

# Angina and Future Cardiovascular Events in Stable Patients With Coronary Artery Disease: Insights From the Reduction of Atherothrombosis for Continued Health (REACH) Registry

Alon Eisen, MD; Deepak L. Bhatt, MD, MPH; P. Gabriel Steg, MD; Kim A. Eagle, MD; Shinya Goto, MD; Jianping Guo, MS; Sidney C. Smith, MD; E. Magnus Ohman, MD; Benjamin M. Scirica, MD, MPH; on Behalf of the REACH Registry Investigators\*

**Background**—The extent to which angina is associated with future cardiovascular events in patients with coronary artery disease has long been debated.

**Methods and Results**—Included were outpatients with established coronary artery disease who were enrolled in the REACH registry and were followed for 4 years. Angina at baseline was defined as necessitating episodic or permanent antianginal treatment. The primary end point was the composite of cardiovascular death, myocardial infarction, or stroke. Secondary end points included heart failure, cardiovascular hospitalizations, and coronary revascularization. The independent association between angina and first/total events was examined using Cox and logistic regression models. Out of 26 159 patients with established coronary artery disease, 13 619 (52%) had angina at baseline. Compared with patients without angina, patients with angina were more likely to be older, female, and had more heart failure and polyvascular disease ( $P<0.001$  for each). Compared with patients without angina, patients with angina had higher rates of first primary end-point event (14.2% versus 16.3%, unadjusted hazard ratio 1.19, CI 1.11–1.27,  $P<0.001$ ; adjusted hazard ratio 1.06, CI 0.99–1.14,  $P=0.11$ ), and total primary end-point events (adjusted risk ratio 1.08, CI 1.01–1.16,  $P=0.03$ ). Patients with angina were at increased risk for heart failure (adjusted odds ratio 1.17, CI 1.06–1.28,  $P=0.002$ ), cardiovascular hospitalizations (adjusted odds ratio 1.29, CI 1.21–1.38,  $P<0.001$ ), and coronary revascularization (adjusted odds ratio 1.23, CI 1.13–1.34,  $P<0.001$ ).

**Conclusions**—Patients with stable coronary artery disease and angina have higher rates of future cardiovascular events compared with patients without angina. After adjustment, angina was only weakly associated with cardiovascular death, myocardial infarction, or stroke, but significantly associated with heart failure, cardiovascular hospitalization, and coronary revascularization. (*J Am Heart Assoc.* 2016;5:e004080 doi: 10.1161/JAHA.116.004080)

**Key Words:** angina • cardiovascular events • coronary artery disease

Stable angina affects more than 8 million people in the United States each year.<sup>1</sup> Patients with stable angina have reduced quality of life and utilize greater healthcare resources.<sup>2</sup> The extent to which angina is independently associated with future cardiovascular events or is just a

marker of disease severity has long been debated.<sup>3–11</sup> While several studies have demonstrated that angina is independently associated with cardiovascular outcome including cardiovascular death and myocardial infarction (MI),<sup>6–9</sup> others have not found a compelling association between angina and

From Brigham and Women's Hospital, Boston, MA (A.E., D.L.B., J.G., B.M.S.); Harvard Medical School, Boston, MA (A.E., D.L.B., J.G., B.M.S.); Département Hospitalo-Universitaire FIRE (Fibrosis, Inflammation, Remodeling), Université Paris-Diderot, Sorbonne Paris Cité, Paris, France (P.G.S.); FACT (French Alliance for Cardiovascular Clinical Trials), Hôpital Bichat, Assistance Publique-Hôpitaux de Paris, Paris, France (P.G.S.); INSERM U-1148, Paris, France (P.G.S.); National Heart and Lung Institute, Royal Brompton Hospital, Imperial College, London, United Kingdom (P.G.S.); University of Michigan Health System, Ann Arbor, MI (K.A.E.); Department of Medicine, Tokai University School of Medicine, Isehara, Japan (S.G.); Heart and Vascular Center, University of North Carolina at Chapel Hill, NC (S.C.S.); Duke University Medical Center, Durham, NC (E.M.O.).

An accompanying Appendix S1 is available at <http://jaha.ahajournals.org/content/5/10/e004080/DC1/embed/inline-supplementary-material-1.pdf>

\*The members of the REACH Registry Investigators are given in Appendix S1.

**Correspondence to:** Benjamin M. Scirica, MD, MPH, TIMI Study Group, Cardiovascular Division, Brigham and Women's Hospital and Harvard Medical School, 75 Francis St, Boston, MA 02115. E-mail: bscirica@partners.org

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“hard” cardiovascular end points.<sup>10,12</sup> In addition, large-scale trials have shown that the alleviation of anginal symptoms by pharmacological treatment or by coronary revascularization improves quality of life measures but does not tend to decrease the rates of future MI or mortality.<sup>13</sup> Furthermore, in outpatients with stable coronary artery disease (CAD), most cardiovascular events actually occur in patients without prior angina.<sup>9</sup> We therefore aimed to examine the independent association between angina at baseline and future cardiovascular events in patients with stable CAD who were included in a large international outpatient registry.

## Methods

### Study Design

The design of the Reduction of Atherothrombosis for Continued Health (REACH) registry has been previously published.<sup>14,15</sup> In brief, REACH is an outpatient registry of patients with either stable symptomatic vascular disease (CAD, cerebrovascular disease, or peripheral artery disease) or with multiple atherosclerotic risk factors. Patients from 3647 centers in 29 countries were enrolled between 2003 and 2004 and treated according to best judgment and practices of their primary care physicians. Detailed information was collected at baseline, with subsequent annual follow-up on a longitudinal outpatient basis at 1, 2, 3, and 4 years. Final database lock was in April 2009. In each country, 10% of all sites underwent data control audits and were monitored for source documentation and accuracy of all case report forms. The protocol was approved by local institutional review boards, and each enrolled patient was required to provide a signed informed consent.

In the current analysis, we included patients with documented CAD at baseline who completed at least 1 postbaseline follow-up visit and were enrolled at centers that participated in the 4-year REACH follow-up study.<sup>16</sup> CAD was defined as having 1 or more of the following: stable angina, history of unstable angina (UAP), previous MI, history of percutaneous coronary intervention (PCI), or history of coronary artery bypass graft surgery (CABG). Patients without CAD at baseline were excluded from the current analysis. A sensitivity analysis included only patients who had a previous MI, history of PCI, or a history of CABG.

### Stable Angina

Patients were stratified by the presence of stable angina symptoms at baseline. Stable angina at baseline was documented by the treating physician using the case report form and was defined as angina necessitating episodic or permanent medication use. The last episode of angina was

documented in the case report form as either occurring  $\leq 1$  year prior to baseline or  $>1$  year prior to baseline.

### Clinical End Points

Data regarding events were collected locally and forwarded to the central research organization. The primary end point was a composite of cardiovascular death, MI, or stroke. The rate of each end point was calculated and stratified by angina status at baseline. End points were not adjudicated. Cardiovascular death included fatal stroke, fatal MI, or other cardiovascular death. Other cardiovascular death included other death of cardiac origin; pulmonary embolism; any sudden death including unobserved and unexpected death (eg, death while sleeping) unless proven otherwise by autopsy; death following a vascular operation, vascular procedure, or amputation; death attributed to heart failure; death following a visceral or limb infarction; and any other death that could not be definitely attributed to a nonvascular cause or hemorrhage. Any MI or stroke followed by a death whatever the cause in the next 28 days was considered to be a fatal MI or fatal stroke.

Secondary end points included all-cause death, heart failure, UAP, cardiovascular hospitalizations, and coronary revascularization. Heart failure was defined as symptoms of heart failure leading to hospitalization. Cardiovascular hospitalization consisted of hospitalization for UAP, transient ischemic attack, worsening of claudication related to peripheral artery disease, other ischemic arterial event, coronary revascularization (PCI or CABG), carotid surgery, carotid angioplasty/stenting, amputation affecting lower limbs, peripheral bypass graft, or angioplasty/stenting for peripheral artery disease. Complete definitions of other clinical end points have been previously described.<sup>15</sup>

The total number of the primary end-point events (total cardiovascular death, MI, or stroke), as well as the total cardiovascular hospitalizations and total coronary revascularizations during follow-up, were also examined and stratified by angina status at baseline.

### Statistical Analysis

Continuous variables are presented as mean  $\pm$  SD, and categorical variables as frequencies and percentages. Cumulative incidence for cardiovascular death, MI, or stroke was examined using the Kaplan–Meier approach. Cox proportional hazard models were used to examine whether angina is associated with cardiovascular death, MI, or stroke. All-cause death was also examined using the Kaplan–Meier approach. Incidence of heart failure, UAP, cardiovascular hospitalizations, and coronary revascularizations are presented as crude rates at 45 months. Logistic regression models were used to

**Table 1.** Baseline Characteristics

| Characteristic                                                         | Angina<br>(n=13 619) | No Angina<br>(n=12 540) | Total<br>(n=26 159) | P-Value |
|------------------------------------------------------------------------|----------------------|-------------------------|---------------------|---------|
| Age, y—mean (SD)                                                       | 68.5 (10.0)          | 67.5 (10.0)             | 68.0 (10.0)         | <0.001  |
| >75 y                                                                  | 3788 (27.9)          | 3094 (24.8)             | 6882 (26.4)         | <0.001  |
| Men                                                                    | 9061 (66.6)          | 9449 (75.4)             | 18 510 (70.8)       | <0.001  |
| Region*                                                                |                      |                         |                     | <0.001  |
| North America                                                          | 4430 (47.6)          | 4881 (52.4)             | 9331 (35.7)         |         |
| Latin America                                                          | 286 (37.2)           | 483 (62.8)              | 769 (2.9)           |         |
| Western Europe                                                         | 4367 (51.6)          | 4102 (48.4)             | 8469 (32.4)         |         |
| Eastern Europe                                                         | 2276 (71.4)          | 912 (28.6)              | 3188 (12.2)         |         |
| Middle East                                                            | 147 (44.8)           | 181 (55.2)              | 328 (1.2)           |         |
| Asia Pacific                                                           | 2113 (51.6)          | 1981 (48.4)             | 4094 (15.7)         |         |
| Hypertension                                                           | 11 316 (83.1)        | 9541 (76.1)             | 20 857 (79.7)       | <0.001  |
| Hypercholesterolemia                                                   | 10 076 (74.0)        | 9666 (77.1)             | 19 742 (75.5)       | <0.001  |
| Diabetes mellitus                                                      | 5308 (39.0)          | 4526 (36.1)             | 9834 (37.6)         | <0.001  |
| Obesity (BMI ≥30)                                                      | 3974 (29.4)          | 3391 (27.3)             | 7365 (28.4)         | <0.001  |
| Current smoker at baseline                                             | 1778 (13.5)          | 1605 (13.2)             | 3383 (13.3)         | <0.001  |
| Prior ischemic event                                                   | 7042 (52.4)          | 8298 (66.7)             | 15 340 (59.3)       | <0.001  |
| Prior MI                                                               | 6010 (44.6)          | 7933 (63.7)             | 13 943 (53.8)       | <0.001  |
| Prior PCI                                                              | 5015 (37.1)          | 5975 (47.9)             | 10 990 (42.2)       | <0.001  |
| Prior CABG                                                             | 3790 (28.0)          | 4579 (36.6)             | 8369 (32.1)         | <0.001  |
| Heart failure                                                          | 3016 (22.5)          | 2007 (16.2)             | 5023 (19.5)         | <0.001  |
| Atrial fibrillation                                                    | 1780 (13.3)          | 1304 (10.5)             | 3084 (12.0)         | <0.001  |
| CVD at baseline                                                        | 2732 (20.1)          | 1670 (13.3)             | 4402 (16.8)         | <0.001  |
| PAD at baseline                                                        | 1633 (12.0)          | 1183 (9.4)              | 2816 (10.8)         | <0.001  |
| Polyvascular disease                                                   | 3888 (28.6)          | 2622 (20.9)             | 6510 (24.9)         | <0.001  |
| Aortic valve stenosis                                                  | 588 (4.5)            | 411 (3.4)               | 999 (4.0)           | <0.001  |
| ≥1 Antithrombotic drug                                                 | 8334 (92.2)          | 7612 (94.8)             | 15 946 (93.4)       | <0.001  |
| ≥1 Lipid-lowering drug                                                 | 7271 (80.6)          | 6850 (85.3)             | 14 121 (82.8)       | <0.001  |
| Medication at 4 y                                                      |                      |                         |                     |         |
| Statins                                                                | 6879 (76.4)          | 6562 (81.9)             | 13 441 (79.0)       | <0.001  |
| ACE inhibitor or ARB                                                   | 6348 (70.3)          | 5670 (70.7)             | 12 018 (70.5)       | <0.001  |
| β-Blocker                                                              | 5875 (65.1)          | 5265 (65.7)             | 11 140 (65.4)       | <0.001  |
| Diuretic                                                               | 4197 (46.7)          | 3359 (42.1)             | 7556 (44.5)         | <0.001  |
| Calcium channel blocker                                                | 3530 (39.3)          | 2620 (32.8)             | 6150 (36.3)         | <0.001  |
| Nitrate or other antianginal†                                          | 3642 (40.5)          | 2194 (27.6)             | 5836 (34.4)         | <0.001  |
| Any β-blockers, calcium channel blocker, nitrate, or other antianginal | 7941 (87.9)          | 6769 (84.3)             | 14 710 (86.2)       | <0.001  |
| Aspirin+another antiplatelet drug                                      | 1248 (13.8)          | 1110 (13.8)             | 2358 (13.8)         | <0.001  |
| Oral anticoagulant drug                                                | 1206 (13.3)          | 1113 (13.8)             | 2319 (13.6)         | <0.001  |

