirmed as malignant neoplasms by the EAC ($n = 26$ vs. $n = 33$ in the liraglutide and placebo groups, respectively). Lack of sufficient documentation, including histopathological data, was the main possible reason why 12/26 events in the liraglutide group and 23/33 events in the placebo group, respectively, were not confirmed. For a total of 8/26 events in the liraglutide group and 3/33 events in the placebo group, there was documentation to support that these events were not malignant neoplasms and therefore not confirmed by the EAC.

The 59 events identified by these searches were distributed across several different tissues, without notable differences between the two treatment arms (Supplementary Table 1). However, this process identified an additional four cases of malignant pancreatic neoplasm that were not confirmed by the EAC neoplasm subcommittee, all of which occurred in the placebo group (Supplementary Table 2 [PANCP6–9]). All four of the patients who experienced these events had imaging documenting suspicious lesions in the pancreas. Although not consistently reported, there was some evidence of elevated tumor markers among these patients. All four of these patients died. The plausible causes of death provided

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by the adjudicators included malignancy and pancreatic cancer. The EAC was not required to specify their reason for not confirming these events, but possible reasons include insufficient documentation or the events not being malignant pancreatic neoplasms. No microscopic examination was performed for the four events of pancreatic malignancy in the placebo arm that were not confirmed by the EAC, which may have contributed to the non-confirmation of these events. One of these cases (PANCP6) seems to be most consistent with pancreatic endocrine neoplasia. When these events were included as part of an additional sensitivity analysis, the imbalance between treatment groups in the number of cases was smaller than in the analyses based on EAC-confirmed data (additional sensitivity analysis: 0.28% [$n = 13$] with liraglutide vs. 0.19% [$n = 9$] with placebo, respectively; HR [95% CI]: 1.44 [0.62;3.37]; analysis based on EAC-confirmed data: 0.28% [$n = 13$] with liraglutide vs. 0.11% [$n = 5$] with placebo, respectively; HR [95% CI]: 2.59 [0.92;7.27]).

A further investigator-reported case of malignant pancreatic neoplasm in the placebo group was confirmed as a malignant lymphoma (Supplementary Table 2 [PANCP10]).

Neoplasms of interest

Pancreatic neoplasms

The evaluation of pancreatic cancer data has been described previously (11). Thirteen cases of pancreatic neoplasms were reported by investigators for patients in the liraglutide treatment group, and were sent for adjudication by the EAC. Eleven of these events were reported by investigators as malignant pancreatic neoplasms, and two as pancreatic neoplasms. All 13 of these events reported by investigators were confirmed by the EAC. Ten cases of pancreatic neoplasms were reported by investigators for patients in the placebo group, and were sent for adjudication. All 10 of these events were reported by investigators as malignant pancreatic neoplasms. Five of these events were confirmed by the EAC; 4 events were not confirmed; and 1 event was confirmed as B-cell lymphoma. Thus, malignant pancreatic neoplasm was confirmed by adjudication for more patients in the liraglutide group ($n = 13$ [0.28%]) than the placebo group ($n = 5$ [0.11%]); estimated hazard ratio [HR] [95% CI]: 2.59 [0.92;7.27]) (Fig. 1A).

Pre-malignant pancreatic neoplasm was confirmed for one patient in the liraglutide group (vs. none in the placebo group). Details for individual cases of malignant or pre-malignant pancreatic neoplasm are shown in Supplementary Table 2.

One patient in the liraglutide group and two patients in the placebo group had a benign pancreatic neoplasm. In the liraglutide group, the benign neoplasm was reported as a 'main duct intradural papillary mucinous neoplasm'. Both events in the placebo group were reported as intraductal papillary mucinous neoplasms, one 'with focal moderate dysplasia'.

From randomization until approximately month 24, confirmed malignant pancreatic neoplasms occurred at constant rates in both treatment groups (Supplementary Fig. 2A). After

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month 24, no additional confirmed malignant pancreatic neoplasms occurred in the placebo group, whereas the event rate was stable for the liraglutide group.

Results from the sensitivity analysis excluding malignant pancreatic neoplasms occurring less than 1 year after randomization to treatment were consistent with the main analysis (Fig. 1A and Fig. 1B).

On average, participants who experienced a malignant pancreatic neoplasm with liraglutide or placebo tended to be older, living in Europe, and have a lower BMI at baseline compared with all liraglutide-treated patients and all placebo-treated patients, respectively (Supplementary Table 3). Several patients who developed malignant pancreatic neoplasm experienced weight loss before their diagnosis: some experienced increases in HbA_{1c} before diagnosis, but there was no clear pattern.

Among participants who had a confirmed malignant pancreatic neoplasm, 11 (84.6%) receiving liraglutide and all five receiving placebo (100%) died. All were categorized as non-cardiovascular (CV) deaths and attributed to malignancy (Table 2). The four participants with investigator-reported events of malignant pancreatic neoplasms not confirmed by the EAC died; three participants within 1–6 months of onset, and one within 14 months of onset. All four deaths were confirmed as non-CV by the EAC CV subcommittee who adjudicated deaths. The plausible causes of death provided by the adjudicators included malignancy and pancreatic cancer.

Thyroid neoplasms

Five patients in the liraglutide group (0.11%) and three patients in the placebo group (0.06%) had confirmed malignant thyroid neoplasms (HR [95% CI]: 1.66 [0.40;6.95]) (Fig. 1A and Supplementary Fig. 2B).

One confirmed medullary thyroid carcinoma occurred during the trial in one patient in the placebo group (0.02%). This was a stage 2, locally advanced carcinoma. The same patient also had two separate confirmed events of medullary micro carcinoma (carcinoma *in situ*; one malignant event and one pre-malignant event) and one confirmed thyroid neoplasm classified as ‘other’ (malignant). There were no further patients who had a confirmed pre-malignant thyroid neoplasm in the placebo group. No confirmed medullary thyroid carcinomas or pre-malignant thyroid neoplasms occurred in liraglutide-treated patients.

Benign thyroid neoplasm was confirmed for two patients treated with liraglutide: goiter was also reported for both of these patients. There were no confirmed benign thyroid neoplasms in the placebo group.

Colorectal neoplasms

The overall frequency of confirmed colorectal neoplasms was 3.6% (1.11 events per

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100 patient-years of observation [PYO]) in the liraglutide group and 3.1% (0.99 events per 100 PYO) in the placebo group.

Confirmed malignant colorectal neoplasms occurred in 0.60% of patients in both treatment groups ($n = 28$ in each group; HR [95% CI] for liraglutide vs. placebo: 0.99 [0.59;1.68]) (Fig. 1A and Supplementary Fig. 2C). Confirmed pre-malignant colorectal neoplasms occurred in three patients in the liraglutide group and one patient in the placebo group.

Colorectal neoplasms constituted the vast majority of the confirmed benign neoplasms in both treatment groups; the frequency was 3.0% ($n = 140$ patients) with liraglutide and 2.6% ($n = 123$ patients) with placebo (HR [95% CI]: 1.13 [0.89;1.45]) (Fig. 1A).

There were two confirmed, unclassified colorectal neoplasms in the liraglutide group (versus none in the placebo group).

Breast neoplasms

There were no confirmed malignant breast neoplasms among male participants. Overall, the proportion of female patients who experienced confirmed malignant breast neoplasms was comparable between the treatment groups (1.27% [$n = 21$] with liraglutide vs. 1.19% [$n = 20$] with placebo, HR [95% CI]: 1.06 [0.57;1.96]) (Fig. 1A and Supplementary Fig. 2D). However, following an initial decrease in the cumulative incidence probability of malignant breast neoplasms with liraglutide versus placebo (occurring ~6–18 months after randomization), there appeared to be a transient increase with liraglutide versus placebo between 18 and 30 months (Supplementary Fig. 2D), and in the sensitivity analysis excluding malignant breast neoplasms occurring less than 1 year after randomization, the HR (95% CI) was 1.22 (0.60;2.48) (Fig. 1B). In the sensitivity analysis excluding malignant breast neoplasms occurring less than 2 years after randomization, the HR (95% CI) was 0.78 (0.29;2.09) (Fig. 1C).

Confirmed pre-malignant breast neoplasms occurred in three female patients in the liraglutide group and one female patient in the placebo group. No pre-malignant breast neoplasm events were confirmed for male patients.

In the placebo group, one female patient had a confirmed benign breast neoplasm (versus no females in the liraglutide group). In the liraglutide group, one male patient had a confirmed benign breast neoplasm (versus no males in the placebo group).

Prostate neoplasms

The proportion of male patients with confirmed malignant prostate neoplasms was lower in the liraglutide group than in the placebo group (0.86% [$n = 26$] vs. 1.57% [$n = 47$], HR [95% CI]: 0.54 [0.34;0.88]) (Fig. 1A and Supplementary Fig. 2E).

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One patient in each treatment group had a confirmed pre-malignant prostate neoplasm. The event in the liraglutide group was reported as ‘benign prostatic hyperplasia’ and the event in the placebo group as ‘worsening of chronic benign prostatic hyperplasia’.

