nature medicine

Article

https://doi.org/10.1038/s41591-024-02796-z

Selection, optimization and validation of ten chronic disease polygenic risk scores for clinical implementation in diverse US populations

In the format provided by the authors and unedited

eMERGE Polygenic Risk Report

PATIENT INFORMATION		REFERRING PROVIDER		SPECIMEN	
Patient Name:	TEST_FN TEST_LN	Provider Name:	TEST_PROVIDER	Report Type:	Final
		Referring Facility:	Vanderbilt University Medical Center	Collected:	01/15/2021
Date of Birth:	11/01/1956			Received:	01/01/2021
Sample ID:	TEST_SAMPLE			Report Date:	03/23/2023
Patient ID:	INTERNAL_TEST_SAMPLE	Test Performed:	Polygenic Risk Evaluation	Material Type:	DNA
				Material Source:	Blood
Accession ID:	test_high_risk	Indication:	N/A		
Site Sample ID:	TEST_SAMPLE				

Results Summary

In this patient the Polygenic Risk Score for the following condition(s) was determined to be **HIGH***:

asthma

*See detailed results for a description for how this risk was determined.

Detailed Results

This patient met the threshold for HIGH POLYGENIC RISK for the following condition(s):

Condition: asthma

1. A high polygenic risk score for asthma was found in this individual. A high polygenic risk score is associated with up to 2 times increased risk for developing asthma relative to a person not in the high risk category. The data is based on pediatric populations of European, African, and Hispanic/Latino descent. Information is insufficient or not available for populations of other descent.
2. Factors including monogenic disease risk, family history, and other clinical measures can have an impact on the individuals overall (absolute) risk and should be considered.
3. This participant was tested as part of the Electronic Medical Records and Genomics (eMERGE) Genomic Risk Assessment and Management Study. The participant's integrated Genome Informed Risk Assessment (GIRA) report will be generated which will incorporate the results from this report as well as family history and monogenic risk status, if available.

Other Results

Specific polygenic risk score details for coronary heart disease and breast cancer

The specific polygenic risk score value (expressed as a z-score) for coronary heart disease and breast cancer are being reported for inclusion in absolute risk models that a healthcare provider may choose to use.

Condition:	Test z-score:
breast cancer	N/A
coronary heart disease	1.00

Limitations

- A polygenic score is neither deterministic nor diagnostic. Some people with a 'high risk' polygenic score will never develop the disease while others with a 'not high risk' polygenic score still have a risk of developing the disease that is equal to the general population. Therefore, this test is not intended to diagnose a disease or to make surgical or pharmacological intervention decisions. This test does not tell a patient anything about their current state of health and should not substitute for regular visits to the doctor. Any diagnostic or treatment decisions should be based on additional testing and/or other information that is managed by a healthcare provider.
- This test will detect genetic variants that are predefined. This test does not evaluate or report on all possible genetic variation related to a given disease. It will not detect novel or rare genetic variants and will not rule out the presence of these additional genetic variants related to a disease.
- The predefined list of genetic variants tested in this assay may be different from another institution or company, therefore genetic risk calculations and polygenic scores may differ if compared across different institutions or companies.
- The odds ratio (OR) listed for each condition does not take into account other factors that may play a role in a patient's overall risk of developing a disease (e.g family history or monogenic risk of developing the disease, or environmental and lifestyle risk factors).
- Receiving genetic test results may induce patient anxiety. Patients should speak to their doctor or healthcare provider regarding these test results and potential implications for their health and lifestyle decisions. If you have questions regarding your test results, you can contact the eMERGE clinical study team using the instructions provided to you during the consent process.
- Although the polygenic score has been developed to maximize the ability to predict risk in all ancestries, the availability of population reference data means that the score is currently most accurate for those with European ancestry. Due to this population limitation, as well as assay performance and processing issues, some patients may not receive a polygenic risk calculation for every condition listed. A result of "Not Resulted" for one condition does not impact the reliability of the risk polygenic score of other conditions.

Methodology

A genotyping microarray (the Global Diversity Array from Illumina, Inc.) was used to call single nucleotide variants (SNVs) at ~1.8 million sites in the genome. Only arrays meeting the QC criteria of >98% Call Rate were passed through to the downstream steps. Millions more SNVs in the sample were determined through imputation using data from the 1000 Genomes Project as a reference panel (Khera et al. 2018). Statistical association of SNVs and each condition listed were previously determined through examination of thousands of patient records and genomic data. The relative contribution of the set of SNVs associated with each condition were combined to provide a score. The score was further adjusted to account for the frequency of SNVs in different ancestry populations. The adjusted score was then represented as odds ratio (OR) and 95% confidence interval (CI) compared to a reference population.