Data shown are n (%) unless otherwise indicated. ACE indicates angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; CABG, coronary artery bypass graft; CVD, cerebrovascular disease; MI, myocardial infarction; PAD, peripheral arterial disease; PCI, percutaneous coronary intervention.

\*Percentages are for each region except for the total population. P-value is calculated using  $\chi^2$ .

†Nitrate as a chronic treatment and not if given episodically. Treatment could have been prescribed for other indications (eg, heart failure). Other antianginal includes molsidomine and nicorandil.

examine the association between angina and heart failure, UAP, cardiovascular hospitalizations, and coronary revascularizations. The variables included in all multivariate models were based on the previously validated REACH model for recurrent cardiovascular events.<sup>17</sup> This model included the following variables: age, sex, current smoker, history of diabetes mellitus, body mass index  $<20$  (calculated as weight in  $\text{kg}/\text{m}^2$ ), ischemic event ( $\leq 1$  year,  $>1$  year, or no ischemic event), vascular disease status (polyvascular disease defined as CAD with concomitant cerebrovascular disease/peripheral artery disease, or single vascular disease [ie, only CAD]), congestive heart failure, atrial fibrillation/flutter, aspirin (at baseline), statins (at baseline), and Eastern Europe and Middle East, or Japan versus other regions (geographic regions were collapsed into higher [Eastern Europe and Middle East] and lower [Japan] risk locations). The total event counts of the composite of cardiovascular death, MI, or stroke, as well as cardiovascular hospitalization and coronary revascularization were fitted by the negative binomial regression model after accounting for varying lengths of individual's total follow-up time as an offset parameter as well as other baseline confounding factors. Results are reported in terms of adjusted incidence rate ratio (RR) and corresponding 95% CI from this model. Similar statistical methods were performed in the sensitivity analysis.

Patients were further stratified to 4 risk-groups according to the REACH model for recurrent cardiovascular events.<sup>17</sup> This model includes traditional risk factors, burden of disease, lack of treatment, and geographic location,<sup>17</sup> whereas angina status was not a candidate variable in the derivation of the REACH model. Cox proportional hazard models were used to examine whether angina is associated with cardiovascular death, MI, or stroke in the different risk-groups. Hazard ratios (HRs) are reported as unadjusted given the stratification by the REACH model, which already includes the adjustment variables.

Statistical significance was considered as a 2-sided probability of  $<0.05$ . Statistical analyses were performed using SAS version 9 (SAS Institute, Cary, NC).

## Results

### Patient Population

Of the 45 227 patients who were included in the REACH 4-year follow-up study, 44 736 patients had data on angina status at baseline. Of these, 18 577 patients without CAD were excluded from the current analysis. Thus, 26 159 patients with CAD were included and were followed for a median of 43.5 months (interquartile range 31.3–45.0). The patients' mean age was 68 years (SD 10) and 70.8% were men. Hypertension (79.7%) and hypercholesterolemia (75.5%)

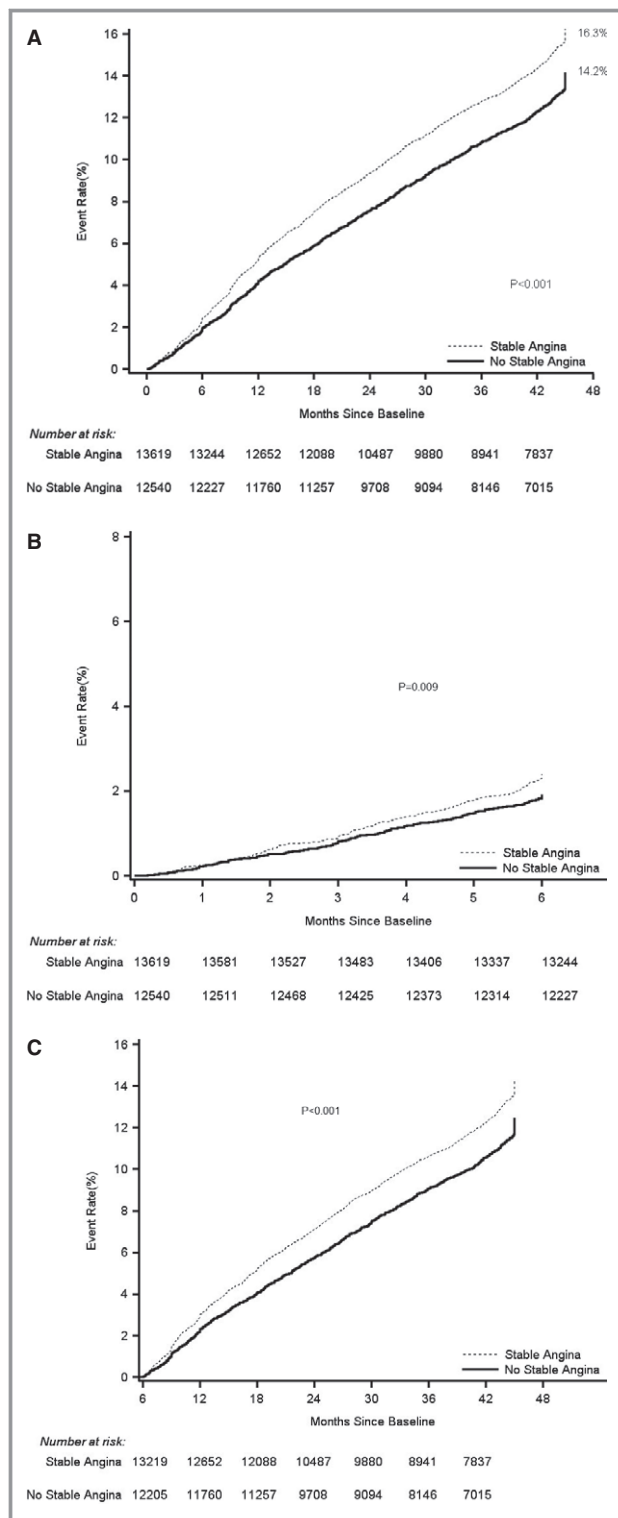
were very common. More than half of the patients had a prior MI, a quarter had polyvascular disease, and a fifth of the patients had prior heart failure (Table 1).

Out of the 26 159 patients with CAD, 13 619 (52%) have had angina prior to baseline and 12 540 (48%) did not have angina prior to baseline. Compared with patients without angina, patients with angina were more likely to be older, female, had more heart failure and polyvascular disease, but had fewer ischemic events and coronary revascularization procedures (PCI or CABG) prior to baseline ( $P<0.001$  for each; Table 1). Angina was more commonly reported in Eastern Europe and less in Latin America (Table 1). Patients with angina at baseline were more likely to be treated with either  $\beta$ -blockers, calcium channel blockers, or nitrates at 4 years of follow-up, but less likely to be treated with statins ( $P<0.001$  for each; Table 1).

### Angina and Cardiovascular Events

During follow-up, the rate of the composite primary end point of cardiovascular death, MI, or stroke was 16.3% in patients with angina and 14.2% in patients without angina (unadjusted HR 1.19, 95% CI 1.11–1.27,  $P<0.001$ ; Figure 1). In a landmark analysis, this difference in the rate of the primary end point between patients with versus without angina became statistically significant after 6 months from baseline and it remained significant at 4 years (Figure 1). The rate of each individual component of the composite primary end point was also higher among patients with angina (Table 2). After adjusting for multiple variables (Tables 2 and 3), the association between angina and the composite of cardiovascular death, MI, or stroke was attenuated (adjusted HR 1.06, 95% CI 0.99–1.14,  $P=0.11$ ), and so was the association between angina and each of the individual components (Table 2). An analysis of the total number of events during follow-up demonstrated that angina was significantly, albeit weakly, associated with the total number of the primary end-point events (rate ratio 1.08, 95% CI 1.01–1.16,  $P=0.03$ ; Table 4).

During follow-up, nearly a quarter of the patients were hospitalized due to cardiovascular causes (Table 2). Compared with patients without angina, patients with angina had higher rates of heart failure (8.0% versus 11.0%,  $P<0.001$ ), cardiovascular hospitalization (21.0% versus 26.9%,  $P<0.001$ ), and coronary revascularization (10.0% versus 11.4%,  $P<0.001$ ). After adjusting for multiple variables, the association between angina and each of these end points remained significant. Compared with patients without angina, patients with angina had a 17% higher relative risk for heart failure ( $P=0.002$ ), a 29% higher relative risk for cardiovascular hospitalization ( $P<0.001$ ), and a 23% higher relative risk for coronary revascularization ( $P<0.001$ ; Table 2). In addition, angina was associated with the total number of cardiovascular



**Figure 1.** Kaplan–Meier rates of the primary composite end point of cardiovascular death, MI, or stroke by presence of angina at baseline in the overall period (A), and landmark analysis during the first 6 months (B) and during 6 months to 4 years (C). The Kaplan–Meier curves demonstrate a higher rate of the composite primary end point of cardiovascular death, MI, or stroke in patients with angina, as compared to patients without angina. MI indicates myocardial infarction.

hospitalizations, as well as the total number of coronary revascularizations (Table 4).