There were no confirmed benign prostate neoplasms in either treatment group.

Non-melanoma skin neoplasms

The most frequently occurring type of confirmed malignant neoplasm in the overall study population was malignant non-melanoma skin neoplasm (1.5% of patients [$n = 140$]). The proportion of patients with confirmed malignant non-melanoma skin neoplasms was 1.67% ($n = 78$) in the liraglutide group and 1.33% ($n = 62$) in the placebo group (HR [95% CI]: 1.25 [0.90;1.75]) (Fig. 1A and Supplementary Fig. 2F).

Among patients who experienced a confirmed malignant non-melanoma skin neoplasm during the trial, a medical history of skin neoplasms was recorded more frequently in those receiving liraglutide (33.3% [$n = 26$]) than those receiving placebo (23.8% [$n = 15$]).

Pre-malignant non-melanoma skin neoplasms were the most frequent type of confirmed pre-malignant neoplasms in both treatment groups, occurring in 0.3% of the participants in both the liraglutide and placebo groups ($n = 15$ and $n = 14$, respectively).

Based on a review of clinical narratives, most patients with confirmed non-melanoma pre-malignant and malignant skin neoplasms had a basal cell carcinoma (64.4% with liraglutide vs. 55.7% with placebo) or squamous-cell carcinoma (43.7% with liraglutide vs. 48.6% with placebo).

Benign non-melanoma skin neoplasm was confirmed in a single participant in the liraglutide group versus none in the placebo group.

Melanoma

Malignant melanoma of the skin was confirmed for more patients in the liraglutide group ($n = 13$ [0.28%]) than the placebo group ($n = 5$ [0.11%]); HR [95% CI]: 2.59 [0.92;7.27] (Fig. 1A and Supplementary Fig. 2G). Pre-malignant melanoma of the skin was confirmed in seven patients receiving liraglutide (0.15%) and four patients receiving placebo (0.09%). Details for individual cases of malignant or pre-malignant melanoma are included in Supplementary Table 4.

Among patients who experienced a confirmed malignant melanoma during the trial, a medical history of skin neoplasms was recorded in four patients receiving liraglutide (30.8%) and no patients receiving placebo. However, the number of cases upon which these observations were made was small.

No benign melanomas of the skin were confirmed in either treatment group.

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Lung and bronchus neoplasms

The proportion of patients who experienced confirmed malignant lung or bronchus neoplasms was comparable between the treatment groups (0.60% [$n = 28$] with liraglutide vs 0.71% [$n = 33$] with placebo, HR [95% CI]: 0.85 [0.51;1.40]) (Fig. 1A and Supplementary Fig. 2H). There were no confirmed pre-malignant or benign lung or bronchus neoplasms in either treatment group.

Malignant hepatic and biliary neoplasms

Between randomization and last follow-up, malignant hepatic or biliary neoplasms were confirmed in 13 patients in the liraglutide group and in 8 patients in the placebo group (0.3% vs 0.2%, respectively; HR [95% CI]: 1.62 [0.67;3.90]) (11).

The sponsor conducted a *post hoc* review of clinical narratives to assess the distribution of the confirmed malignant hepatobiliary neoplasms between the liver and gallbladder or bile duct. Based on this review, hepatic-related malignancies occurred in 7 patients in the liraglutide group and in 4 patients in the placebo group. Gallbladder/bile duct malignancies occurred in 6 patients in the liraglutide group and in 2 patients in the placebo group. One patient in the liraglutide group and 2 patients in the placebo group had malignant hepatobiliary neoplasms with an undetermined tissue site.

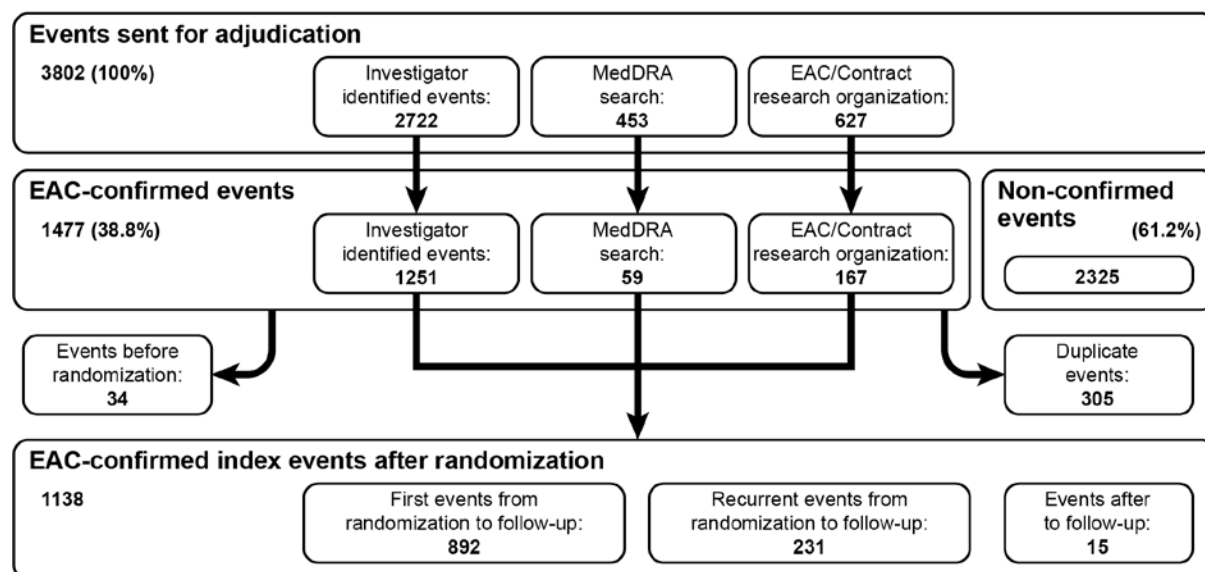
Signs or symptoms of the event were reported to be present at baseline for 2 patients in the liraglutide group (1 with a hepatic-related malignancy and 1 with a gallbladder/bile duct malignancy) and no patients in the placebo group.

The investigator-reported terms for the hepatic-related malignancies were reviewed. In both groups, most patients with hepatic-related malignancies had hepatocellular carcinomas (5/7 patients in the liraglutide group and 3/4 patients in the placebo group). For the remaining patients in the liraglutide group, the hepatic-related malignancies were reported as 'hepatic carcinoma' (1 patient) or 'right lobe liver adenocarcinoma' (1 patient). For the remaining patient in the placebo group, the hepatic-related malignancy was reported as an 'undifferentiated carcinoma of the liver (unlikely hepatocellular carcinoma) as per biopsy result'.

The investigator-reported terms for the gallbladder/bile duct malignancies were also reviewed. Except for 1 patient in the liraglutide group who had adenocarcinoma of the gallbladder, all of the patients with gallbladder/bile duct malignancies had cholangiocarcinomas.

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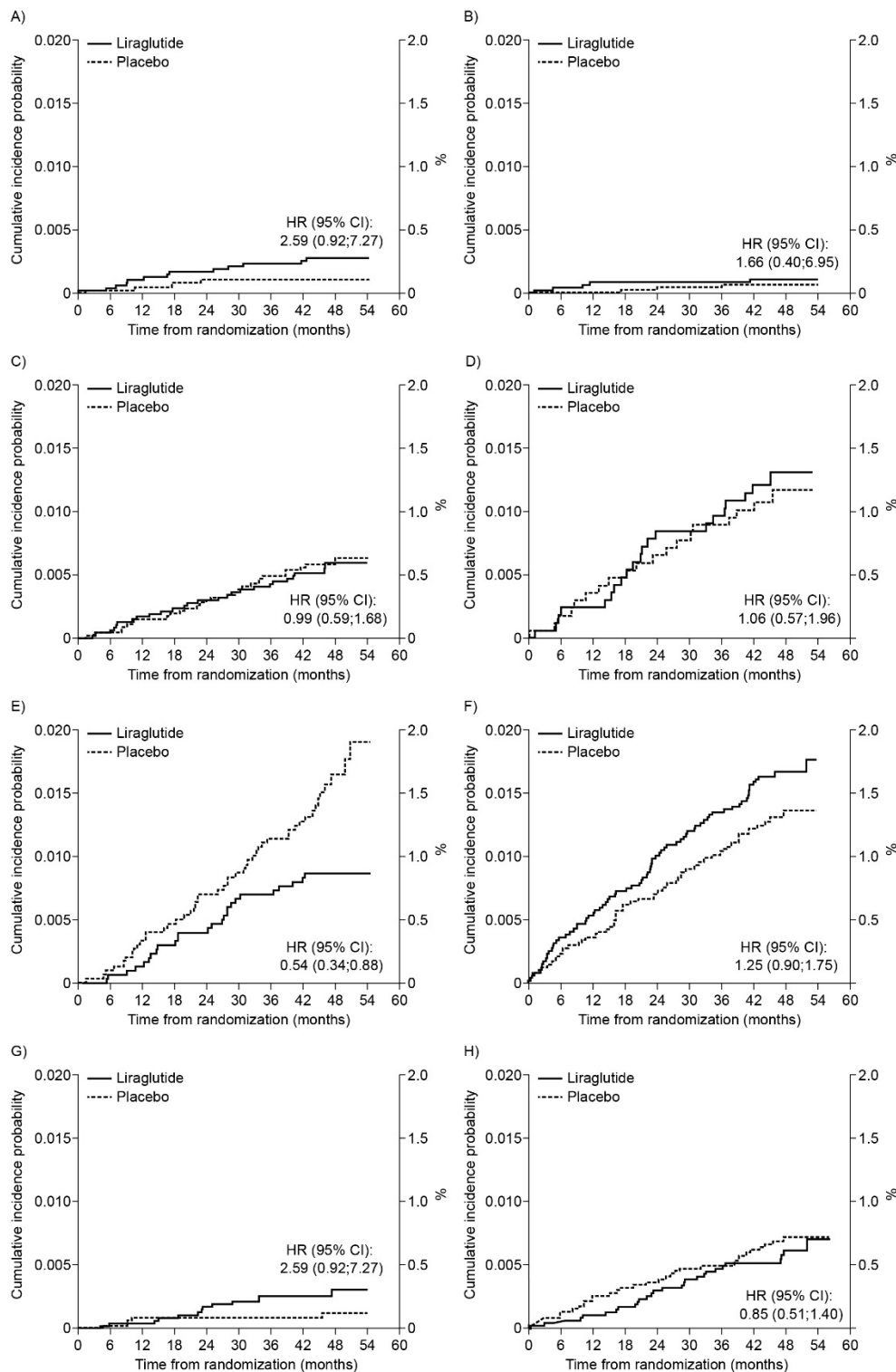
Supplementary Fig. 1–Adjudication flow diagram for neoplasms.