The test is validated to determine polygenic risk for 10 conditions: asthma, atrial fibrillation, breast cancer, chronic kidney disease, coronary heart disease, hypercholesterolemia, obesity, prostate cancer, type 1 diabetes, and type 2 diabetes. Only conditions that meet the condition-specific criteria for high polygenic risk are reported as such by this test. In patients younger than 18 years of age, ONLY the following conditions are examined for risk: asthma, obesity, type 1 diabetes, and type 2 diabetes. Breast cancer is only assessed for individuals who elected their sex at birth as female and prostate cancer is only assessed for individuals who have elected their sex at birth as male. The methodologies used to determine the risk criteria for each condition are listed below:

asthma polygenic risk status was determined based on a method that scores 985,837 sites in the genome. A Bayesian regression framework method was applied using the Trans-National Asthma Genetic Consortium (TAGC) GWAS to derive a multi-ancestral PRS score (PMID: 29273806). In a multiethnic study, individuals in the top 5% of the risk percentile had an increased risk of developing asthma. Values within the top 5% of this polygenic risk score are associated with a 1.95 odds ratio (OR) in pediatric populations of European descent at a 95% CI [1.43-2.65], 1.83 OR in pediatric populations of African descent at a 95% CI [1.24-2.70], and 3.12 OR in pediatric populations of Hispanic/Latino descent at 95% CI [1.32-7.44]. Information is insufficient or not available for populations of other descent.

atrial fibrillation polygenic risk status was determined based on a method developed by Nielsen et al. (PMID: 30061737) that scores 161 sites in the genome. In a multiethnic study, individuals in the top 3% of the risk percentile exhibited an increased risk of developing atrial fibrillation. Values within the top 3% of this polygenic risk score are associated with a 2.32 OR in populations of European descent at a 95% CI [2.07-2.61], 2.19 OR in populations of African descent at a 95% CI [1.38-3.38], and 2.27 OR in populations of Hispanic/Latino descent at a 95% CI [1.09-4.50]. Information is insufficient or not available for populations of other descent.

breast cancer polygenic risk status was determined based on a method developed by Mavaddat et al. (PMID: 30554720) that scores 308 sites in the genome. In a multiethnic study, individuals who fell in the top 5% of the risk percentile exhibited an increased risk of developing breast cancer. Values within the top 5% of this polygenic risk score are associated with a 2.47 OR in populations of European descent at a 95% CI [2.20 - 2.77] (PMID: 30554720), 1.61 OR in populations of African descent at a 95% CI [1.38-1.87] (PMID: 33769540), 2.05 OR in populations of Hispanic/Latino descent at a 95% CI [1.10-3.83] (PMID: 34347061), and 2.22 OR in populations of Asian descent at a 95% CI [1.99-2.47] (PMID: 32737321). Information is insufficient or not available for populations of other descent.

chronic kidney disease polygenic risk status was determined based on a study of renal function by Wuttke et al. (PMID: 31152163) and includes 471,316 sites in the genome. In a multiethnic validation study, individuals who fell in the top 2% of the risk percentile exhibited an increased risk of developing chronic kidney disease. Values within the top 2% of this polygenic risk score are associated with a 3.60 OR in populations of European descent at a 95% CI [3.11-4.17], 2.66 OR in populations of African descent at a 95% CI [2.01-3.51], 4.93 OR in populations of Hispanic/Latino descent at a 95% CI [2.46-9.89], and 2.81 OR in populations of Asian descent at a 95% CI [1.91-7.59]. Information is insufficient or not available for populations of other descent.

coronary heart disease polygenic risk status was determined based on a method that scores 458,384 sites in the genome. In a multiethnic study, individuals in the top 5% of the risk percentile exhibited an increased risk of developing coronary heart disease. Values within the top 5% of this polygenic risk score are associated with a relative risk of 2.30 in populations of European descent at a 95% CI [2.07-2.56], 1.68 in populations of African descent at a 95% CI 1.39-2.032], and 2.16 in populations of Hispanic/Latino descent at a 95% CI [1.47-3.19]. For Asian populations, the relative risk is similar to that in European populations. Information is insufficient or not available for populations of other descent.