No significant difference in the association between angina and the primary end point was observed in subgroups by age, sex, time from ischemic event, current smoking, heart failure, or prior coronary revascularization (PCI or CABG) (Figure 2). However, a significant interaction was observed between angina and the primary end point by polyvascular disease status (adjusted HR 0.99, 95% CI 0.88–1.12, in patients with polyvascular disease; adjusted HR 1.13, 95% CI 1.03–1.24, in patients without polyvascular disease;  $P$ -interaction=0.015). In addition, a marginal interaction was observed between angina and the primary end point by diabetes mellitus status (adjusted HR 0.99, 95% CI 0.89–1.10, in patients with diabetes mellitus; adjusted HR 1.13, 95% CI 1.02–1.25, in patients without diabetes mellitus;  $P$ -interaction=0.08).

No association was observed between angina and the primary end point by the time of last angina episode. In patients who had anginal symptoms during  $\leq 1$  year prior to baseline ( $n=4085$ ), the rate of the primary end point was 16.1%, whereas in patients who have had the last anginal symptoms  $>1$  year prior to baseline ( $n=9534$ ), the rate of the primary end point was 16.5% (adjusted HR angina versus no angina 1.06, 95% CI 0.96–1.18,  $P=0.26$ ; 1.06, 95% CI 0.98–1.15,  $P=0.14$ , respectively).

Stratifying the patients to quartiles according to the REACH risk score for recurrent cardiovascular events,<sup>17</sup> patients in higher quartiles had higher rates of the primary end point of cardiovascular death, MI, or stroke (Figure 3). Interestingly, angina was associated with the primary end point in lower-risk patients (unadjusted HR angina versus no angina 1.17, 95% CI 0.98–1.41,  $P=0.09$  in quartile I; 1.21, 95% CI 1.02–1.43,  $P=0.03$  in quartile II), whereas it was not associated with the primary end point in patients at higher risk for recurrent cardiovascular events (unadjusted HR angina versus no angina 0.95, 95% CI 0.84–1.09,  $P=0.47$  in quartile III; 0.98, 95% CI 0.87–1.10,  $P=0.69$  in quartile IV; Figure 3).

In a sensitivity analysis that included only patients with previous MI, history of PCI, or CABG ( $n=21\,344$ ), consistent qualitative results for the association between angina and future cardiovascular events were obtained (adjusted HR for the primary end point 1.08, 95% CI 1.00–1.17,  $P=0.07$ ; Table 5).

## Discussion

This study from a large international registry demonstrates several observations. First, patients with stable CAD who have angina substantially differ in their baseline characteristics, atherosclerotic risk factors, concomitant cardiovascular

**Table 2.** Clinical End Points by Angina Status at Baseline

| End Point                               | Angina (n=13 619)<br>4-Y KM Rate, n (%) | No Angina (n=12 540)<br>4-Y KM Rate, n (%) | Unadjusted HR (95% CI) | P-Value | Adjusted HR* (95% CI) | P-Value |
|-----------------------------------------|-----------------------------------------|--------------------------------------------|------------------------|---------|-----------------------|---------|
| CVD, MI, or stroke                      | 1911 (16.3)                             | 1479 (14.2)                                | 1.19 (1.11–1.27)       | <0.001  | 1.06 (0.99–1.14)      | 0.11    |
| CVD                                     | 964 (8.4)                               | 781 (7.6)                                  | 1.12 (1.02–1.23)       | 0.02    | 0.95 (0.86–1.05)      | 0.33    |
| MI                                      | 541 (4.8)                               | 428 (4.2)                                  | 1.16 (1.02–1.31)       | 0.03    | 1.14 (1.00–1.31)      | 0.06    |
| Stroke                                  | 606 (5.4)                               | 406 (4.1)                                  | 1.37 (1.21–1.55)       | <0.001  | 1.19 (1.04–1.37)      | 0.01    |
| Any-cause death                         | 1473 (12.6)                             | 1260 (12.1)                                | 1.06 (0.99–1.15)       | 0.11    | 0.93 (0.85–1.01)      | 0.07    |
| CVD, or MI                              | 1429 (12.3)                             | 1156 (11.1)                                | 1.13 (1.04–1.22)       | 0.002   | 1.01 (0.93–1.10)      | 0.83    |
| Heart failure <sup>†</sup>              | 1498 (11.0)                             | 1006 (8.0)                                 | 1.42 (1.30–1.54)       | <0.001  | 1.17 (1.06–1.28)      | 0.002   |
| CVD, or heart failure <sup>†</sup>      | 2167 (15.9)                             | 1578 (12.6)                                | 1.31 (1.23–1.41)       | <0.001  | 1.08 (1.00–1.17)      | 0.06    |
| Unstable angina <sup>†</sup>            | 2073 (15.2)                             | 1334 (10.6)                                | 1.51 (1.40–1.62)       | <0.001  | 1.40 (1.29–1.52)      | <0.001  |
| CVH <sup>†</sup>                        | 3664 (26.9)                             | 2637 (21.0)                                | 1.38 (1.31–1.46)       | <0.001  | 1.29 (1.21–1.38)      | <0.001  |
| Coronary revascularization <sup>†</sup> | 1547 (11.4)                             | 1258 (10.0)                                | 1.15 (1.06–1.24)       | 0.001   | 1.23 (1.13–1.34)      | <0.001  |

CAD indicates coronary artery disease; CVD, cardiovascular death; CVH, cardiovascular hospitalization; HR, hazard ratio; KM, Kaplan–Meier; MI, myocardial infarction.

\*Adjusted for age, sex, current smoker, history of diabetes mellitus, body mass index <20, ischemic event ≤1 year, ischemic event >1 year, polyvascular disease (CAD+ cerebrovascular disease/peripheral arterial disease), congestive heart failure, atrial fibrillation/flutter, aspirin (at baseline), statins (at baseline), and region.

<sup>†</sup>Event rates are crude rates at 45 months. Logistic regression models were used. Data presented are odds ratio (95% CI).

diseases, and medications use from patients without angina. Second, patients with angina have higher rates of future cardiovascular events, including cardiovascular death and MI. Third, the independent association between angina and cardiovascular events was attenuated after a rigorous adjustment for baseline comorbidities. Specifically, angina was only weakly associated with cardiovascular death, MI, or stroke,

but the association with heart failure, cardiovascular hospitalization, and coronary revascularizations remained significant after multivariable adjustment. Finally, stratifying the patients by their risk of recurrent cardiovascular events, angina seemed to be associated with cardiovascular death, MI, or stroke in lower-risk patients, but not in high-risk patients.

**Table 3.** Cox-Proportional Hazard Model for Predictors of Cardiovascular Death, Myocardial Infarction, or Stroke

| Variable                                                | Adjusted HR (95% CI) | $\chi^2$ | P-Value |
|---------------------------------------------------------|----------------------|----------|---------|
| Age, per 1-y increase                                   | 1.035 (1.031–1.039)  | 284.3    | <0.001  |
| Congestive heart failure, yes vs no                     | 1.75 (1.62–1.89)     | 191.1    | <0.001  |
| Polyvascular disease vs single vascular disease         | 1.52 (1.41–1.64)     | 118.5    | <0.001  |
| History of diabetes mellitus, yes vs no                 | 1.44 (1.34–1.56)     | 100.6    | <0.001  |
| Ischemic event ≤1 y vs no ischemic event                | 1.67 (1.50–1.85)     | 87.7     | <0.001  |
| Ischemic event >1 y vs no ischemic event                | 1.48 (1.36–1.61)     | 85.6     | <0.001  |
| Statins, yes vs no                                      | 0.74 (0.68–0.80)     | 57.0     | <0.001  |
| Japan vs other regions                                  | 0.61 (0.53–0.72)     | 39.6     | <0.001  |
| Current smoker vs former or never                       | 1.37 (1.24–1.52)     | 35.9     | <0.001  |
| Eastern Europe and Middle East vs other regions         | 1.27 (1.16–1.40)     | 23.1     | <0.001  |
| Atrial fibrillation/flutter, yes vs no                  | 1.24 (1.13–1.36)     | 19.4     | <0.001  |
| Sex, male vs female                                     | 1.12 (1.03–1.21)     | 7.7      | 0.005   |
| BMI <20, yes vs no                                      | 1.28 (1.06–1.54)     | 6.8      | 0.009   |
| Aspirin, yes vs no                                      | 0.93 (0.86–1.01)     | 3.0      | 0.08    |
| History of stable angina vs no history of stable angina | 1.06 (0.99–1.14)     | 2.6      | 0.11    |

BMI indicates body mass index; HR indicates hazard ratio.

**Table 4.** Total Events During 4 Years by Angina Status at Baseline

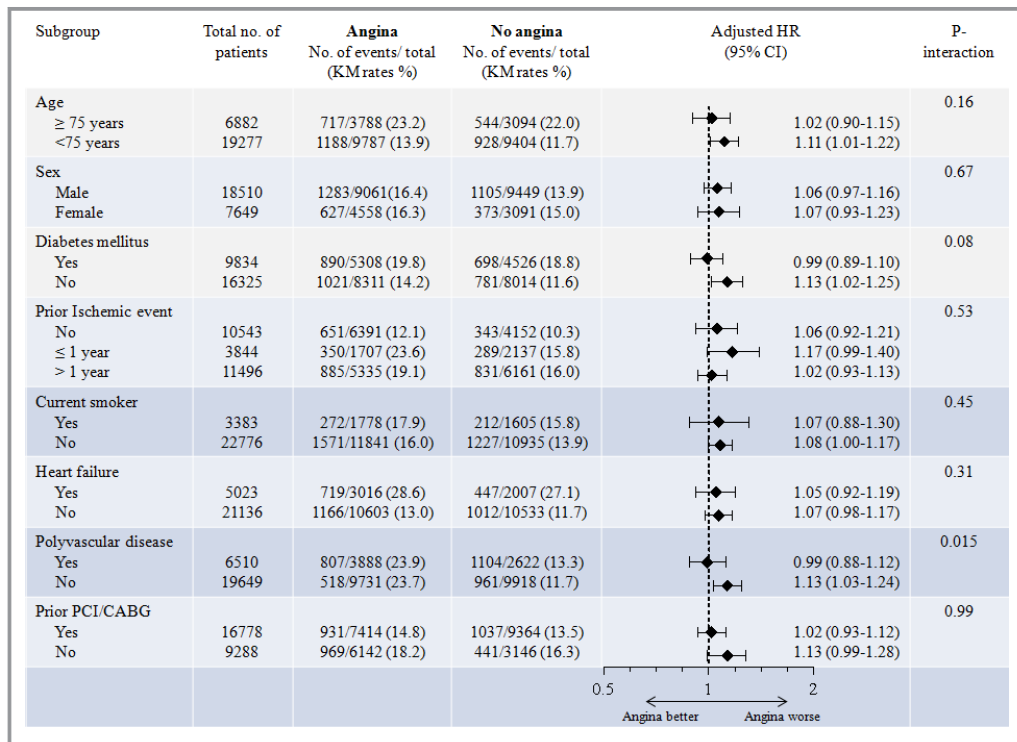
| Total End Point            | Angina (n=13 619)<br>Total Events, n | No Angina (n=12 540)<br>Total Events, n | Unadjusted RR (95% CI) | P-Value | Adjusted RR* (95% CI) | P-Value |
|----------------------------|--------------------------------------|-----------------------------------------|------------------------|---------|-----------------------|---------|
| CVD, MI, or stroke         | 2176                                 | 1649                                    | 1.21 (1.12–1.29)       | <0.001  | 1.08 (1.01–1.16)      | 0.03    |
| CVH                        | 7488                                 | 5065                                    | 1.36 (1.28–1.44)       | <0.001  | 1.27 (1.20–1.35)      | <0.001  |
| Coronary revascularization | 1814                                 | 1499                                    | 1.11 (1.03–1.20)       | 0.006   | 1.19 (1.10–1.29)      | <0.001  |

BMI indicates body mass index; CAD, coronary artery disease; CVD, cardiovascular death; CVH, cardiovascular hospitalization; MI, myocardial infarction; RR, rate ratio.