Full analysis set. All events of thyroid disease resulting in thyroidectomy and/or thyroid neoplasms, as well as all potential/suspected neoplasms, were sent for adjudication. EAC, event adjudication committee; MedDRA, Medical Dictionary for Regulatory Activities.

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Supplementary Fig. 2—Cumulative incidence plots for confirmed malignant neoplasms of interest. A) Pancreatic; B) thyroid; C) colorectal; D) breast (female only); E) prostate (male only); F) non-melanoma skin; G) melanoma; H) lung/bronchus.



Cumulative incidence was estimated using the Aalen-Johansen method with death as a competing risk. A cumulative incidence probability of 0.1 is equivalent to 10%. HRs are derived from a Cox proportional hazard regression model adjusted for treatment and are for the proportion of patients with an event with liraglutide versus placebo. HR, hazard ratio.

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Supplementary Table 1—Investigator-reported adverse events of malignant neoplasms captured by the sponsor’s MedDRA searches and not confirmed by the EAC.

	Liraglutide (<i>n</i> = 4,668)				Placebo (<i>n</i> = 4,672)			
	N	%	E	R	N	%	E	R
Events	26	0.6	26	0.15	33	0.7	33	0.19
Benign, malignant, and unspecified neoplasms, including cysts and polyps	26	0.6	26	0.15	33	0.7	33	0.19
Malignant and unspecified breast neoplasms, including nipple	1	<0.1	1	<0.01	0	0.0	0	0.00
Malignant and unspecified endocrine neoplasms	1	<0.1	1	<0.01	1	<0.1	1	<0.01
Malignant and unspecified gastrointestinal neoplasms	0	0.0	0	0.00	5	0.1	5	0.03
Malignant and unspecified hepatobiliary neoplasms	0	0.0	0	0.00	2	<0.1	2	0.01
Non-Hodgkin’s B-cell lymphomas	0	0.0	0	0.00	2	<0.1	2	0.01
Non-Hodgkin’s lymphomas, unspecified histology	1	<0.1	1	<0.01	1	<0.1	1	<0.01
Metastases	4	<0.1	4	0.02	4	<0.1	4	0.02
Malignant and unspecified neoplasms, miscellaneous and unspecified site	1	<0.1	1	<0.01	0	0.0	0	0.00
Plasma-cell neoplasms	1	<0.1	1	<0.01	0	0.0	0	0.00
Malignant and unspecified renal and urinary tract neoplasms	2	<0.1	2	0.01	3	<0.1	3	0.02
Malignant and unspecified reproductive neoplasms, female	2	<0.1	2	0.01	1	<0.1	1	<0.01
Malignant and unspecified reproductive neoplasms, male	0	0.0	0	0.00	2	<0.1	2	0.01

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Malignant and unspecified respiratory and mediastinal neoplasms	5	0.1	5	0.03	5	0.1	5	0.03
Malignant and unspecified skin neoplasms	8	0.2	8	0.04	5	0.1	5	0.03
Malignant and unspecified soft tissue neoplasms	0	0.0	0	0.00	2	<0.1	2	0.01

Data are for the full analysis set. The observation period was 17822 PYO in the liraglutide group and 17741 PYO in the placebo group. %, proportion of patients; E, number of events; EAC, event adjudication committee; MedDRA, Medical Dictionary for Regulatory Activities; N, number of patients; PYO, patient-years of observation; R, event rate per 100 patient-years of observation.

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Supplementary Table 2—Individual cases of malignant/pre-malignant pancreatic neoplasm identified in patients randomized to liraglutide or placebo.

Patient number	Age (years)/sex/smoking status	Investigator-reported term/EAC-confirmation status/EAC malignancy status	Study day of event	Cumulative exposure to trial product at time of neoplasm (days)/total exposure in trial (days)	Reason for examination/description	Tumor size/TNM/histological grade/stage	Tumor markers CEA/CA 19-9	Treatment due to the event	Patient outcome/time from neoplasm onset to death (days)	Cause of death
Cases of malignant pancreatic neoplasm in patients randomized to liraglutide										
PANCL1	64/M/ previous smoker	'Adenocarcinoma of the pancreas'/EAC-confirmed/ malignant	765	757/757	Signs/symptoms/epigastric-algia, intense abdominal pain, weight loss	NR/cT3 cN0 cM0/ unknown /IIA	NR/NR	Chemotherapy	Died/85	'Pancreatitis or pancreatic ca' [Pancreatitis or pancreatic cancer]
Additional details for patient PANCL1	<ul style="list-style-type: none"> Imaging findings: CT showed a non-homogenous lesion of soft tissue in the area of body of pancreas, with infiltration of the area behind the pancreas, portal upper vein mesenterium Diagnosis details: a biopsy revealed adenocarcinoma of the pancreas; diagnosed as adenocarcinoma of the pancreas with liver metastases Histopathology: ductal adenocarcinoma 									
PANCL2	63/F/current smoker	'Pancreatic carcinoma'/EAC-confirmed/ malignant	374	343/343	Signs/symptoms/abdominal pain, anorexia, nausea, vomiting, weight loss	35 mm/ pT3 pN1 cM0/G2 /IIB	7 (ref. range <3)/NR	Surgery (Whipple procedure), chemotherapy	Died/949	'Pancreatic ca' [Pancreatic cancer]
Additional	<ul style="list-style-type: none"> Imaging findings: CT showed an edematous duodenal bulb and enlarged head of pancreas; MRI showed a pathological lesion of the pancreatic head, 									

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details for patient PANCL2	peripheral dilatation of the main pancreatic duct in the body and tail of the pancreas										
	<ul style="list-style-type: none"> • Diagnosis details: clinical staging T3 N1 MX • Histopathology: ductal adenocarcinoma 										
PANCL3	68/M/previous smoker	'Malignant pancreatic neoplasm'/EAC-confirmed/malignant	505	505/506	Signs/symptoms/jaundice	33 mm/cT2 cN1 cM0/unknown/IB	8 (ref. range 0.2–3.4 for non-smokers, 0.2–4.3 for smokers)/324	8 (ref. range 0–33)	Surgery (surgical resection)	Died/382	'Pancreatic cancer/malignancy'
Additional details for patient PANCL3	<ul style="list-style-type: none"> • Imaging findings: abdominal MRI showed pancreatic tumor formation at the head of the pancreas • Diagnosis details: diagnosed as neoplasm of pancreatic head provoking biliary stasis • Histopathology: unknown 										
PANCL4	70/M/previous smoker	'Tumor caput pancreatis'/EAC-confirmed/malignant	278	278/284	Signs/symptoms/abdominal and thoracic pain, chronic diarrhoea for many years, weight loss	27 mm/cT3 cN0 cM1/unknown/V	3/NR		Palliative gastroenterostomy, chemotherapy	Died/837	'Malignancy/pancreatic cancer'
Additional details for patient PANCL4	<ul style="list-style-type: none"> • Imaging findings: initial gastroscopy showed duodenal ulcers and esophageal erosion; emergency MRCP and ERCP performed (and stent inserted) following diagnosis of hypertonic pylorus stenosis and development of jaundice • Diagnosis details: treatment was discontinued following a diagnosis of chronic pancreatitis; also diagnosed with hypertonic pylorus stenosis and developed jaundice; explorative laparotomy revealed an inoperable tumor in caput pancreatis and disseminated carcinomatosis; histology revealed metastasis from adenocarcinoma in peritoneum • Histopathology: ductal adenocarcinoma 										
PANCL5	70/M/current smoker	'Metastatic pancreatic cancer'/EAC-confirmed/malignant	517	512/512	Signs/symptoms/dyspnoea, weight loss	NR/cT3 cN1 cM1/unknown/V	NR/NR		Stent implantation, palliative treatment	Died/83	'Cancer/pancreatic cancer'