hypercholesterolemia polygenic risk status was determined based on a method that scores 9,009 sites in the genome. In a multiethnic study, individuals who fell in the top 3% of the risk percentile exhibited an increased risk of developing hypercholesterolemia. Values within the top 3% of this polygenic risk score are associated with a 4.16 OR in populations of European descent at a 95% CI [2.59-6.44], 3.16 OR in populations of African descent at a 95% CI [1.92-5.01], 4.02 OR in populations of Hispanic/Latino descent at a 95% CI [2.72-5.83], and 3.75 OR in populations of Asian descent at a 95% CI [3.15-4.42]. Information is insufficient or not available for populations of other descent.

obesity polygenic risk status was determined based on a method that scores 1,217,710 sites in the genome. In a multiethnic study, individuals who fell in the top 3% of the risk percentile exhibited an increased risk above baseline of developing obesity. Values within the top 3% of this polygenic risk score are associated with a 4.08 OR in populations of European descent at a 95% CI [3.02-5.52], 2.54 OR in populations of African descent at a 95% CI [1.66-3.98], 2.33 OR in populations of Hispanic/Latino descent at a 95% CI [1.64-3.31], and 5.73 OR in populations of Asian descent at a 95% CI [2.28-14.57]. Information is insufficient or not available for populations of other descent.

prostate cancer polygenic risk status was determined based on a method developed by Conti et al. (PMID: 33398198) that scores 264 sites in the genome. In this multiethnic study of individuals of African, European, Asian, and Hispanic/Latino descent, individuals who fell in the top 10% of the risk percentile exhibited an increased risk of developing prostate cancer. Values within the top 10% of this polygenic risk score are associated with a 3.67 OR in populations of European descent at a 95% CI [3.57-3.76] and a 2.95 OR in populations of African descent at a 95% CI [2.60-3.30]. Information is insufficient or not available for populations of other descent.

type 1 diabetes polygenic risk status was determined based on a method developed by Sharp et al. (PMID: 30655379) that scores 71 sites in the genome. In a separate multiethnic study, individuals who fell in the top 3% of the risk percentile exhibited an increased risk of developing type 1 diabetes. Values within the top 3% of this polygenic risk score are associated with a 12.97 OR in populations of European descent at a 95% CI [7.29-20.40] and 20.45 OR in populations of African descent at a 95% CI [10.77-38.83]. Information is insufficient or not available for populations of other descent.

type 2 diabetes polygenic risk status was determined based on a method developed by Ge et al. (medRxiv 2021.09.11.21263413) that scores 1,259,754 sites in the genome. In a multiethnic study, individuals who fell in the top 2% of the risk percentile exhibited an increased risk of developing type 2 diabetes. Values within the top 2% of this polygenic risk score are associated with a 4.21 OR in populations of European descent at a 95% CI [3.66-4.84], 2.55 OR in populations of African descent at a 95% CI [2.09-3.11], 4.58 OR in populations of Asian descent at a 95% CI [4.00-5.23], and 6.87 OR for Hispanic/Latino populations at a 95% CI [3.11, 15.15]. Information is insufficient or not available for populations of other descent.

Regulatory Disclosures

This test was performed by the Clinical Research Sequencing Platform (CRSP), LLC. (320 Charles Street, Cambridge, MA 02141; CLIA: 22D2055652). CRSP, LLC. is authorized under the Clinical Laboratory Improvement Amendments (CLIA) to develop and perform high complexity clinical laboratory testing. This test was developed and its performance characteristics determined by CRSP, LLC. The U.S. Food and Drug Administration (FDA) has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use.