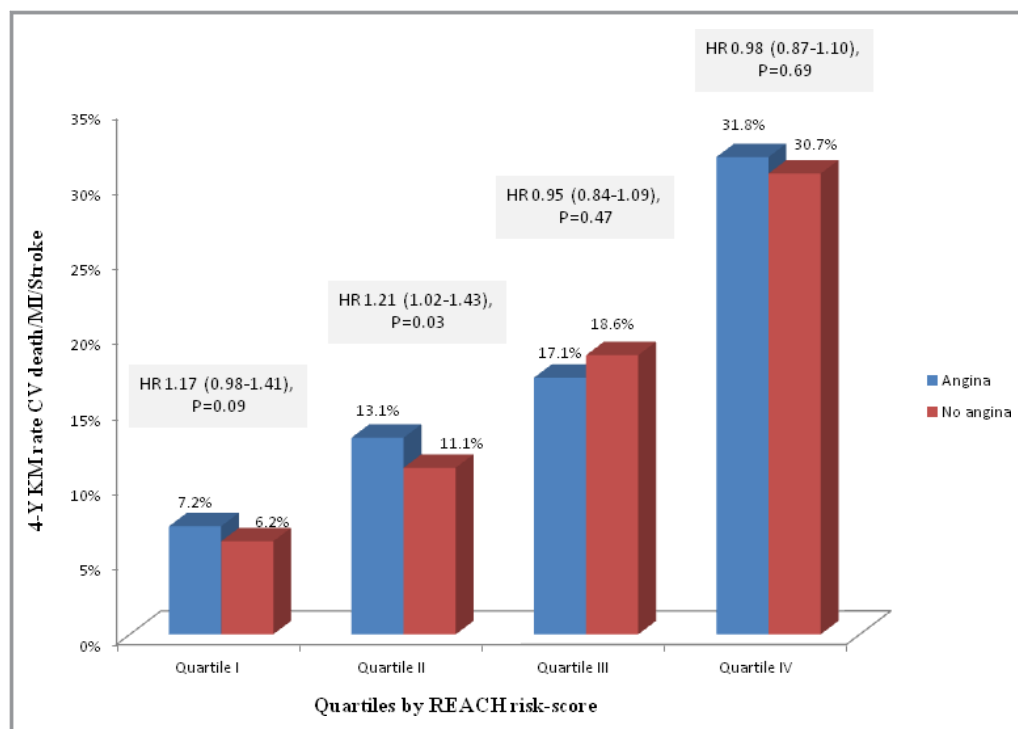
\*Adjusted for age, sex, current smoker, history of diabetes mellitus, BMI <20, ischemic event (≤1 year, ischemic event >1 year), polyvascular disease (CAD+ cerebrovascular disease/peripheral arterial disease), congestive heart failure, atrial fibrillation/flutter, aspirin (at baseline), statins (at baseline), and region.

In patients with CAD included in the REACH registry, prior cardiovascular disease, particularly prior ischemic events, heart failure, cerebrovascular disease, and peripheral artery disease were common and found to be robust and independent markers of subsequent cardiovascular end points, even more so than traditional atherosclerotic risk factors<sup>18,19</sup> (Table 3). Indeed, several prior studies have examined angina-associated risk with cardiovascular events after adjusting solely for traditional risk factors such as diabetes mellitus,

hypertension, and hyperlipidemia and thus their results might be different based on the degree of multivariable modeling.<sup>6–8</sup> Our results are consistent with findings from several prior studies such as the Bypass Angioplasty Revascularization Investigation 2 Diabetes trial (BARI 2D)<sup>10</sup> and the Heart and Soul study,<sup>12</sup> in which angina was not or was very weakly associated with future cardiovascular death, MI, or stroke. Nevertheless, a recent analysis from the CLARIFY registry<sup>9</sup> demonstrated a consistent association between angina, with



**Figure 2.** Rates and adjusted hazard ratios (95% CI) of the primary composite end point of cardiovascular death, MI, or stroke, in patients with and without angina at baseline by subgroups. Adjustment variables: age, sex, current smoker, history of diabetes mellitus, body mass index <20, ischemic event (≤1 year, ischemic event >1 year), polyvascular disease (CAD+ cerebrovascular disease/peripheral arterial disease), congestive heart failure, atrial fibrillation/flutter, aspirin (at baseline), statins (at baseline), and region. No significant interaction in the association between angina and the primary end point was observed in subgroups by age, sex, time from ischemic event, current smoking, heart failure, or prior PCI/CABG. However, a significant interaction was observed by polyvascular disease status and a marginal interaction was observed by diabetes mellitus status. CABG, coronary artery bypass graft surgery; CAD, coronary artery disease; HR, hazard ratio; KM, Kaplan–Meier; MI, myocardial infarction; PCI, percutaneous coronary intervention.



**Figure 3.** Kaplan–Meier rates and unadjusted hazard ratios (95% CI) of the primary composite end point of CVD, MI, or stroke in patients with and without angina, stratified by patients' risk according to the REACH risk score for recurrent Cardiovascular events.<sup>17</sup> Data were available for 24 315 patients. Stratifying the patients to quartiles according to the REACH risk score for recurrent Cardiovascular events, patients in higher quartiles had higher rates of the primary end point of CVD, MI, or stroke. Angina was associated with the primary end point in lower-risk patients, whereas it was not associated with the primary end point in patients at higher risk of recurrent Cardiovascular events. CVD indicates cardiovascular death; HR, hazard ratio; KM, Kaplan–Meier; MI, myocardial infarction.

or without ischemia, and cardiovascular death or MI, even after adjusting for the REACH risk score. Interestingly, compared with CLARIFY, the patients included in this analysis from REACH had a higher-risk profile and had a 2-fold annual rate of the composite end point of cardiovascular death, MI, or stroke and of each of the individual components. Thus, it is not clear whether angina has different prognostication according to the patient's risk: While it may be independently associated with “hard” cardiovascular events in patients at lower risk, it is perhaps only a surrogate for more advanced disease in patients at higher risk. Interestingly, by stratifying the patients by their risk of recurrent cardiovascular events, we indeed demonstrated that angina might be associated with “hard” cardiovascular events only in patients at lower risk and not in patients at higher risk. In addition, our subgroup analysis also demonstrated that angina was independently associated with cardiovascular death, MI, or stroke, in several lower-risk groups such as patients without diabetes mellitus and without other vascular beds involved besides CAD. Nevertheless, the complex association between angina and “hard” cardiovascular end points should be further delineated in future research.

The clinical diagnosis of stable angina has been linked historically to the classic chronic condition caused by epicardial coronary stenosis.<sup>2</sup> Nevertheless, stable angina includes other less common presentations such as microvascular angina, vasospastic angina, and angina caused by ischemic cardiomyopathy.<sup>2</sup> In each of these conditions, myocardial ischemia is present, albeit each with a different burden and mechanism. The association between angina, ischemia, and cardiovascular outcome is complex and is probably not consistent across all patients. In the BARI 2D trial, among patients with diabetes mellitus, myocardial ischemia, rather than anginal symptoms, appeared to be prognostic for future cardiovascular events.<sup>10</sup> These results are consistent with our findings in diabetic patients in whom angina by itself was not predictive of cardiovascular death, MI, or stroke. Interestingly, in the CLARIFY registry, patients who had only ischemia without angina had adjusted risk for cardiovascular outcomes comparable to patients without both, whereas patients who had both angina and ischemia had the worst outcome.<sup>9</sup> Interestingly, more than half of the cardiovascular death and MI events in the CLARIFY study occurred in patients without detectable ischemia or angina at

**Table 5.** Sensitivity Analysis—Clinical End Points by Angina Status at Baseline of Patients With Previous MI, History of PCI or CABG

| End Point                               | Angina (n=9415)<br>4-Y KM Rate, n (%) | No Angina (n=11 929)<br>4-Y KM Rate, n (%) | Unadjusted HR (95% CI) | P-Value | Adjusted HR* (95% CI) | P-Value |
|-----------------------------------------|---------------------------------------|--------------------------------------------|------------------------|---------|-----------------------|---------|
| CVD, MI, or stroke                      | 1338 (16.6)                           | 1401 (14.4)                                | 1.21 (1.12–1.30)       | <0.001  | 1.08 (1.00–1.17)      | 0.07    |
| CVD                                     | 691 (8.7)                             | 736 (7.5)                                  | 1.18 (1.06–1.30)       | 0.002   | 1.00 (0.90–1.12)      | 0.94    |
| MI                                      | 427 (5.4)                             | 415 (4.3)                                  | 1.30 (1.13–1.49)       | <0.001  | 1.20 (1.04–1.38)      | 0.01    |
| Stroke                                  | 366 (4.7)                             | 379 (4.0)                                  | 1.22 (1.05–1.41)       | 0.007   | 1.11 (0.96–1.30)      | 0.17    |
| Any-cause death                         | 1048 (13.1)                           | 1199 (12.1)                                | 1.09 (1.01–1.19)       | 0.04    | 0.97 (0.89–1.06)      | 0.48    |
| CVD, or MI                              | 1056 (13.2)                           | 1100 (11.1)                                | 1.21 (1.11–1.32)       | <0.001  | 1.06 (0.97–1.16)      | 0.19    |
| Heart failure <sup>†</sup>              | 1063 (11.3)                           | 953 (8.0)                                  | 1.47 (1.34–1.61)       | <0.001  | 1.18 (1.06–1.31)      | 0.002   |
| CVD, or heart failure <sup>†</sup>      | 1534 (16.3)                           | 1492 (12.5)                                | 1.36 (1.26–1.47)       | <0.001  | 1.12 (1.02–1.22)      | 0.02    |
| Unstable angina <sup>†</sup>            | 1573 (16.7)                           | 1175 (9.9)                                 | 1.84 (1.69–1.99)       | <0.001  | 1.68 (1.54–1.83)      | <0.001  |
| CVH <sup>†</sup>                        | 2704 (28.7)                           | 2432 (20.4)                                | 1.57 (1.48–1.68)       | <0.001  | 1.48 (1.39–1.59)      | <0.001  |
| Coronary revascularization <sup>†</sup> | 1258 (13.4)                           | 1198 (10.0)                                | 1.38 (1.27–1.50)       | <0.001  | 1.39 (1.27–1.52)      | <0.001  |

CABG indicates coronary artery bypass graft surgery; CAD, coronary artery disease; CVD, cardiovascular death; CVH, cardiovascular hospitalization; HR, hazard ratio; KM, Kaplan–Meier; MI, myocardial infarction; PCI, percutaneous coronary intervention.