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Additional details for patient PANCL5	<ul style="list-style-type: none"> Imaging findings: MRI showed significant intrahepatic and extrahepatic cholangiectasis and ectasia of the pancreatic duct; short segment malignant stenosis determined via ERCP (stent inserted) Diagnosis details: diagnosed with pancreatic cancer with metastases to the lung and liver; clinical staging T3 N2 M1 Histopathology: ductal adenocarcinoma 									
PANCL6	71/M/previous smoker	'Pancreatic cancer'/EAC-confirmed/malignant	1,268	1,268/1,325	Incidental finding/CT check during chemotherapy after surgery for colon adenocarcinoma	35 mm/pT3 pN0 cM0/G1 /IIA	7 (ref. range 0–5)/NR	Surgery (pancreaticoduodenectomy)	Died/121	'Malignancy/GI bleed in setting of cancer'
Additional details for patient PANCL6	<ul style="list-style-type: none"> Imaging findings: routine CT scan showed intrahepatic common bile duct and pancreatic duct wall enhancement with narrowing and possible isoattenuating pancreas head cancer (3 cm); MRI showed obstruction of the common bile duct and pancreatic duct: there was no major vascular invasion, but invasion to the duodenal 2nd portion Diagnosis details: additional details NR Histopathology: ductal adenocarcinoma; Ki-67 labelling index: 10% 									
PANCL7	59/F/never smoked	'Pancreatic neoplasm malignant'/EAC-confirmed/malignant	162	99/99	Signs/symptoms/lumbar pain, nausea, cholestatic jaundice	NR/cT3 cN0 cM1/unknown/V	NR/NR	Percutaneous ethanol injection of celiac plexus, prosthesis placement into choledochal, radiation	Died/82	'Malignancy/panc ca' [Malignancy/pancreatic cancer]
Additional details for patient PANCL7	<ul style="list-style-type: none"> Imaging findings: MRI showed malignant pancreatic neoplasm with hepatic metastases and invasion of portal vein and common bile duct Diagnosis details: additional details NR Histopathology: unknown; the pathology report showed no neoplasia 									
PANCL8	60/F/never smoked	'The adenocarcinoma of the head of the	936	936/940	Signs/symptoms/jaundice, itch	40 mm/cT3 cN0 pM1/un	NR/NR	Surgery, chemotherapy	Died/276	'Malignancy/pancreatic ca' [Malignancy/pancreatic

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		pancreas with many hepatic metastasis'/EAC-confirmed/malignant				known/I V				c cancer]
Additional details for patient PANCL8										
PANCL9	67/M/never smoked	'Pancreatic adenocarcinoma moderately differentiated'/EAC-confirmed/malignant	214	214/224	Signs/symptoms/abdominal pain, jaundice	35 mm/pT2 pN1 cM0/G2 /IIB	2 (ref. range 0–3)/508 (ref. range 0–28)	Surgery, chemotherapy, radiation	Died/357	'Pancreatic ca' [Pancreatic cancer]
Additional details for patient PANCL9										
PANCL10	60/M/never smoked	'Adenocarcinoma pancreas'/EAC-confirmed/malignant	1,297	1,292/1,292	Signs/symptoms/icterus, fatigue, disturbance in falling asleep	40 mm/c T2 cN0 cM1/un known/I V	NR/NR	No treatment due to patient's inoperability and high bilirubin value	Died/66	'Pancreatic malignancy/pancreatic cancer'
Additional details for patient PANCL10										
PANCL11	66/F/previous smoker	'Adenocarcinoma of pancreas'/EAC-confirmed/malignant	853	852/877	Signs/symptoms/short of breath	35 mm/c T4 cN1 cM1/un	2 (ref. range 0–2.5)/16700 (ref. range 0–	Removed by fine needle aspiration	Died/26	'PNA and worsening pancreatic ca/pancreatic ca'

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	ant					known/I V	40)	through endoscopic ultrasound		[Pneumonia and worsening pancreatic cancer/pancreatic cancer]
Additional details for patient PANCL11	<ul style="list-style-type: none"> Imaging findings: CT scan showed a pulmonary embolism and irregular mass in the pancreatic body/neck (42 x 30 mm); endoscopic ultrasound also performed Diagnosis details: fine needle aspiration performed; pathology showed adenocarcinoma Histopathology: ductal adenocarcinoma 									
PANCL12	69/M/never smoked	'Liver cancer'/EAC- confirmed/malign ant	277	98/98	NR	NR/NA NA cM1/un known/ IV	NR/NR	NR	Died/49	'Malignancy/pancreatic cancer'
Additional details for patient PANCL12	<ul style="list-style-type: none"> Imaging findings: MRI and MRCP showed numerous, non-enhancing nodules throughout the liver, suggestive of metastases; CT-guided biopsy revealed invasive ductal carcinoma, stage 4 Diagnosis details: patient presented with syncope, weakness, weight loss and elevated blood sugar; his sclera was icteric. The patient was examined for another confirmed malignant pancreatic event, reported as 'pancreatic cancer – stage 4', with onset on day 280, due to severe hiccups, fatigue, and weight loss (for the latter event, the patient received palliative treatment, paracentesis and taps with fluid removal only) Histopathology: ductal adenocarcinoma 									
PANCL13	61/M/previous smoker	'Stable 2 cm hypodense lesion in the head of the pancreas'/EAC- confirmed/malign ant	1	NA/777	Signs/symptoms/increased lipase and amylase	18 mm/ NA NA NA/unk nown/un known	NR/NR	Surgery	Not recovered /NA	NA
PANCL13	61/M/previous smoker	'Borderline, nonspecific enlarged peripancreatic lymph node'/EAC- confirmed/malign	589	525/777	Signs/symptoms/increased lipase and amylase	34 mm/ NA cN1 cM0/G2 /≥IIB	NR/NR	Chemotherapy	Not recovered /NA	NA

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ant										
Additional details for patient PANCL13	<ul style="list-style-type: none"> Imaging findings: investigations included CT (with and without contrast enhancement), MRI, PET, and ultrasound. After month 19, these investigations consistently identified a pancreatic head lesion, right hepatic lobe mass, and borderline enlarged periportal and subcentimeter peripancreatic lymph nodes Diagnosis details: fine needle aspiration biopsy material from the pancreatic lesion showed necrosis and degenerating atypical cells, negative for malignancy. Patient also had an intrahepatic cholangiocarcinoma; biopsy material from hepatic lesion showed adenocarcinoma with immunohistochemistry suggesting origin in biliary tract, pancreas or lung. A pancreatic biopsy after chemotherapy did not show malignancy Histopathology for event on day 1: 1.8 cm pancreatic mass; no cytology or pathology confirming an adenocarcinoma Histopathology for event on day 589: cholangiocarcinoma; 3.4 cm liver mass with pathology confirming an adenocarcinoma 									
Cases of malignant pancreatic neoplasm in patients randomized to placebo										
PANCP1	70/F/never smoked	NR/EAC-confirmed/malignant	531	528/528	NR	37 mm/cT2 cN0 cM1/unknown/I	NR/1759	NR	Died/198	'Pancreatic ca' [Pancreatic cancer]
Additional details for patient PANCP1										
<ul style="list-style-type: none"> Imaging findings: CT scan showed a tumor 'at the pancreas caput' and two tumors 'in the right hepatic lap' Diagnosis details: fine needle biopsy showed adenocarcinoma of the pancreas. The patient was examined for another confirmed malignant pancreatic event, reported as 'pancreatic head carcinoma', with onset on the same day as the index event (day 531), due to abdominal pain, weight loss, and poor appetite (for the latter event, the patient received palliative treatment) Histopathology: ductal adenocarcinoma 										
PANCP2	75/M/never smoked	'Pancreas adenocarcinoma'/EAC-confirmed/malignant	525	524/556	Signs/symptoms/weight loss, white stool, dark urine, lower abdominal pain, jaundice	25 mm/cT3 cN0 cM0/unknown/IA	NR/NR	None (chemotherapy planned but not performed due to death)	Died/49	'Pancreatic ca/pancreatic cancer' [Pancreatic cancer]
Additional details for patient PANCP2										
<ul style="list-style-type: none"> Imaging findings: acute colonoscopy revealed no pathology; CT scan showed a pancreatic tumor, stenosis of the duct and no metastasis in the liver Diagnosis details: patient also diagnosed with pancreatitis Histopathology: ductal adenocarcinoma; T3 N0 M0; brush biopsy from bile duct showed malignant tumor cells 										
PANCP3	66/M/current smoker	'Pancreas cancer'/EAC-	43	43/321	Incidental finding/conn	25 mm/pT3	NR/NR	Surgery	Died/483	'Pancreatic cancer/pancreatic ca'