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Teresa Nutile[200] , Anita Pandit[21] , Paraskevi Christofidou[178] , Katri P.rna[28,41] , Marc Pauper[170] , Eva R. B. Petersen[201] , Liselotte V. Petersen[105,202] , Niina Pitk.nen[203,204] , Ozren Polašek[205,206] , Alaitz Poveda[157] , Michael H. Preuss[207,208] , Saiju Pyarajan[5,57,81] , Laura M. Raffield[19] , Hiromi Rakugi[149] , Julia Ramirez[4,209,210] , Asif Rasheed[211] , Dennis Raven[212] , Nigel W. Rayner[26,198,213,214] , Carlos Riveros[215,216] , Rebecca Rohde[9] , Daniela Ruggiero[200,217] , Sanni E. Ruotsalainen[47] , Kathleen A. Ryan[218,219] , Maria Sabater-Lleal[220,221] , Richa Saxena[3,186] , Markus Scholz[122,123] , Anoop Sendamarai[81] , Botong Shen[222] , Jingchunzi Shi[12] , Jae Hun Shin[223] , Carlo Sidore[224] , Colleen M. Sitlani[54] , Roderick C. Slieker[225,226,227] , Roelof A. J. Smit[207,228] ,Albert V. Smith[46,229] , Jennifer A. Smith[46,90] , Laura J. Smyth[60] ,Lorraine Southam[213,230] ,Valgerdur Steinthorsdottir[231] , Liang Sun[132] , Fumihiko Takeuchi[135] ,DivyaSriPriyanka Tallapragada[45,232] , Kent D. Taylor[107] , Bamidele O. Tayo[233] ,Catherine Tcheandjieu[234,235] , Natalie Terzikhan[78] , Paola Tesolin[93] ,Alexander Teumer[236,237] , Elizabeth Theusch[238] ,Deborah J. Thompson[239,240] ,Gudmar Thorleifsson[231] ,Paul R. H. J. Timmers[152,181] ,
Stella Trompet[199,241] , Constance Turman[125] , Simona Vaccargiu[224] , Sander W. van der Laan[242] , Peter J. van der Most[41] , Jan B. van Klinken[243,244,245] , Jessica van Setten[246] , Shefali S. Verma[67] , Niek Verweij[247] , Yogasudha Veturi[51] , Carol A. Wang[215,216] , Chaolong Wang[86,248] , Lihua Wang[74] , Zhe Wang[207] , Helen R. Warren[4,249] , Wen Bin Wei[250] , Ananda R. Wickremasinghe[148] , Matthias Wielscher[251,252] , Kerri L. Wiggins[54] , Bendik S. Winsvold[253,254] , Andrew Wong[255] , Yang Wu[1] , Matthias Wuttke[256,257] , Rui Xia[258] , Tian Xie[41] , Ken Yamamoto[259] , Jingyun Yang[260,261] , Jie Yao[107] , Hannah Young[34] , Noha A. Yousri[262,263] , Lei Yu[260,261] , Lingyao Zeng[264] , Weihua Zhang[265,266] , Xinyuan Zhang[51] , Jing-Hua Zhao[267] , Wei Zhao[46] , Wei Zhou[3,268,269,270] , Martina E. Zimmermann[82] , Magdalena Zoledziewska[224] , Linda S. Adair[271,272] , Hieab H. H. Adams[273,274,275] , Carlos A. Aguilar-Salinas[276,277] , Fahd Al-Mulla[116] , Donna K. Arnett[278,] Folkert W. Asselbergs[246,279,280] , Bj.rn Olav .svold[281,282,283] , John Attia[121] , Bernhard Banas[284] , Stefania Bandinelli[285] , David A. Bennett[260,261] , Tobias Bergler[284] , Dwaipayan Bharadwaj[286] , Ginevra Biino[287] , Hans Bisgaard[10] , Eric Boerwinkle[288] , Carsten A. B.ger[284,289,290] , Klaus B.nnelykke[10] , Dorret I. Boomsma[124] , Anders D. B.rglum[104,105,291,292] , Judith B. Borja[293,294] , Claude Bouchard[295] , Donald W. Bowden[85,296] , Ivan Brandslund[297,298] , Ben Brumpton[281,299] , Julie E. Buring[5,73] , Mark J. Caulfield[4,249] , John C. Chambers[265,266,300,301] , Giriraj R. Chandak[45,302] , Stephen J. Chanock[15] , Nish Chaturvedi[255] , Yii-Der Ida Chen[107] , Zhengming Chen[27,190] , Ching-Yu Cheng[62,303] , Ingrid E. Christophersen[304,305] , Marina Ciullo[200,217] , John W. Cole[306,307] , Francis S. Collins[48] , Richard S. Cooper[233] , Miguel Cruz[308] , Francesco Cucca[224,309] , L. Adrienne Cupples[80,115] , Michael J. Cutler[310] , Scott M. Damrauer[51,311,312] , Thomas M. Dantoft[146] , Gert J. de Borst[313] , Lisette C. P. G. M. de Groot[314] , Philip L. De Jager[3,315] , Dominique P. V. de Kleijn[313] , H. Janaka de Silva[148] , George V. Dedoussis[84] , Anneke I. den Hollander[170] , Shufa Du[271,272] , Douglas F. Easton[239,316] , Petra J. M. Elders[317] , A. Heather Eliassen[57,125,318] , Patrick T. Ellinor[69,319,320] , S.lve Elmst.hl[321] , Jeanette Erdmann[192] , Michele K. Evans[222] , Diane Fatkin[322,323,324] , Bjarke Feenstra[101] , Mary F. Feitosa[74] , Luigi Ferrucci[325] , Ian Ford[326] , Myriam Fornage[258,327] , Andre Franke[75] , Paul W. Franks[157,318,328] , Barry I. Freedman[329] , Paolo Gasparini[61,93] , Christian Gieger[99,137] , Giorgia Girotto[61,93] , Michael E. Goddard[330,331] , Yvonne M. Golightly[9,44,332,333] , Clicerio Gonzalez-Villalpando[334] , Penny Gordon-Larsen[271,272] , Harald Grallert[99,137] , Struan F. A. Grant[49,335,336,337] , Niels Grarup[40] , Lyn Griffiths[160] , Vilmundur Gudnason[229,338] , Christopher Haiman[339] , Hakon Hakonarson[49,335,340,341] , Torben Hansen[40] , Catharina A. Hartman[212] , Andrew T. Hattersley[342] , Caroline Hayward[181] , Susan R. Heckbert[343] , Chew-Kiat Heng[344,345] , Christian Hengstenberg[346] , Alex W. Hewitt[347,348,349] , Haretsugu Hishigaki[134] , Carel B. Hoyng[170] , Paul L. Huang[5,320,350] , Wei Huang[351] , Steven C. Hunt[262,352] , Kristian Hveem[281,282] , Elina Hypp.nen[353,354] , William G. Iacono[34] , Sahoko Ichihara[355] , M. Arfan Ikram[78] , Carmen R. Isasi[356] , Rebecca D. Jackson[357] , Marjo-Riitta Jarvelin[251,358,359,360] , Zi-Bing Jin[145,361] ,