\*Adjusted for age, sex, current smoker, history of diabetes mellitus, body mass index <20, ischemic event (≤1 year, ischemic event >1 year), polyvascular disease (CAD+ cerebrovascular disease/peripheral arterial disease), congestive heart failure, atrial fibrillation/flutter, aspirin (at baseline), statins (at baseline), and region.

<sup>†</sup>Event rates are crude rates at 45 months. Logistic regression models were used. Data presented are odds ratio (95% CI).

baseline. In our study, ischemia status during follow-up was not available and could not be accounted for. Nevertheless, angina, regardless of ischemia status, was independently associated with more cardiovascular hospitalization and coronary revascularization procedures. Of interest, the association between angina and revascularization, although statistically significant, was not robust, perhaps reflecting the fact that the majority of patients with angina (70%) had their last angina symptoms >1 year prior to baseline, thus reducing the clinical impetus for revascularization. In addition, this may also reflect regional differences in the treatment of angina with revascularization.

Prior studies have demonstrated that the major benefit of optimal medical therapy or revascularization in patients with stable CAD is the relief of anginal symptoms rather than a reduction in cardiovascular death or MI.<sup>13,20,21</sup> Thus, the relationship between angina, ischemia, and future cardiovascular events remains an area of debate.<sup>22–24</sup> The ongoing International Study of Comparative Health Effectiveness With Medical and Invasive Approaches (ISCHEMIA trial, NCT 01471522) might address this intricate relationship. Regardless, in this analysis from REACH, patients with angina have greater healthcare utilization with higher rates of total hospitalizations and revascularizations and therefore present an opportunity to improve care and reduce costs.

## Limitations

This analysis is based on a registry, which has inherent limitations. The end points in the study were not adjudicated. Analysis of patients with angina might have introduced a

selection bias. Angina was ascertained by the investigator's report in the electronic case report form at baseline, and patient self-reporting data were not available. Data regarding the exact date of last anginal episode, grading of angina severity, or change in angina over time were not available. In addition, data on the presence of objective coronary ischemia at baseline, or on left ventricular ejection fraction were also not available. Logistic regression models were used to examine the secondary end points since the exact time of event was not available for all subjects.

## Conclusions

Patients with stable CAD and angina have higher rates of future cardiovascular events compared with patients without angina. After accounting for baseline differences, angina was only weakly associated with cardiovascular death, MI, or stroke, but was significantly associated with heart failure, cardiovascular hospitalization, and coronary revascularization.

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# SUPPLEMENTAL MATERIAL

## REACH Registry Investigators:

**Australia:** Heidi Andersen-Dalheim, Paul Anderson, Bill Anell, Sam Arber, Kathleen Armstrong, Dean Arnot, Alan Baldam, Ian Barratt, Sebastian Barresi, Jeff Beder, Michael Benson, Frederick Bergman, James Best, Rajesh Bhasim, Geoff Bovell, Neil Bowman, Mal Brkic, David Bromberger, David Brown, Jean Brown, Michael Brownstein, Angela Bruce, John Buonopane, Steven Burns, Alexis Butler, Danny Byrne, Judith Carson, Peter Cassimatis, Greig Chaffey, Dianne Chambers, Wing-Jung Chan, Ben Chan, James Cheatham, Rachel Chen, Brian Cheong, Christina Cheung, John Chin, Anthony Chiu, Eric Choo, Andrew Chow, Anna Marie Chow, Dara Chung, Michael Conos, Nicholas Cooke, Simon Cooper, Peter Coulton, Mariam Cranswick, Garth Crichton, Adrian Dabscheck, Jonathan Dalitz, Jammal Danishar, Andris Darzins, Deborah Davidson, Paul Davis, Norfreet Dawood, Maxwell de Clifford, Fred de Looze, Antonio de Sousa, Santhramani Devi, John Dickman, Hillary Donald, Barry Dowell, Katrina Dowe, Peter Eizenberg, Claire Eizenberg, Liliana Elberg, Peter Enten, Adolf Erhardt, Roger Fagan, David Fairweather, Noni Ferguson, Peter Ferguson, Colin Fernando, Michael Ferres, Peter Foley, Sonnie Fong, Peter Francis, Doron Gaddie, Brad Gallagher, Robert Gan, Jon Garland, Andrew Gault, Nick Gianarakis, David Gibson, Ian Gill, Michael Giltrap, Robert Gingold, Neil Gordon, Margaret Graham, Murray Grave, James Grigg, Lynn Hall, Merilie Hall, Kerry Hancock, Colin Harrison, Richard Harrison, Rodney Hayden, Judith Heale, Prue Healy, Eva Herold, Elaine Hirst, Stephen Hodby, Chris Hogan, Peter Horsfall, Allan Hutchinson, Chia Irmgard, Suresh Jain, Duncan Jefferson, Richard John, Therese John, Brendan Kay, Patricia Kelly, Darren Kester, John Khury, John Kirmos, Susan Kloot, Danielle Kolos, Jacqueline Korner, Colin Kratzing, Jana Kubicek, Ashok Kumar, Clive Lacey, Con Lahanis, Daniel Lajoie, Loi Lam, Maryanne Lancaster, Henry Law, Carolyn Lawlor-Smith, Richard Laycock, Ivan Lee, Conway Leung, Leon Levitt, Leon Lewi, James Liew, Stephen Liew, David Lleweslyn, Peter Loth, Eldon Lyon, Shane Maclaren, Clare Maher, Frank Maldari, John Manderson, Linda Mann, Muhammed Abdul Mannan, Frank Marano, Damian Marinucci, Anne Matthews, Clare Matthews, Rebecca McGowan, Larry McGrath, John McKenna, Elizabeth McNaughton, Margaret McNiff, John Meaney, John Menzies, Anthony Michaelson, Samir Mikhail, Geoff Mitchell, Rohan Molenaar, Paul Molloy, Elena Monaco-Mugliston, Clare Mooney, Michael Moor, Brian Moylan, Vajira Nanayakkara, Peter Nathan, Wendy Naughton, Robert Ng, Ken Nicholson, Murray Nixon, Geoff Nuendorf, Chris O'Brien, Paul O'Hanlon, James Olesen, Andrew Ong, Say Gark Ong, Michael O'Toole, Michael Page, Peter Pahuja, Hugh Palmer, Stephen Parker, Stephanie Partridge, Helen Patronay, John Pattison, Gary Pellizzari, Anna Marie Perlesz, David Phillips, Alan Phillips, John Philpot, Leon Piterman, Jock Plenderleith, Harry Preston, Mark Preston, Christopher Priest, Andy Psaradellis, Warner Quarles, Michael Quinn, Jennifer Randle, Collette Reeves, Tamsin Rhodes, Frank Rhodes, Nigel Rosen, Jacqueline Rounsevell, Warwick Rouse, Ernest Rozsa, Indrani Saharay, Joseph Sakowsky, Mahinda Samararatna, Neil Same, Victor Sammut, Les Sands, David Schepisi, Derek Scurry, John See, Jan Sheringham, Keith Shing, Henry Simmons, Hira Singh, Lynette Skardoorn, David Slonim, Jane Smith, Stuart Smith, Geoff Spurling, Stephen Stowe, Violetta Stoyanova, Subbaram Sundar, Hedley Sutcliffe, Ian Sutherland, Pauline Swan, Jane Tam, Mary Tapsall, Patrick Teh, Stan Theodoros, Susan Thomas, Jon Thomas, Karen Thompson, David Thompson, Mark Thompson, Siobhan Tiernan, David Tillet, Simon Tong, Henry Tran, Ha Tran, Tuan Tran, Ivan Treagus, Ching Tang Tsang, Trena Turner, Edwin Turner, John van Bavel, Christopher Verrall, Robert Vorich, Hugh Wall, William Walton, Gary Ward, Bruce Wauchope, Cole Weatherall, Peter Wexler, Andrew White, Gabrielle Wiehle, Robert Wight, Ian Williams, Martin Williams, Stephen Williams, Frank Wilson, Peter Winterton, Steven Wong, Richard Wrennall, Joan Yat, Michael Yelland, Gordon Yip, Nathan Zhou, Michael Ziccone, Barbara Zochowski.

**Austria:** Charles Allen, Gerald Andracher, Marcus Atteneder, Gabriela Barbieri, Johannes Brandstetter, Christian Bsteh, Heinz Peter Deiser, Alexander Doder, Wolfgang Eckert, Astrid Fahrleitner-Pammer, Walter Fiala, Lothar Fiedler, Florian Fiedler, Wolfgang Filip, Johannes Föchterle, Karl Forstner, Karl Freynhofer, Thomas Frieden, Engelbert Frühwirth, Alfons Gegenhuber, Alfred Gewessler, Herbert Goldsteiner, Manfred Grisold, Franz Gruber, Wolfgang Gspandl, Walter Hauer, Michael Herg, Jakob Herk, Günter Heyer, Horst Hiemetzberger, Wolfgang Hof, Johann Hohenecker, Franz Hohensinn, Thomas Honsig, Gerhard Huber, Heinz Hutter, Gabriele Iampaglia-Springer, Karl Itzroiher, Kurt Jenny, Elisabeth Jenull, Michael Jung, Karl Jungbauer, Raimund Kaserbacher, Reinhold Katzenschlager, Josef Kimeswenger, Ernst Kittler, Gerhard Kitzler, Martin Koschutnik, Harald Kotzmann, Wolfgang Krasselt, Manfred Kuhler, Bernhard Kunauer, Herwig Kunczicky, Susanne Kurzemann, Paul Lachner, Walter Lux, Thomas Maca, Bernhard Mayer, Regina Mika, Beate Mörz, Heidemarie Müller-Ringl, Helmut Nimmerfall, Walter Nowotny, Helmut Ortner, Dieter Pätzold, Thomas Perger, Friedrich Petuely, Peter Pichler, Kurt Pinter, Johann Pollak, Harald Pressl, Susanne Pusarnig, Kveta Pusch, Momen Radi, Manfred Rausch, Siegfried Reisenbichler, Reinald Riedl, Heinz Sattler, Jürgen Schatz, Peter Scheibner, Hans Schimbach, Christof Schmidauer, Dieter Schmidt, Helmut Schossleitner, Martin Schumacher, Josef Schützenberger, Hans Schwaiger, Hans Peter Seit, Gabriele Sepp, Gerhard Stadlbauer, Erwin Hans Steiner, Franz Stradner, Walter Streichsbier, Andreas Stummer, Andreas Stümpflen, Ursula Teleky, Kurt Tiesenhausen, Raffi Topakian, Hermann Toplak, Manfred Türkis, Wolfgang Unterberger, Elisabeth Wais, Heribert Waitzer, Alois Waschng, Harald Waxenegger, Wolfgang Friedrich Weber, Manfred Weindl, Wolfgang Werner, Eugen Zadra, Elisabeth Zaruba, Wolfgang Ziegelmeier, Klaus Zitt.

**Belgium:** Serge Blecic, Youssef Bouhddid, Patricia Champagne, Willy Coenegrachts, Patrick Cras, Jean-Marie Dalcq, Eric Decock, Antonio Di Mascio, Luc Dieudonné, Robert Dobbelaere, Stephanie Duhoux, Benoit Fesler, Alain Friart, Louis Gallez, Jean Marie Jaumotte, Sandrine Jeanette, Jean-Michel Knop, Robert Leuridan, Niels Libbrecht, Jean-Marie Massart, Guido Mehuys, Jean-Marie Merlin, Serge Motte, Muriel Sprynger, Justina Surma, Vincent Thijs, John Thoen, Francois Vanholsbeeck, Geert Vanhooren, Joseph Varga, Frank Vermassen, Marc Vermeulen.