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		confirmed/malignant			ection with investigation on peripheral arterial disease	pN0 cM0/G3 /IIA				[Pancreatic cancer]
Additional details for patient PANCP3										<ul style="list-style-type: none"> Imaging findings: NR Diagnosis details: large cystic tumor revealed due to investigation for peripheral artery disease. Partial pancreatectomy performed; microscopy revealed malignant tumor in pancreas Histopathology: ductal adenocarcinoma
PANCP4	63/M/previous smoker	'Metastatic pancreatic carcinoma'/EAC-confirmed/malignant	695	683/683	Signs/symptoms/rise in liver function tests	43 mm/cT3 cN0 cM1/unknown/V	NR/NR	Chemotherapy, palliative treatment	Died/66	'Pancreatic ca/malignancy' [Pancreatic cancer/malignancy]
Additional details for patient PANCP4										<ul style="list-style-type: none"> Imaging findings: initial CT scan showed a pancreatic lesion; CT scan of chest, abdomen, and pelvis showed multiple lung nodules, metastatic primary pancreatic tail malignancy, malignant ascites, hepatic metastasis, left renal metastasis, and potential vertebral bone metastasis Diagnosis details: tumor marker level 4132 (ref. range <37; tumor marker type and unit NR) Histopathology: ductal adenocarcinoma; ascitic drainage cytology revealed adenocarcinoma and mild diverticular disease
PANCP5	78/M/never smoked	'Pancreatic carcinoma'/EAC-confirmed/malignant	326	89/89	Signs/symptoms/intermittent right upper quadrant pain, nausea	13 mm/cT1 cN0 cM0/unknown/A	NR/NR	NR	Died/193	'Sepsis/pancreatic cancer'; patient died following cardiac arrest
Additional details for patient PANCP5										<ul style="list-style-type: none"> Imaging findings: endoscopic ultrasound with biopsy showed a lesion in the pancreatic wall Diagnosis details: patient diagnosed with pancreatic carcinoma with bile duct obstruction post stent placement Histopathology: ductal adenocarcinoma
PANCP6	69/F/never smoked	'Pancreas malign neoplasm'/not confirmed/NR	1,079	295/295	Signs/symptoms/indigestion, swelling	NR/cT3 cN1 cM0/NR /IIB	NR/NR	NR	Died/34	'Malignancy'
Additional										<ul style="list-style-type: none"> Imaging findings: PET scanning showed lesions (increased Ga-68 DOTATATE involvement) with heterogeneous borders in the head and body section of

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details for patient	pancreas/extending into peripancreatic and paraaortocaval area; pancreatic neuroendocrine tumor suspected									
PANCP6	<ul style="list-style-type: none"> • Diagnosis details: additional details NR • Histopathology: microscopic examination not performed 									
PANCP7	80/M/previous smoker	'Pancreatic tumor with hepatic metastasis'/not confirmed/NR	1,248	1,072/1,090	Signs/symptoms/abdominal pain	NR/cT2 cN0 cM1/NR /IV	18/21,000	Palliative treatment	Died/32	'Malignancy/pancreatic ca'[Malignancy/pancreatic cancer]
Additional details for patient	<ul style="list-style-type: none"> • Imaging findings: abdominal ultrasound showed hepatic nodules and pancreatic tissue damage; CT scan showed a 44 mm tissue lesion at the level of the body of pancreas, and dilation of ductus (20 mm). Hypodense lesions of the hepatic parenchyma • Diagnosis details: additional details NR • Histopathology: microscopic examination not performed 									
PANCP8	72/F/never smoked	'Pancreas cancer'/not confirmed/NR	138	138/150	Signs/symptoms/vomiting, fatigue, high glycemia values and epigastric pain	39 mm/c T2 cN0 cM0/NR /IB	NR/123 (ref. range 0–39)	Patient denied surgery; oncological follow-up recommended (not further specified)	Died/178	'Malignancy/pancreatic cancer'
Additional details for patient	<ul style="list-style-type: none"> • Imaging findings: abdominal echography and CT scan showed necrotising lesion (47/48 mm lesion in uncinate process) • Diagnosis details: additional details NR • Histopathology: microscopic examination not performed 									
PANCP9	67/M/previous smoker	'Malignant neoplas of pancreas'/not confirmed/NR	20	20/22	Signs/symptoms/worsening of abdominal pain, weight loss, intermittent constipation	50 mm/c T4 cN1 cM1/NR /IV	NR/NR	Oncological treatment recommended (not further specified); neoplasm not suitable for surgery	Died/448	'Malignancy/pancreatic ca' [Malignancy/pancreatic cancer]
Additional details for patient	<ul style="list-style-type: none"> • Imaging findings: abdominal ultrasound and CT showed lesion in pancreas body with signs of local spread and pressure on the pancreas duct and distal dilation to the lesion; metastases in the liver and lymphadenopathy • Diagnosis details: additional details NR 									

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patient PANCP9	• Histopathology: microscopic examination not performed									
PANCP10	69/M/previous smoker	'Malignant neoplasm head of pancreas'/confirmed by EAC as a lymphoma/malignant	954	953/1,007	Incidental finding/radiographic workup following rib cage injury	55 mm/NR/NR	NR/NR	NR; treatment dependent on obtaining further tissue for definitive diagnostic evaluation	Not recovered /NA	NA
Additional details for patient PANCP10	<ul style="list-style-type: none"> • Imaging findings: the patient sustained an injury to their rib cage following a slip and fall. During radiographic workup, a 5.5 cm mass was identified in the head of the pancreas • Diagnosis details: fine needle aspiration was performed; cytology was consistent with lymphoma. Subtyping was not possible. B-cell lymphoma was reported for this patient after 1,007 days of cumulated exposure in the trial • Histopathology: NR 									
Case of pre-malignant pancreatic neoplasm in a patient randomized to liraglutide										
PANCL14	65/M/current smoker	'Pancreatic lesion'/EAC-confirmed/pre-malignant/carcinoma <i>in situ</i> /borderline	1,415	265/265	Acute pancreatitis/history of pancreatitis and cholecystectomy	48 mm/pT0 pN0 cM0/PanIN 1B*/0	NR/NR	Surgery	Recovered/NA	NA
Additional details for case PANCL14	<ul style="list-style-type: none"> • Imaging findings: pancreatic lesions identified worsened throughout the trial, as they increased in size • Diagnosis details: diagnosed with pancreatitis and acute gallbladder disease. Patient was admitted for Whipple procedure to analyse cysts; no evidence of metastases • Histopathology: intraductal papillary mucinous neoplasm 									

Data are for all index events, including events not confirmed by the EAC. The index event is the event selected among multiple events if these were assessed and confirmed to be one and the same event. All deaths among these cases were categorized as non-CV by the CV adjudication subcommittee. Patient numbers are randomly assigned and not linked to their actual study identification number. Units and reference ranges for tumor markers are reported where available. Square brackets are used to denote interpretation of the reported text. *The event of intraductal papillary mucinous neoplasm was of moderate dysplasia. As this was not a pre-specified option in the assessment form, the external reviewer selected 'PanIN 1B' as histological grade. CA 19-9, carbohydrate antigen 19-9; CEA, carcinoembryonic antigen; CT, computed tomography; CV, cardiovascular; EAC, event adjudication committee; ERCP, endoscopic retrograde cholangiopancreatography; F, female; GI, gastrointestinal; M, male; M, metastasis; MRCP, magnetic resonance cholangiopancreatography; MRI, magnetic resonance imaging; N, node; NR, not reported or not available; PET, positron emission tomography; ref., reference; T, tumor.

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Supplementary Table 3—Demographics and baseline characteristics of patients who experienced a malignant neoplasm with liraglutide or placebo, all liraglutide-treated patients and all placebo-treated patients.