Karl-Heinz J.ckel[184] , Peter K. Joshi[153] , Pekka Jousilahti[111] , J. Wouter Jukema[241,362,363] ,
Mika K.h.nen[364,365] , Yoichiro Kamatani[6,366] , Kui Dong Kang[367] , Jaakko Kaprio[47] ,
Sharon L. R. Kardia[46] , Fredrik Karpe[214,368] , Norihiro Kato[135] , Frank Kee[60] ,
Thorsten Kessler[264,369] , Amit V. Khera[3,186] , Chiea Chuen Khor[86] ,
Lambertus A. L. M. Kiemeney[96,370] , Bong-Jo Kim[133] , Eung Kweon Kim[371,372] , Hyung-Lae Kim[373] ,
Paulus Kirchhof[374,375,376,377] , Mika Kivimaki[378] , Woon-Puay Koh[379] , Heikki A. Koistinen[111,380,381] ,
Genovefa D. Kolovou[382] , Jaspal S. Kooner[265,301,383,384] , Charles Kooperberg[109] ,
Anna K.ttgen[256] , Peter Kovacs[385] , Adriaan Kraaijeveld[246] , Peter Kraft[125] , Ronald M. Krauss[238] ,
Meena Kumari[386] , Zoltan Kutalik[31,32] , Markku Laakso[387] , Leslie A. Lange[388] ,
Claudia Langenberg[171,389] , Lenore J. Launer[222] , Loic Le Marchand[390] , Hyejin Lee[391] ,
Nanette R. Lee[293] , Terho Lehtim.ki[174,175] , Huaixing Li[132] , Liming Li[392,393] , Wolfgang Lieb[394] ,
Xu Lin[132,395] , Lars Lind[108] , Allan Linneberg[146,396] , Ching-Ti Liu[80] , Jianjun Liu[86] ,
Markus Loeffler[122,123] , Barry London[397] , Steven A. Lubitz[69,319,320] , Stephen J. Lye[398] ,
David A. Mackey[347,349] , Reedik M.gi[28] , Patrik K. E. Magnusson[399] , Gregory M. Marcus[400] ,
Pedro Marques Vidal[401,402] , Nicholas G. Martin[103] , Winfried M.rz[76,403,404] , Fumihiko Matsuda[150] ,
Robert W. McGarrah[405,406] , Matt McGue[34] , Amy Jayne McKnight[60] , Sarah E. Medland[407] ,
Dan Mellstr.m[194,408] , Andres Metspalu[28] , Braxton D. Mitchell[218,219,409] , Paul Mitchell[410] ,
Dennis O. Mook-Kanamori[228,411] , Andrew D. Morris[412] , Lorelei A. Mucci[125] ,
Patricia B. Munroe[4,249] , Mike A. Nalls[162,163,164] , Saman Nazarian[413] , Amanda E. Nelson[44,414] ,
Matt J. Neville[214,368] , Christopher Newton-Cheh[186,320] , Christopher S. Nielsen[415,416] ,
Markus M. N.then[417] , Claes Ohlsson[194,418] , Albertine J. Oldehinkel[212] , Lorena Orozco[419] ,
Katja Pahkala[203,204,420] , P.ivi Pajukanta[39,421] , Colin N. A. Palmer[422] , Esteban J. Parra[159] ,
Cristian Pattaro[95] , Oluf Pedersen[40] , Craig E. Pennell[215,216] , Brenda W. J. H. Penninx[187] ,
Louis Perusse[71,423] , Annette Peters[100,137,424] , Patricia A. Peyser[46] , David J. Porteous[59] ,
Danielle Posthuma[138] , Chris Power[425] , Peter P. Pramstaller[95] , Michael A. Province[74] ,