**Brazil:** Luiz Ataíde Junior, Jacob Atie, Álvaro Avezum, Francisco Bandeira, Luiz Bodanese, Antonio Brasileiro, Antonio Carlos Carvalho, Roberto Esporcatte, José Péricles Esteves, Angela Maria Eugênio, Gilson Feitosa, Jefferson Fernandes, Alfredo Halpern, Cícero Lopes, Ruy Lyra, Nilton Machado, Léa Maciel, Roberto Marino, Ayrton Massaro, Amélio Matos, Evandro Mesquita, Maria Moreira, Yosio Nagato, José Carlos Nicolau, Paulo Roberto Nogueira, Antonio Pazin Filho, Marco Tulio Pires, Antonio Rocha, Ricardo Rocha, José Francisco Saraiva, Helena Schmid, João Serro Azul, Marcos Tambascia, Sérgio Xavier, Fabio Yamamoto, Winston Yoshida, Maria Tereza Zanella.

**Bulgaria:** Maria Alexandrova, Vesseldina Andonova, Ognian Assenov, Penka Atanassova, Valentina Baleva, Haralambi Benov, Vera Bogdanova, Valentin Bonev, Nikolay Botushanov, Tihomir Daskalov, Alexander Daskalov, Ivan Deltchev, Stefan Denchev, Simeon

Dimitrov, Miroslav Dimitrov, Bojidar Dimov, Temenuca Donova, Todor Draganov, Assen Dramov, Elisaveta Enicheynova, Bojidar Fin kov, Krassimir Gen ov, Stefko Georgiev, Svetoslav Georgiev, Zhaneta Georgieva-Tyaneva, Mariana Gospodinova, Valentina Grigorova, Erna Hadjolian, Varbitza Hergeldjieva, Eva Hrant, Lilia Ivanova, Sonya Ivanova Hristova, Darina Kaneva, Zdravko Karagiozov, Sonya Karakaneva-Cholakova, Marko Klissurski, Rumen Kolarov, Mariana Konteva, Stoyan Lekushev, Detelina Loukanova, Ani Madjarov, Ivan Manchev, Zdravka Maslarska, Haygushi Matosyan-Bogdanova, Georgi Mazhdrakov, Teodina Michева, Mihail Mihailov, Ivan Milanov, Ivo Milyotev, Evdokia Naidenova, Valcho Naydenov, Eugeni Nedialkov, Galina Nikolova, Mariana Panova, Simona Panteleeva, Zoritz Papazian, Vasilka Pasheva, Atanas Peltekov, Atanas Penev, Stanislav Petranov, Ivo Petrov, Julia Petrova, Elena Petrova, Arman Postadjian, Ivo Raychev, Nizar Rifai, Ira Rousseva, Nikolay Runev, Rumen Runkov, Veselin Rusinov, Penko Shotev, Nina Simeonova, Diana Smilkova, Ivan Staikov, Elena Staikova, Paraskeva Stamenova, Krasimira Stankova, Georgi Stefanov, Varban Stoyanov, Vassil Stoyanovsky, Velislava Teneva, Snezhanka Tisheva, Latchezar Traykov, Diana Trendafilova-Lazarova, Margarita Tsoolova, Galina Tsonevska, Maria Tzekova, Moris Tzolov, Liliana Valcheva, Elisaveta Valcheva, Roumyana Valtcheva, Eugenia Vassileva, Vasil Velchev, Tzetzta Velkova, Maria Vlahova, Stefka Yancheva, Zahari Zahariev, Vladimir Zhelev.

**Canada:** Alnoor Abdulla, Glenn Andrea, Catherine Andrew, Guy April, Jeff Ashley, Richard Audet, Ramesh Avinashi, John Axler, Carolyn Baer, Allan Bailey, Greg Banta, Alan Bell, Ira Bernstein, Claude Bérubé, Pierre Bolduc, Jean Bouthillier, Teresa Bree, Gerald Brown, David Caplan, John Chan, William Chan, Chris Chan, Richard Chen, James Cherry, John Chiu, Kenneth Cho, Betty Choi - Fung, Guy Chouinard, Anthony Ciavarella, Christian Constance, James Robin Conway, Mario Côté, Ronald Cox, Gordon Crdinsten, Marie-Josée Cucuzza, Mehboob Damji, John Paul de Young, Langis Dionne, Frank Doane, Jean Duckett, Sylvie Emond, Sherali Esmail, Alan Faiers, Donald Fay, Linda Ferguson, Murdo Ferguson, Gilles Gaudreau, Caroline Geenen, Jean-Paul Gendron, Peter Gianoccaro, Jean Godbout, Yolanda Gonzalez, Shaun Goodman, Krishnasamy Govender, Pierre Goyer, Vojtech Gregus, Jeff Habert, Nader Habib, Sam Henein, Robert J. Herman, James Hii, Michael Hill, Hanna M. Hinnawi, Ralph Hollands, Tommy Hong, Blair Hrabarchuk, Peter Hum, Shiraz Ismail, Naaz Jaffer, Amir Janmohamed, Allan Kelly, Anne Kenshole, Brian Kessel, Jack Kooy, Gilles Lafrance, Sheung-Ying Lam, Daniel Landry, Clement Lang, Luc Lanthier, Christian Lauriston, Claude Lauzon, Denis Lavigne, Alex Leung, William Lipsett, Bruce Lubelsky, Lawrence Luftspring, Robert Luton, Patrick Ma, Ariane Mackey, David Marsh, Jean Marie Martel, Altaf Mawji, Pravinsagar Mehta, Kenneth Melvin, Karim Merali, Pierre Meunier, Jeffrey Meyerson, Marie-Josée Miron, Karl Misik, Peter Mitha, David Morgenthau, Rolf-Dieter Neu, Phuong B. Nguyen, Amarjit Nirwan, Claire Nunes-Vaz, Edward Nykiforuk, William O'Mahony, Michael Omichinski, Marc Paquin, Kalpana Patel, Rajni Patel, Pierre Payer, Allen Payne, Keyvan Pazuki, Ismail Peer, Claude Phaneuf, Gilles Plamondon, Henryk Pluta, Kent Pottle, Jim Price, Ann Rebane, Thomas Rebane, Claude Roberge, Gerald Rockman, David Rosenberg, Wendy Rosenthal, Julie Ross, Howard Rudner, Salwa Saad, Kevin Saunders, Georgia Savvidou, Nawal Sharma, Wojciech Sobkowski, Eric St-Amour, Brian Strom, Jack Sussman, Christine Szparaga, Paul Talbot, Prafullchandra A. Talwalkar, Lyne Thériault, Graham Turpie, Felix Veloso, George Vertes, Jean Villeneuve, Trevor Vu, Michael Weinstock, Rosemary White, Danny Wong, Wilfred Wong, Daniel Yim, David Yip, Linda Yolles, Bruce Zimmermann.

**Chile:** Monica Acevedo, Fernando Araya, Nelson Barrientos, Victor Bianchi, Eduardo Chavez, Rienti Diaz, Humberto Dighero, Jorge Gajardo, Bernardita Garayar, Berta Garrido, Vicente Gutierrez, Arnold Hoppe, Ronald Kauffmann, Albrecht Kramer, Sonia Kunstmann, Leopoldo Manriquez, Eliana Srur, Jorge Tapia, Paola Varleta, Raul Villar.

**China:** Nai Sheng Cai, Shi Ping Cao, Sheng Di Chen, Jilin Chen, Xiaoping Chen, Yan Cheng, Li Ying Cui, Qing Di, Xin Sheng Ding, Zhi Min Du, Wei Fan, Jian Hui Fu, Lu Yue Gai, Wei Gao, Guo Xiang He, Chang Lin Hu, Yi Ning Huang, Shu Wei Huang, Qu an Yue Huang, Dexin Jin, Wei Li, Jin Li, Chun Jian Li, Zhu Yi Li, Jian Wen Lin, Ming Ya Liu, Xin Feng Liu, Ming Liu, Ben Yan Luo, Lei Lv, Ai Qun Ma, Ling Miao, Huan Chun Ni, Guozhong Niu, Guo Guang Peng, Chuan Qiang Pu, Pei Li Pu, Guo Xian Qi, Ming Li Rao, Jie Song, Shui Jiang Song, Xiao Jiang Sun, Qing Ling Tao, Ji Jun Teng, Zheng Wan, Shao Shi Wang, Wei Qing Wang, Yongjun Wang, De Xin Wang, Jian-An Wang, Wei Wang, Li Juan Wang, Jia Ping Wei, Shao Xiang Wang, Zhong Gui Wu, Shi Yao Wu, Chen Bin Wu, Bo Xiao, Feng Xu, Yun Xu, Xiao Wei Yan, Bo Yu, Hu ai Qin Zhagn, Feng Ru Zhang, Bao Wei Zhang, Yong Zhang, Sheng Nian Zhou, Ying Ling Zhou, Jianhua Zhu.

**Denmark:** Erik Agner, Gudrun Boysen, Ole Davidsen, Birger Engby, Jens Jorgen Frifeldt, Per Fruergaard, Karin Geisler, Gyllich Gulliksen, Allan K. Hansen, Palle Holck, Helle K. Iversen, Nils Johannesen, Ole Kahr, Anders Kastrup, Jens Ole Kjærgaard, Ib Christian Klausen, Mads Lessing, Per Lund, Henrik Madsen, Allan McNair, Per Meden, Hans Michley, Hans Mickley, Torben Munck Mortensen, Walter Nielsen, Mogens Odde Kjær, Morteza Oskoie, Jan Petersen, Tina Poulsen, Niels Ralfkier, Frode K Rømer, Mette Sondergaard, Troels Sørensen, Niels Svaneborg, Christian Tuxen, Anette Wildschødtz Hansen, Birgit Wolff.

**Finland:** Vooitto Aittola, Juha-Pekka Erälä, Ville Hällberg, Veli-Pekka Harjola, Heikki Huikuri, Raimo Hyttinen, Rainer Icen, Timo Ikonen, Timo Kaitila, Juhani Karmakoski, Sirkka Keinänen-Kiukaanniemi, Raimo Kettunen, Paula Kohonen-Jalonen, Juhani Koistinen, Päivi Korhonen, Petri Korkeila, Ilkka Kuisma, Mikko Laaksonen, John Melin, Markku Nissilä, Jorma Ohisalo, Osmo Pammo, Juha Puranen, Mikael Railo, Arto Rantala, Marja Repo-Outakoski, Erkki Säkö, Olli Sallinen, Arto Strandberg, Sakari Sulosaari, Jyrki Taurio, Marja-Leena Tuominen, Antti Virkamäki.