	Experienced malignant neoplasm with liraglutide	All liraglutide-treated patients	Experienced malignant neoplasm with placebo	All placebo-treated patients
Malignant pancreatic neoplasms				
<i>N</i> (%)	13 (100.0)	4,668 (100.0)	5 (100.0)	4,672 (100.0)
Gender, <i>n</i> (%)				
Female	4 (30.8)	1,657 (35.5)	1 (20.0)	1,680 (36.0)
Male	9 (69.2)	3,011 (64.5)	4 (80.0)	2,992 (64.0)
Region, <i>n</i> (%)				
Europe	6 (46.2)	1,639 (35.1)	3 (60.0)	1,657 (35.5)
North America	3 (23.1)	1,401 (30.0)	1 (20.0)	1,446 (31.0)
Asia	1 (7.7)	360 (7.7)	0 (0.0)	351 (7.5)
Rest of world	3 (23.1)	1,268 (27.2)	1 (20.0)	1,218 (26.1)
Race, <i>n</i> (%)				
White	10 (76.9)	3,616 (77.5)	4 (80.0)	3,622 (77.5)
Black or African American	1 (7.7)	370 (7.9)	1 (20.0)	407 (8.7)
Asian	1 (7.7)	471 (10.1)	0 (0.0)	465 (10.0)
American Indian or Alaska Native	0 (0.0)	5 (0.1)	0 (0.0)	6 (0.1)
Native Hawaiian or other Pacific Islander	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)
Other	1 (7.7)	202 (4.3)	0 (0.0)	168 (3.6)
Smoking status, <i>n</i> (%)				
Current smoker	2 (15.4)	567 (12.1)	1 (20.0)	563 (12.1)
Previous smoker	6 (46.2)	2,151 (46.1)	1 (20.0)	2,189 (46.9)
Never smoked	5 (38.5)	1,950 (41.8)	3 (60.0)	1,920 (41.1)
Age, years	65.2 (4.3)	64.2 (7.2)	70.4 (6.2)	64.4 (7.2)
BMI, kg/m ²	31.3 (4.2)	32.5 (6.3)	29.3 (2.5)	32.5 (6.3)
Duration of diabetes, years	13.0 (7.1)	12.8 (8.0)	9.8 (6.1)	12.9 (8.1)
HbA _{1c} , %	8.8 (1.2)	8.7 (1.6)	8.3 (1.1)	8.7 (1.5)
HbA _{1c} , mmol/mol*	73 (13)	72 (18)	67 (12)	72 (16)
Malignant thyroid neoplasms				
<i>N</i>	5 (100.0)	4,668 (100.0)	3 (100.0)	4,672 (100.0)

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Gender, <i>n</i> (%)				
Female	1 (20.0)	1,657 (35.5)	2 (66.7)	1,680 (36.0)
Male	4 (80.0)	3,011 (64.5)	1 (33.3)	2,992 (64.0)
Region, <i>n</i> (%)				
Europe	0 (0.0)	1,639 (35.1)	0 (0.0)	1,657 (35.5)
North America	2 (40.0)	1,401 (30.0)	2 (66.7)	1,446 (31.0)
Asia	0 (0.0)	360 (7.7)	0 (0.0)	351 (7.5)
Rest of world	3 (60.0)	1,268 (27.2)	1 (33.3)	1,218 (26.1)
Race, <i>n</i> (%)				
White	5 (100.0)	3,616 (77.5)	3 (100.0)	3,622 (77.5)
Black or African American	0 (0.0)	370 (7.9)	0 (0.0)	407 (8.7)
Asian	0 (0.0)	471 (10.1)	0 (0.0)	465 (10.0)
American Indian or Alaska Native	0 (0.0)	5 (0.1)	0 (0.0)	6 (0.1)
Native Hawaiian or other Pacific Islander	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)
Other	0 (0.0)	202 (4.3)	0 (0.0)	168 (3.6)
Smoking status, <i>n</i> (%)				
Current smoker	1 (20.0)	567 (12.1)	0 (0.0)	563 (12.1)
Previous smoker	3 (60.0)	2,151 (46.1)	2 (66.7)	2,189 (46.9)
Never smoked	1 (20.0)	1,950 (41.8)	1 (33.3)	1,920 (41.1)
Age, years	61.6 (8.1)	64.2 (7.2)	62.7 (8.3)	64.4 (7.2)
BMI, kg/m ²	33.4 (4.1)	32.5 (6.3)	48.9 (28.4)	32.5 (6.3)
Duration of diabetes, years	8.8 (3.9)	12.8 (8.0)	11.9 (2.6)	12.9 (8.1)
HbA _{1c} , %	9.4 (1.4)	8.7 (1.6)	8.6 (0.4)	8.7 (1.5)
HbA _{1c} , mmol/mol*	79 (15)	72 (18)	70 (4)	72 (16)
Malignant colorectal neoplasms				
<i>N</i> (%)	28 (100.0)	4,668 (100.0)	28 (100.0)	4,672 (100.0)
Gender, <i>n</i> (%)				
Female	7 (25.0)	1,657 (35.5)	11 (39.3)	1,680 (36.0)
Male	21 (75.0)	3,011 (64.5)	17 (60.7)	2,992 (64.0)
Region, <i>n</i> (%)				
Europe	17 (60.7)	1,639 (35.1)	20 (71.4)	1,657 (35.5)
North America	4 (14.3)	1,401 (30.0)	4 (14.3)	1,446 (31.0)
Asia	1 (3.6)	360 (7.7)	1 (3.6)	351 (7.5)
Rest of world	6 (21.4)	1,268 (27.2)	3 (10.7)	1,218 (26.1)
Race, <i>n</i> (%)				
White	26 (92.9)	3,616 (77.5)	25 (89.3)	3,622 (77.5)
Black or African American	1 (3.6)	370 (7.9)	2 (7.1)	407 (8.7)

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Asian	1 (3.6)	471 (10.1)	1 (3.6)	465 (10.0)
American Indian or Alaska Native	0 (0.0)	5 (0.1)	0 (0.0)	6 (0.1)
Native Hawaiian or other Pacific Islander	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)
Other	0 (0.0)	202 (4.3)	0 (0.0)	168 (3.6)
Smoking status, <i>n</i> (%)				
Current smoker	3 (10.7)	567 (12.1)	4 (14.3)	563 (12.1)
Previous smoker	19 (67.9)	2,151 (46.1)	14 (50.0)	2,189 (46.9)
Never smoked	6 (21.4)	1,950 (41.8)	10 (35.7)	1,920 (41.1)
Age, years	66.6 (6.2)	64.2 (7.2)	66.3 (5.8)	64.4 (7.2)
BMI, kg/m ²	31.1 (5.5)	32.5 (6.3)	31.2 (4.8)	32.5 (6.3)
Duration of diabetes, years	15.0 (9.2)	12.8 (8.0)	13.8 (7.6)	12.9 (8.1)
HbA _{1c} , %	8.8 (1.3)	8.7 (1.6)	8.8 (1.4)	8.7 (1.5)
HbA _{1c} , mmol/mol*	73 (14)	72 (18)	73 (15)	72 (16)
Malignant breast neoplasms (female only)				
<i>N</i> (%)	21 (100.0)	1,657 (100.0)	20 (100.0)	1,680 (100.0)
Region, <i>n</i> (%)				
Europe	7 (33.3)	492 (29.7)	8 (40.0)	493 (29.3)
North America	8 (38.1)	482 (29.1)	7 (35.0)	503 (29.9)
Asia	2 (9.5)	120 (7.2)	2 (10.0)	117 (7.0)
Rest of world	4 (19.0)	563 (34.0)	3 (15.0)	567 (33.8)
Race, <i>n</i> (%)				
White	17 (81.0)	1,238 (74.7)	13 (65.0)	1,230 (73.2)
Black or African American	0 (0.0)	188 (11.3)	4 (20.0)	221 (13.2)
Asian	3 (14.3)	153 (9.2)	2 (10.0)	154 (9.2)
American Indian or Alaska Native	0 (0.0)	1 (0.1)	0 (0.0)	0 (0.0)
Native Hawaiian or other Pacific Islander	0 (0.0)	1 (0.1)	0 (0.0)	0 (0.0)
Other	1 (4.8)	76 (4.6)	1 (5.0)	75 (4.5)
Smoking status, <i>n</i> (%)				
Current smoker	2 (9.5)	155 (9.4)	5 (25.0)	126 (7.5)
Previous smoker	7 (33.3)	442 (26.7)	6 (30.0)	485 (28.9)
Never smoked	12 (57.1)	1,060 (64.0)	9 (45.0)	1,069 (63.6)
Age, years	68.1 (7.6)	64.2 (7.3)	64.0 (6.1)	64.6 (7.0)
BMI, kg/m ²	32.9 (5.7)	33.5 (6.8)	34.2 (6.8)	33.7 (6.9)
Duration of diabetes, years	12.9 (8.3)	13.2 (8.2)	15.9 (7.4)	13.6 (8.4)
HbA _{1c} , %	8.9 (1.8)	8.9 (1.6)	9.2 (1.9)	8.8 (1.6)
HbA _{1c} , mmol/mol*	74 (20)	74 (18)	77 (21)	73 (18)
Malignant prostate neoplasms (male only)				