Qibin Qi[356] , Jia Qu[361] , Daniel J. Rader[51,426] , Olli T. Raitakari[203,204,427] , Sarju Ralhan[428] ,
Loukianos S. Rallidis[429] , Dabeeru C. Rao[430] , Susan Redline[5,57] , Dermot F. Reilly[431] ,
Alexander P. Reiner[109,432] , Sang Youl Rhee[433] , Paul M. Ridker[5,73] , Michiel Rienstra[247] ,
Samuli Ripatti[3,47,434] , Marylyn D. Ritchie[51] , Dan M. Roden[435] , Frits R. Rosendaal[228] ,
Jerome I. Rotter[107] , Igor Rudan[152] , Femke Rutters[436] , Charumathi Sabanayagam[62,303] ,
Danish Saleheen[211,437] , Veikko Salomaa[111] , Nilesh J. Samani[52,53] ,
Dharambir K. Sanghera[438,439,440,441] , Naveed Sattar[442] , B.rge Schmidt[184] , Helena Schmidt[443] ,
Reinhold Schmidt[119] , Matthias B. Schulze[136,137,444] , Heribert Schunkert[445] , Laura J. Scott[21] ,
Rodney J. Scott[446] , Peter Sever[384] , Eric J. Shiroma[222] , M. Benjamin Shoemaker[447] ,
Xiao-Ou Shu[58] , Eleanor M. Simonsick[325] , Mario Sims[97] , Jai Rup Singh[448] ,
Andrew B. Singleton[162] , Moritz F. Sinner[369,449] , J. Gustav Smith[450,451,452] , Harold Snieder[41] ,
Tim D. Spector[178] , Meir J. Stampfer[57,125,318] , Klaus J. Stark[82] , David P. Strachan[453] ,
Leen M. ‘t Hart[225,226,227,454] , Yasuharu Tabara[150] , Hua Tang[455] , Jean-Claude Tardif[169,456] ,
Thangavel A. Thanaraj[116] , Nicholas J. Timpson[112,191] , Anke T.njes[385] , Angelo Tremblay[71,423] ,
Tiinamaija Tuomi[47,173,457,458] , Jaakko Tuomilehto[111,459,460] , Maria-Teresa Tusi.-Luna[461,462] ,
Andre G. Uitterlinden[29] , Rob M. van Dam[33,463,464] , Pim van der Harst[246,247] ,
Nathalie Van der Velde[29,465] , Cornelia M. van Duijn[27,78] , Natasja M. van Schoor[466] ,
Veronique Vitart[181] , Uwe V.lker[237,467] , Peter Vollenweider[401,402] , Henry V.lzke[236,237] ,
Niels H. Wacher-Rodarte[468] , Mark Walker[469] , Ya Xing Wang[145] , Nicholas J. Wareham[171] ,
Richard M. Watanabe[470,471,472] , Hugh Watkins[26,102] , David R. Weir[90] , Thomas M. Werge[43,396,473] ,
Elisabeth Widen[47] , Lynne R. Wilkens[390] , Gonneke Willemsen[124] , Walter C. Willett[125,318] ,
James F. Wilson[152,181] , Tien-Yin Wong[62,303] , Jeong-Taek Woo[433] , Alan F. Wright[181] ,
Jer-Yuarn Wu[64,474] , Huichun Xu[218,219] , Chittaranjan S. Yajnik[475] , Mitsuhiro Yokota[476] ,
Jian-Min Yuan[477,478] , Eleftheria Zeggini[213,230,479] , Babette S. Zemel[51,68,337,340] , Wei Zheng[58] ,

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