**France:** Leila Abdi-Kriaa, Nathan Abenheim, Philippe Aerts, Laurent Aigle, Jean-Paul Albert, Alain Albouy, Anfari Ali-Mirode, Jacques Allix, Marc Amendola, Gerard Amigues, Hafid Amougay, Pascale Anderson, Pierre Andreani, Claude Antoine, Claude Arnold, Michel Arnould, Marie-Anne Arrondel, Pierre Attali, Raymond Attuill, Pierre Aubois, Michel Aucouturier, Monique Audibert, Patrick Audouy, Christian Auge, Jean Rene Auriault, Jean-Luc Azoulay, Philippe Bachongy, Georges Badoc, Michel Baehrel, Christophe Baer, Olivier Baissas, Youssef Barada, Marc Baragnon, Charles Baranes, Marianne Barbellion, Guy Barberet, Alain Bardoux, Jacques Bargier, Antoine Bariaud, Claude Barjhoux, Fabrice Baron, Denis Baron, Stephane Bartoli, Philippe Bayle, Charles Beck, Christian Bell, Olivier Benais, Herve Benichou, Jean-Louis Bensoussan, Vincent Benvenuto, Philippe Berdague, Patricia Bernet-Bernady, Jean-Marc Bernier, Gilles Berrut, Nathalie Berto, David Berville, Philippe Bessette, Thierry Betta, Gilles Bindler, Guy Birry, Olivier Bisch, Michel Bismuth, Philippe Blanc-Vannet, Pascal Blouin, Henri Boccalon, Pierre Jean Bodiou, Thierry Boely, Eric Boely, Georges Boitelle, Thierry Bontemps, Claude Bortolotti, Delphine Bortolotti, Gerard Bosselut, Marc Bouche, Philippe Bouche, Henri Bouchetoux, Philippe Boulanger, Amina Bourahoui, Michel Bourgoin, Francois Boutelier, Eric Boutfol, Philippe Boyer, Pierre Boyer, Agnes Brachet, Olivier Brafman, Rene Brassac, Nicolas Breton, Isabelle Bringer-Raingard, Jean Broussaud, Françoise Broutin, Claude Brunaud, Philippe Bruneau, Olivier Brunet, Daniel Buchon, Philippe Buffler, Jean Cabane, Didier Cadinot, Andreia Calmeiro, Alain Campagnac, Jerome Campagnac, Thierry Canali, Marie Elizabeth Cano, Pascal Canu, Dominique Caparros, Cyril Cardon, Muriel Carlotti, Francois Carniaux, Pascale Carre, Michel Casanova, Isabelle Casanova, Bruno Casedevant, Marc Castaner, Jacqueline Castany, Benoit Cauchy, Pierre Causse, Christine Cavat, Philippe Cayron, Marie Anne Cazale-Richier, Christian Cazals, Christophe Cazard, Bruno Ceccarelli, Pierre Cerda, Christine Cerna, Pierre Chabreron, Patrick Chalaux, Alain Chaleon, Alain Chalignac, Raymond Chaperon, Pierrick Chaplin, Stephane Chapuis, Laurent Charbonnel, Pascal Charbonnel, Marie

Françoise Chatelet, Christian Chauvois, Michel Chay, Patrick Chemouni, Chabane Cherbi, Jean Marie Chevalier, Jean-François Cheynel, Bernard Chiausa, Remi Choussat, Michel Chretien, Isabelle Cibois-Honorat, Luc Cimini, Serge Cini, Christian Claudel, Yvon Claudel, Gerard Codron, Thierry Coeure, Monique Cohen, Samuel Cohen, Jean-Philippe Cohen-Bacry, Felix Cohen-Seban, Marie-Pierre Coispeau, Herve Colin, Jean Philippe Collet, Anne Colobert, Robert Combet, Philippe Conchonnet, Claude Conri, Bernard Coppe, Claudine Cordier, Francis Coriol, Isabelle Coriol, Vanessa Corre, Stephane Cosson, Alain Costargent, Marc Cothenet, Jean-François Cottencin, Yves Cottin, Gilles Couderc, Jean-Pierre Courreges, Bertrand Cuisinier, Emmanuel Custozza, Laurence Dages, Simon Dahan, Patrick Dary, Christophe Daumas, Marie-Laure Daumas, Michel David, Alain de Almeida, Antoine de Guilbert, Emmanuel de Joux, Bernard de la Grandville, Erik de Mautort, Etienne de Saint-Martin, Joelle Debout, Olivier Decloux, Françoise Defrance, Frederick Defreyn, Maryse Degeilh, Edith Delan, Thierry Delandre, Irene Delbachian, Alain Delcros, Dominique Defosse, Christian Delplace, Bruno Dely, Jean-Claude Deme, Marie-Helene Demortiere, Paul Deneuille, Michel Depoisier, Gerard Depret-Bixio, Max Derochet, Sylvie Descombes, Jean-Pierre Desgranges, Pascal Dessales-Quentin, Jacques Dewulf, Bernard Dimon, Patrick Doat, Jean-Philippe Doazan, Jean-Yves Doerr, Andre Domenech, Valerie Domingo, Erwan Donald, Catherine Dormard, Bernard Doucet, Dominique Dreux, Bruno Dubedout, Jean-Christophe Ducarme, Gerard Duclos, Gerard Dugny, Philippe Dumond, Thierry Dunand, Pierre Dupouy, Jean Pierre Dupre, Olivier Dupuy, Thierry Durand, Jean Francois Durbiano, Patrice Dutilleul, Marc Duval, Louis Duvoche, Verena Eckert, Dominique Edet, Jean-Michel Ehrlich, Pierre Eisde, Chantal Elbhar-Pouchoue, Brigitte Escourrou, Pierre Espinasse, Jean-Christophe Etienne, Joel Etienne, Francois-Xavier Eveillard, Dominique Eveno, Christian Fabregue, Salam Farhat, Corinne Fauchard-Renard, Veronique Fauchier, Sandrine Favre, Patrick Fayard, Israel Feldmann, Dominique Felten, Pascal Ferchaud, Daniel Feret, Nicole Ferreira-Malcent, Renaud Ferrier, Jean Ferrieres, Jean Feuillet, Christian Fivel, Christelle Fleury, Michel Flizot, Marc Flosi, Eric Foltzer, Xavier Fontaine, Remi Fonteny, Bertrand Forestier, Michel Forne, Andre Fortis, Christiane Fouillat, Bruno Fouillen, Yves Foure, Pierre Fournier, Jean-Claude Fournillon, Marc Franchet, Agnes Francillotti, Christian Francois, Magali Frayssinhes, Jean-Luc Gabrielli, Pierre Galy, Jerome Garnier, Pierre Garnier, Eric Garnier, Eric Garrel, Christian Gasiot, Isabelle Gaudisart-Amblard, Bruno Gauthier, Philippe Gay, Dominique Genoud, Bernard Geoffray, Philippe Germain, Olivier Geronimi, Luc Gilles, Henri Gin, Pierre Ginestet, Jean Paul Giorgi, Charles Giraldi, Christian Girard, Michel Gissler, Vincent Gleye, Isabelle Glorieux, Laurent Goepfert, Marie Chantal Gournay-Lahoussine, Paul Gouyon, Michaela Grabovescu, Philippe Grange, Serge Michel Gran-Ortiz, Jean-Paul Grazzini, Dominique Grevet, Bruno Grivet, Francois Grivet, Remy Groell, Marc Grohar, Gilles Grollier, Pierre Gros, Bernard Gros, Sabine Grutter, Gerard Guichard, Robert Guilhaumet, Herve Guillaumot, Daniel Guillemot, Claude Haller, Claudine Hamel-Desnos, Edward Hannoush, Michel Harroch, Jean-Claude Haus, Manuela Hebert, Eric Helms, Marc Hemocq, Frederic Henriot, Bruno Henry, Marc Herent, Robert Hertling, Philippe Hild, Christine Hild, Hassan Hosseini, Jean Claude Hourcq, Jean-Luc Hovine, Jean-Louis Huberschwiller, Remi Huet, Dominique Huot, Thierry Humbert, Didier Ihli, Jean-Louis Iriart, Yves Jacamon, Sophie Jacqueminet, Valerie Jacques, Cecile Jacquet, Jean-Pierre Jacquet, Alain Jacquot, Jean Francois Jamet, Dominique Jamilloux, Lise Jappy, Pierre Jaudon, Françoise Jean, Georges Jean, Frederic Jeanjean, Claude Jedynak, Franck Jonot, Eric Jordan, Thierry Joseph, Christine Jouin, Pierre Jourdan, Jean-Thierry Jusserand, Edmond Kaltenbach, Anne Kerharo-Nicolas, Abbes Khennouf, Catherine Kleimberg, Didier Kleimberg, Pierre Kohser, Arnaud Koubbi, Michel Krempf, Pierre Kuhn, Christophe Kurtz, Francois Lacoïn, Valerie Lagrange, Stephane Lahoussine, Patrick Lambert, Jean-Michel Lamperin, Georges Lanusse-Cazale, Christine Largillier, Daniel Lascaux, Robert Latour, Jean-Michel Lauer, Dominique Lauga, Francis Lauhe, Jacques Launay, Marie-Paule Laur, Bruno Laureille, Philippe Laurent, Françoise Laurent-Montero, Philippa Lavallee, Marie-Catherine Lavigne, Claude Le Devehat, Raphael Le Diacon, Jacques Le Du, Stephane Le Mouel, Dominique Lecaigard, Christophe Lecarme, Florence Leclercq, Victor Lecue, Francois Ledru, Denis Lefort, Christian Legrand, Anne-Marie Leguerrier, Jacques Legouarch, Laurent Lemaire, Maurice Lemaire, Patrice Lemaire, Bruno Lemarie, Bernard Lemettre, Philippe Lemoine, Michel Lenormand, Jean-Luc Lepoutre, Bernard Lerich, Jean-Michel Lerouge, Monique Lescoute-Jabot, Pierre-Yves Letellier, Jean-Marie Letzelter, Michel Leveque, Marc Levy, Bernard Levy-Casson, Pierre Leygnac, Jean-Paul Lhosmot, Francois Liard, Alain Lion, Jean Locquet, Jean-François Loewert, Boris Lormeau, Jacques Louis, Alain Louison, Pascale Louveau, Michel Louy, Gerard Lussiana, Pascal Mabire, Yvan Machero, Francisco Macian-Montoro, Christian Magnaval, Patricia Magnus, Martine Maillan-Martin, Philippe Mainetti, Christian Mallemon, Philippe Mallet, Patrice Manigold, Philippe Marchand, David Marciano, Jean-Louis Marger, Bernard Marino, Philippe Marissal, Philippe Martial, Remy Martin, Jacques Martin, Michel Martin-Perdier, Helder Martins, Gregoire Martocq, Jean-Jacques Masson, Isabelle Mathys, Yves Maupin, Daniel Maury, Antoine Medvedowsky, Patrick Meimoun, Yves Mercey, Alain Mercier, Christian Meresse, Patrick Messner, Marianne Metivier, Bruno Meyrand, Jerome Mezin, Bozena Michalak, Christian Michel, Philippe Michellier, Didier Milhaud, Mohamed Mohsen, Jean-François Molinier, Michel Molinier, Gerard Mollet, Jean Molleville, Paul Monsegur, Frederic Montloin, Raphael Moreno, Didier Moritz, Paul Morvan, Jean Mottin, Betty Mougenot-Pierson, Herve Moura, Pierre Mours, Pascal Moussu, Patrick Moutier, Mahmoud Mteirek, Jean-Joseph Muller, Eric Nabedian, Jonas Naybodokama, Jean-Philippe Neau, Marc Nejman, Jacques Nerson, Pierre Nevians, Bruno Nguyen, Jean-Luc Nicodeme, Luc Niel, Elisabeth Nivellet, Richard Noel, Jean-Claude Nusimovici, Desire Obadia, Thierry Oger, Alain Olive, Charles Olivier, Pierre-Louis Olland, Daniele Orenstein, Alain Outteryck, Jean-Marie Pabst, Didier Pachod, Eric Page, Francois Paillard, Jean-Eric Panacciuoli, Didier Paneau, Claude Paradis, Daniel Parent, Marc Paris, Christian Pellenc, Alfred Penfornis, Charles Antoine Percheron, Gerard Perez, Antonia Perez-Martin, Beatrice Perin, Dominique Pernin, Philippe Perreur, Eric Perrier, Bernard Perrin, Jean-Louis Perrotet, Michel Perrousse, Valerie Perroux, Laurent Petit, Olivier Petit, Jerome Peyraud, Jean-Michel Philipp, Frederic Philippeau, Yves Picard, Jean-François Piera, Marc Pieretti, Joel Pierini, Eddie Pierre-Justin, Philippe Pietri, Denis Pinaud, Jean-François Pinel, Guillaume Pinel, Francois-Xavier Pinson, Christophe Piot, Marc Antoine Pistorius, Michele Python, Anni Python, Pascal Plan, Jean-Noel Poggi, Philippe Poinot, Patrick Poisson, Alan Poquet, Yvon-Yann Pouedras, Françoise Pouedras-Raton, Michel Pouget, Jacques Pourcin, Regis Pradeau, Jacques Prat, Christiane Prat-Caillo, Thierry Prieur, Bernard Prijac, Jean-Michel Provile, Alain Pucheu, Jean-Bernard Pueyo, Charles-Philippe Puiggali, Francis Pujol, Jacques Quarelli, Alain Queguiner, Isabelle Quere, Fabrice Quillou, Anne Quimpois-Kaminski, Francois Rabut, Sanae Rahili-Pollette, Jacques Rambaud, Pascal Raucourt, Sylvie Ravel, Philippe Ravoire, Serge Rebiere, Serge Rebmman, Jerome Regnier, Marie-Therese Reichard, Jean-François Reinard, Pierre Reins, Adrien Remade, Jean-Jacques Remerieras, Jean-François Renucci, Jean-Luc Reny, Yves Ressen, Georges Reumont, Jean-Luc Reynier, Christel Riera, Jean-François Rietsch, Marc Ripoll, Patrick Ritz, Jean-Pierre Robert, Jean Robert, Dominique Robert, Francois Robin, Christian Roche, Gilles Rodier, Jean-Jacques Roger, J. Francois Rolland, Eric Romen, Jean-Luc Rondeau, Gilles Ronziere, Andre Roques, Sophie Rosenberg, Frederic Rosier, Eugenio Rosset, Eric Rouchaud, Camelia Roudiere, Ronan Roussel, Aime Rousset, Gerard Rouviere, Marcel Ruetsch, Marc Ruivard, Didier Sacareaux, Jean-François Sagez, Dominique Saillard, Patrick Salerno, Antoine Salloum, Martin Salzmann, Jacques Samat, Nabil Saouma, Herve Sarfati, Jean-Pascal Sastourne, Jean-Louis Saunier, Alain Saurat, Desire Savoyen, Christian Scellier, Christian Schaal, Pierre Schatzkine, Andre Schmitt, Christian Schnebelen, Raymond Schordan, Katia Schroeder, Yves Schultz, Rodolphe Schwab, Christophe Seinturier, Sylvie Sement,