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<i>N</i> (%)	26 (100.0)	3,011 (100.0)	47 (100.0)	2,992 (100.0)
Region, <i>n</i> (%)				
Europe	13 (50.0)	1,147 (38.1)	25 (53.2)	1,164 (38.9)
North America	4 (15.4)	919 (30.5)	11 (23.4)	943 (31.5)
Asia	3 (11.5)	240 (8.0)	2 (4.3)	234 (7.8)
Rest of world	6 (23.1)	705 (23.4)	9 (19.1)	651 (21.8)
Race, <i>n</i> (%)				
White	20 (76.9)	2,378 (79.0)	42 (89.4)	2,392 (79.9)
Black or African American	3 (11.5)	182 (6.0)	2 (4.3)	186 (6.2)
Asian	3 (11.5)	318 (10.6)	3 (6.4)	311 (10.4)
American Indian or Alaska Native	0 (0.0)	4 (0.1)	0 (0.0)	6 (0.2)
Native Hawaiian or other Pacific Islander	0 (0.0)	3 (0.1)	0 (0.0)	4 (0.1)
Other	0 (0.0)	126 (4.2)	0 (0.0)	93 (3.1)
Smoking status, <i>n</i> (%)				
Current smoker	3 (11.5)	412 (13.7)	9 (19.1)	437 (14.6)
Previous smoker	15 (57.7)	1,709 (56.8)	21 (44.7)	1,704 (57.0)
Never smoked	8 (30.8)	890 (29.6)	17 (36.2)	851 (28.4)
Age, years	66.1 (6.2)	64.2 (7.2)	66.3 (6.3)	64.2 (7.3)
BMI, kg/m ²	31.9 (4.7)	32.0 (6.0)	31.2 (4.5)	31.8 (5.8)
Duration of diabetes, years	13.8 (8.0)	12.6 (7.8)	12.6 (9.8)	12.5 (7.9)
HbA _{1c} , %	8.3 (1.3)	8.7 (1.5)	8.6 (1.4)	8.6 (1.4)
HbA _{1c} , mmol/mol*	67 (14)	72 (16)	70 (15)	70 (15)
Malignant non-melanoma skin neoplasm				
<i>N</i> (%)	78 (100.0)	4,668 (100.0)	62 (100.0)	4,672 (100.0)
Gender, <i>n</i> (%)				
Female	14 (17.9)	1,657 (35.5)	12 (19.4)	1,680 (36.0)
Male	64 (82.1)	3,011 (64.5)	50 (80.6)	2,992 (64.0)
Region, <i>n</i> (%)				
Europe	28 (35.9)	1,639 (35.1)	19 (30.6)	1,657 (35.5)
North America	35 (44.9)	1,401 (30.0)	33 (53.2)	1,446 (31.0)
Asia	0 (0.0)	360 (7.7)	1 (1.6)	351 (7.5)
Rest of world	15 (19.2)	1,268 (27.2)	9 (14.5)	1,218 (26.1)
Race, <i>n</i> (%)				
White	78 (100.0)	3,616 (77.5)	61 (98.4)	3,622 (77.5)
Black or African American	0 (0.0)	370 (7.9)	0 (0.0)	407 (8.7)
Asian	0 (0.0)	471 (10.1)	1 (1.6)	465 (10.0)
American Indian or Alaska Native	0 (0.0)	5 (0.1)	0 (0.0)	6 (0.1)

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Native Hawaiian or other Pacific Islander	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)
Other	0 (0.0)	202 (4.3)	0 (0.0)	168 (3.6)
Smoking status, <i>n</i> (%)				
Current smoker	9 (11.5)	567 (12.1)	8 (12.9)	563 (12.1)
Previous smoker	47 (60.3)	2,151 (46.1)	35 (56.5)	2,189 (46.9)
Never smoked	22 (28.2)	1,950 (41.8)	19 (30.6)	1,920 (41.1)
Age, years	69.8 (7.5)	64.2 (7.2)	69.6 (6.8)	64.4 (7.2)
BMI, kg/m ²	32.4 (5.9)	32.5 (6.3)	32.9 (6.2)	32.5 (6.3)
Duration of diabetes, years	15.0 (8.6)	12.8 (8.0)	15.2 (8.1)	12.9 (8.1)
HbA _{1c} , %	8.1 (0.9)	8.7 (1.6)	8.4 (1.3)	8.7 (1.5)
HbA _{1c} , mmol/mol*	65 (10)	72 (18)	68 (14)	72 (16)
Malignant melanoma				
<i>N</i> (%)	13 (100.0)	4,668 (100.0)	5 (100.0)	4,672 (100.0)
Gender, <i>n</i> (%)				
Female	7 (53.8)	1,657 (35.5)	3 (60.0)	1,680 (36.0)
Male	6 (46.2)	3,011 (64.5)	2 (40.0)	2,992 (64.0)
Region, <i>n</i> (%)				
Europe	8 (61.5)	1,639 (35.1)	2 (40.0)	1,657 (35.5)
North America	2 (15.4)	1,401 (30.0)	2 (40.0)	1,446 (31.0)
Asia	0 (0.0)	360 (7.7)	0 (0.0)	351 (7.5)
Rest of world	3 (23.1)	1,268 (27.2)	1 (20.0)	1,218 (26.1)
Race, <i>n</i> (%)				
White	13 (100.0)	3,616 (77.5)	5 (100.0)	3,622 (77.5)
Black or African American	0 (0.0)	370 (7.9)	0 (0.0)	407 (8.7)
Asian	0 (0.0)	471 (10.1)	0 (0.0)	465 (10.0)
American Indian or Alaska Native	0 (0.0)	5 (0.1)	0 (0.0)	6 (0.1)
Native Hawaiian or other Pacific Islander	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)
Other	0 (0.0)	202 (4.3)	0 (0.0)	168 (3.6)
Smoking status, <i>n</i> (%)				
Current smoker	1 (7.7)	567 (12.1)	0 (0.0)	563 (12.1)
Previous smoker	5 (38.5)	2,151 (46.1)	2 (40.0)	2,189 (46.9)
Never smoked	7 (53.8)	1,950 (41.8)	3 (60.0)	1,920 (41.1)
Age, years	66.9 (5.3)	64.2 (7.2)	66.8 (6.7)	64.4 (7.2)
BMI, kg/m ²	33.7 (5.6)	32.5 (6.3)	37.1 (7.4)	32.5 (6.3)
Duration of diabetes, years	11.6 (7.0)	12.8 (8.0)	11.7 (7.2)	12.9 (8.1)
HbA _{1c} , %	8.4 (1.2)	8.7 (1.6)	8.3 (1.2)	8.7 (1.5)
HbA _{1c} , mmol/mol*	68 (13)	72 (18)	67 (13)	72 (16)

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Malignant lung and bronchus neoplasms				
<i>N (%)</i>	28 (100.0)	4,668 (100.0)	33 (100.0)	4,672 (100.0)
Gender, <i>n (%)</i>				
Female	12 (42.9)	1,657 (35.5)	7 (21.2)	1,680 (36.0)
Male	16 (57.1)	3,011 (64.5)	26 (78.8)	2,992 (64.0)
Region, <i>n (%)</i>				
Europe	16 (57.1)	1,639 (35.1)	16 (48.5)	1,657 (35.5)
North America	8 (28.6)	1,401 (30.0)	12 (36.4)	1,446 (31.0)
Asia	0 (0.0)	360 (7.7)	1 (3.0)	351 (7.5)
Rest of world	4 (14.3)	1,268 (27.2)	4 (12.1)	1,218 (26.1)
Race, <i>n (%)</i>				
White	24 (85.7)	3,616 (77.5)	31 (93.9)	3,622 (77.5)
Black or African American	3 (10.7)	370 (7.9)	1 (3.0)	407 (8.7)
Asian	1 (3.6)	471 (10.1)	1 (3.0)	465 (10.0)
American Indian or Alaska Native	0 (0.0)	5 (0.1)	0 (0.0)	6 (0.1)
Native Hawaiian or other Pacific Islander	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)
Other	0 (0.0)	202 (4.3)	0 (0.0)	168 (3.6)
Smoking status, <i>n (%)</i>				
Current smoker	9 (32.1)	567 (12.1)	9 (27.3)	563 (12.1)
Previous smoker	14 (50.0)	2,151 (46.1)	23 (69.7)	2,189 (46.9)
Never smoked	5 (17.9)	1,950 (41.8)	1 (3.0)	1,920 (41.1)
Age, years	68.6 (7.7)	64.2 (7.2)	67.2 (6.1)	64.4 (7.2)
BMI, kg/m ²	31.8 (6.4)	32.5 (6.3)	32.4 (4.7)	32.5 (6.3)
Duration of diabetes, years	10.9 (10.2)	12.8 (8.0)	11.2 (6.4)	12.9 (8.1)
HbA _{1c} , %	8.2 (1.5)	8.7 (1.6)	8.4 (1.3)	8.7 (1.5)
HbA _{1c} , mmol/mol*	66 (16)	72 (18)	68 (14)	72 (16)

Events from randomization to last follow-up are included. Data are mean (standard deviation) unless otherwise stated. *Calculated, not measured.

SUPPLEMENTARY DATA

Supplementary Table 4—Individual cases of confirmed, malignant/pre-malignant melanoma identified in patients randomized to liraglutide or placebo.

Patient number	Age (years)/sex/smoking status	Investigator-reported term/EAC malignancy status	Study day of event	Cumulative exposure to trial product at time of neoplasm (days)/total exposure in trial (days)	Reason for examination/description	Tumor size/TNM/stage	Patient outcome/time from neoplasm onset to death (days)	Cause of death
Cases of malignant melanoma in patients randomized to liraglutide								
MELAL1	70/M/never smoked	'Melanoma right upper arm'/malignant	701	701/1,274	NR	4 mm/pT3a N0 M0/IIA	Not recovered/ NA	NA
MELAL2	72/F/never smoked	'Malignant melanoma'/malignant	568	557/1,550	NR	0.8 mm/pT1b N0 M0/IB	Recovered/ NA	NA
MELAL3	72/F/current smoker	'Malignant melanoma upper arm right'/malignant	127	127/1,553	NR	0.51 mm/pT1a N0 NR/NR	Recovered/ NA	NA
MELAL4	76/F/previous smoker	'Metastatic melanoma of epithelioid cells (left little toe)'/malignant	173	172/185	Symptoms/new/change in pre-existing skin element	NR/TX >N1 M1c/IV	Died/868	'Probable melanoma related'
MELAL5	64/M/previous smoker	'Malignant melanoma'/malignant	1,442	1,442/1,649	Symptoms/new/change in pre-existing skin element	1.39 mm/pT2a N0 M0/IB	Recovered/ NA	NA
MELAL6	62/F/never	'Malignant	455	455/1,645	Symptoms/new/change in pre-	1.0–	Not	NA

SUPPLEMENTARY DATA

	smoked	melanoma' / malignant			existing skin element	2.0 mm/pT2a NX MX/NR	recovered/ NA	
MELAL7	64/F/never smoked	'Melanoma malignum colli l sin.'/malignant	759	759/1,259	Symptoms/new/change in pre-existing skin element	0.65 mm/pT1a N0 M0/IA	Not recovered/ NA	NA
MELAL8	70/M/previous smoker	'Metastatic malignant melanoma on back'/malignant	875	874/1,279	NR	NR/TX NX M1c/IV	Recovered with sequelae/NA	NA
MELAL9	69/M/never smoked	'Malignant melanoma of skin left parietal region'/malignant	700	700/870	Symptoms/new/change in pre-existing skin element	2.0 mm/pT2b >N0 M1x/IV	Died/227	'Malignancy/malignant melanoma'
MELAL10	65/F/never smoked	'Melanoma of skin of back'/malignant	1,025	1,025/1,304	Symptoms/new/change in pre-existing skin element	1.5 mm/pT2a N0 M0/IB	Recovered/ NA	NA
MELAL11	56/M/never smoked	'Melanoma malignant'/malignant	1,024	1,024/1,465	Symptoms/new/change in pre-existing skin element	0.58 mm/pT1b N0 M0/IB	Recovered/ NA	NA
MELAL12	64/M/previous smoker	'Malign melanoma right thigh'/malignant	434	434/1,289	Symptoms/new/change in pre-existing skin element	0.34 mm/pT1a N0 M0/IA	Recovered/ NA	NA
MELAL13	66/F/previous smoker	'Malignant melanoma <i>in situ</i> '/malignant	679	679/1,549	Symptoms/new/change in pre-existing skin element	NR/T1b N0 M0/IB	Recovered/ NA	NA
Cases of malignant melanoma in patients randomized to placebo								
MELAP1	67/F/never smoked	'Melanom Clark level IV right buttock'/malignant	296	296/1,282	Symptoms/new/change in pre-existing skin element	1.8 mm/pT2a NX M0/NR	Recovered/ NA	NA
MELAP2	76/M/previous smoker	NR/malignant	274	274/376	NR; the patient was examined for another confirmed malignant melanoma event, reported as 'metastatic malignant melanom on the back' with	NR/TX NX M1a/IV for the event reported as 'metastatic	Not recovered/ NA	NA

SUPPLEMENTARY DATA

					onset on the same day as the index event (day 274), due to symptoms/new/change in pre-existing skin element	malignant melanoma on the back' with onset on the same day as the index event		
MELAP3	62/F/never smoked	'Malignant melanoma on the right heel'/malignant	1,386	1,366/1,366	Symptoms/new/change in pre-existing skin element	3.2 mm/NR/NR	Not recovered/NA	NA
MELAP4	59/F/never smoked	'Malignant melanoma, upper lip'/malignant	144	114/114	Symptoms/bleeding/hemorrhagic; the patient was examined for another confirmed malignant melanoma event, reported as 'metastatic melanoma, lymph node' with onset on day 149, due to local itching	NR/TX N2 M1a/IV for the event reported as 'metastatic melanoma, lymph node'	Died/1,150	Unknown
MELAP5	70/M/previous smoker	'Malignant melanoma mid upper back'/malignant	278	278/1,022	Symptoms/ulceration	0.45 mm/pT1a N0 M0/IA	Recovered/NA	NA
Cases of pre-malignant melanoma in patients randomized to liraglutide								
MELAL5	64/M/previous smoker	'Melanomas on the back'/pre-malignant/carcinoma <i>in situ</i> /borderline	1,678	1,649/1,649	Screening/new/change in pre-existing skin element	NR/Tis N0 M0/0	Recovering/NA	NA
MELAL1 4	70/F/never smoked	'Lentigo maligna melanoma'/pre-malignant/carcinoma <i>in situ</i> /borderline	1,073	1,073/1,381	Symptoms/new/change in pre-existing skin element	NR/pTis N0 M0/0	Recovered/NA	NA
MELAL1 5	72/F/never smoked	'Malignant melanoma'/pre-	256	256/1,278	Symptoms/new/change in pre-existing skin element	NR/Tis N0 M0/0	Recovered/NA	NA

SUPPLEMENTARY DATA

		malignant/carcinoma <i>in situ</i> /borderline						
MELAL1 6	79/M/never smoked	'Focal <i>in situ</i> melanoma low lumbar midline'/pre-malignant/carcinoma <i>in situ</i> /borderline; another confirmed pre-malignant melanoma event was reported for this patient as ' <i>in situ</i> melanoma left trapezius', with onset on the same day as the index event (day 1,243)	1,243	1,243/1,288	Screening/new/change in pre-existing skin element	NR/Tis N0 M0/0	Recovered/ NA	NA
MELAL1 7	79/M/never smoked	' <i>In situ</i> melanoma to left ear'/pre-malignant/carcinoma <i>in situ</i> /borderline	987	987/1,214	Symptoms/new/change in pre-existing skin element	NR/Tis N0 M0/0	Recovered/ NA	NA
MELAL1 8	69/M/previous smoker	'Melanoma on back'/pre-malignant/carcinoma <i>in situ</i> /borderline	335	335/1,562	Symptoms/new/change in pre-existing skin element	NR/Tis N0 M0/0	Recovered/ NA	NA
MELAL1 9	76/M/never smoked	NR/pre-malignant/carcinoma <i>in situ</i> /borderline	394	194/194	NR; the patient was examined for another pre-malignant event, reported as ' <i>in situ</i> melanoma <i>in situ</i> ' with onset on the same day as the index event (day 394), due to screening/new/change in pre-	NR/Tis N0 M0/0 for the event reported as ' <i>in situ</i> melanoma <i>in situ</i> ' with onset on the	Died/1,028	Unknown; adjudicated as CV death

SUPPLEMENTARY DATA

					existing skin element	same day as the index event		
Cases of pre-malignant melanoma in patients randomized to placebo								
MELAP6	76/F/previous smoker	'Lentigo maligna'/pre-malignant/carcinoma <i>in situ</i> /borderline	292	100/100	Symptoms/new/change in pre-existing skin element	0.35 mm/pTis N0 M0/0	Recovered/NA	NA
MELAP7	61/M/never smoked	'Malignant melanoma – left mid back paraspinal'/pre-malignant/carcinoma <i>in situ</i> /borderline	410	409/1,282	Screening/new/change in pre-existing skin element	NR/Tis N0 M0/0	Recovered/NA	NA
MELAP8	68/M/current smoker	'Malignant melanoma right temple skin lesion'/pre-malignant/carcinoma <i>in situ</i> /borderline	494	494/1,302	Symptoms/new/change in pre-existing skin element	NR/Tis N0 M0/0	Recovered/NA	NA
MELAP9	62/M/previous smoker	'Malignant melanoma of left lower back'/pre-malignant/carcinoma <i>in situ</i> /borderline; two other pre-malignant events were reported for this patient with onset on the same day as the index event (day 1,153), one of which was	1,153	1,153/1,653	Symptoms/new/change in pre-existing skin element	NR/Tis N0 M0/0	Recovered for 'malignant melanoma of left lower back', not recovered for 'actinic keratosis on entire scalp, upper back, rt. and lft. ant. upper	NA

SUPPLEMENTARY DATA

		reported as 'actinic keratosis on entire scalp, upper back, rt. and lft. ant. upper arm, face' (reported term not available for the second event)					arm, face'/NA	
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Data are for all index events. The index event is the event selected among multiple events if these were assessed and confirmed to be one and the same event. Patient numbers are randomly assigned and not linked to their actual study identification number. CT, computed tomography; CV, cardiovascular; EAC, event adjudication committee; F, female; M, male; M, metastasis; N, node; NA, not applicable; NR, not reported or not available; T, tumor.