Daniel Senk, Isabelle Sesoren, Jean-Francois Seveyrac, Olivier Simorre, Pierre-Francois Sinoir, Gerard Slama, Gilles Sorbe, Francis Soret, Sandrine Soria-Berdugo, Philippe Soskin, Jean-Claude Soulayr, Patrick Spiess, Francois Spilthooren, Marc Steinberger, Jean-Jacques Stoll, Alain Stoll, Patrick Strentz, Noel Tallet, Denis Taminau, Sunhok Tan, Michel Tap, Philippe Tarouel, Patrick Taverne, Elisabeth Templier-Gauthier, Michel Terrail, Jean-Pierre Terrien, Jean Theoule, Pascal Tiberghien, Kiet Phong Tiev, Remy Tisserand, Judah Toledano, Bernard Tomaszewski, Corinne Toto-Grisoni, Pierre Touzet, Eric Tricoire, Francois Tricot, Pierre Triot, Thierry Valette, Elodie Vandooren, Christine Vanhoutte, Stephane Vanier, Frederic Vayre, Jose Vedrenne, Paul Venjus, Gabriel Venturini, Erick Verlet, Gilles Verney, Jean-Francois Vernhes, Michel Verquerre, Jean-Christophe Viale, Rodrigue Vienne, Philippe Vigier, Jean-Luc Vignoulle, Laetitia Villon, Christian Vincey, Jean Yves Vogel, Patrick Vogt, Jean Vonarx, Manh-Hung Vuong, Jean-Luc Weigel, Christian Wencker, Nathalie Wey, Philippe Winter, Veronique Wodey, Jean-Louis Wurtz, Frank Yoh, Stephane Yvenov, Antoine Zaknune, Gilles Zamaria, Fernand Zerbib, Patrice Zoro.

**Germany:** Patrick Abdul-Malak, Christoph Abel, Michael Achatz, Sahika Akalin, Christian Alexander, Hendrik Altenkämper, Manuela Andres, Christoph Angenvoort, Matthias Appy, Cord Arkenau, Martin Bach, Stefan Baier, Claus Ballstaedt, Constantin Baran, Marius Barbuia, Christian Barho, Alexandra Bassen auf dem Brinke, Oskar Bauer, Martin Bauersachs, Clemens Bauknecht, Isabel Baumann, Christian Beck, Rudolf Becker, Hans-Joachim Becker, Helmut Beermann, Dieter Bemann, Sibylle Berdermann, Olaf Besser, Ronald Beyer, Rainer Birke, Michael Bodammer, Ralf Bodenschatz, Michael Bögel, Jan-Peter Bohe, Günter Böhm, Jörg Böhm, Christina Boncke, Andreas Bonenkamp, Snezana Booz, Andreas Börgmann, Rudolf Brachmann, Bernadette Brado, Hans-Joachim Braun, Ralf-Markus Braun, Heinz Hubert Breuer, Stefan Brockmann, Friedrich Bröer, Berthold Bronder, Gabriela Brück, Herbert Brück, Claudia Brückmann-Stautner, Christoph Brückner, Stephan Brune, Petra Buchholz, Rudolf Buchkremer, Karsten Bunge, Udo Burczyk, Gudrun Burgei-Seifert, Hans-Martin Busch, Lutz Buschmann, Ulrich Butz, Andreas-Christoph Cebulski, Rainer Clob, Klaus Copenrath, Dominik Cornely, Richard Daikler, Jens Daniel, Andreas Daxer, Walter Deeg, Heinz Degering, Christian Delank, Karsten Diehls, Fred Dobiasch, Martin Dobner, Adel Doumit, Christoph Drechsler, Rainer Dresler, Holmer Drews, Karsten Droese, Jens Drummer, Regina Drzymala, Joachim Du bowy, Martin Dürsch, Frank Dusold, Klaus Ebeling, Hans-Holger Ebert, Dietmar Eckert, Verena Eckert, Rolf Eichner, Josef El Shamsy, Nicole Eltges, Erich Emde, Peter Engeser, Aman Esmaty, Hannelore Exner, Ulrich Faber, Herbert Facius, Dirk Falkenhahn, Thomas Feldmann, Gottfried Fiala, Andreas Fiedler, Manfred Finck, Jörg Finkenthe, Herbert Fissan, Ulrich Fleischer, Klaus Flohr, Dirke Franke, Heidrun Franke, Robert Franz, Frank Franzmann, Udo Frees, Michael Freimuth, Dierk Freundt, Ansgar Frieling, Barbara Froehlich, Anja Fröhlich, Michael Frommhold, Helmut Garten, Jenny Gärtner, Uwe Gerbaulet, Andreas Gerhardt, Thomas Gerlach, Walter Glaser, Heinz Glomm, Jürgen Glös, Ulrich Godt, Gholamreza Goudarzi, Oliver Grams, Klaus-Dieter Greie, Andreas Grosschaedl, Josef Grobkopf, Ludwig K. J. Grün, Ekkehard Grützner, Hans-Georg Grzeschik, Joachim Haaf, Maria Haas-Weber, Gerold Hadlich, Klaus Hafender, Andreas Hagenow, Wolfgang Hahn, Dieter Hailer, Michael Hammerl, Ulrich Hanselle, Sabine Hansen, Michael Hardt, Ralf Hauer, Liane Hauk-Westerhoff, Ernst Richard Hauser, Jan-Pieter Hecht, Christoph U. Hedtkamp, Voker Heffler, Diethard Heilmann, Thomas Heint, Ullus Heinrich, Gerd-Ulrich Heinz, Susann Henke, Wolfgang Henrich, Harald Herber, Jürgen Herbers, Heinz Herbst, Georg Herman, Peter Hertzer, Wolfgang Herzog, Hans Hess, Carsten Hebeling, Martin Hestermann, Markus Heyenbrock, Silke Hietkamp, Peter Hildebrand, Manfred Hilgedieck, Matthias Hofmann, Hartmut Hohensee, Evelyn Hohnstein, Herbert Huch, Gerhard Humke, Rudolph Hündgen, Hendrik Hüning, Rolf Huntemann, Wolfgang Huppertz, Thomas Hütt, Horst Huttner, Werner Ihle, Stefan Jacobi, Johannes Jäger, Bernd-Ulrich Jäger, Norbert Jahnke, Andreas Jankowski, Sybille Jänsch, Dirk Jesinghaus, Judith Jeske, Martin Jung, Gerhard Jungblut, Ulrich Junge, Wolfgang G. Jungmann, Jost Kaiser, Wolfram Kaiser, Martin Kajzar, Tunca Karakas, Erdogan Karatay, Sabine Karl, Karim Kaviani-Nejad, Nader Kayali, Thomas Keienburg, Horst Keller, Guido Ralf Kebler, Andreas Kirsch, Christiane Klein, Michael Klein, Axel Kleinert, Arthur Klementz, Johann-Wilhelm Klöpper, Eva Kmoth, Olaf Knispel, Erich Knobloch, Volker Koch, Stephan Kochen, Wilfried Kochhäuser, Andreas Koepfel, Steffen Christian Köhl, Andreas Köhler, Christian Köhler, Klaus Kohlhas, Ralph D. Köhn, Kai Könnemann, Ariana Konschak, Annette Konstanzer, Ute Kopplin, Tillmann Kornadt, Robert Kortas, Thomas Kossow, Katja Kraaz, Alfred Krämer, Gudun Krause, Peter Kreckel, Klaus Kretschmer, Stephan Kretschmer, Wolf Kretschmar, Christian Krupp, Reinhard Kuhn, Richard Kuhn, Heike Kunert, Steffi Kunze, Doris Kütter, Cornelia Kutscherskij, Beata Kutz, Susanna Labitzke, Hans-Joseph Lang, Thomas Lange, Laurentius Lanta, Christoph Lanzendörfer, John E. Lasana, Suso Lederle, Kurt Lempke, Martin Lenfers, Ute Lenk, Matthias Leyer, Ina Lipp, Regina Lippert, Berthold Litzinger, Bruno Löprich, Konrad Lössl, Sabine Ludewig, Guido Ludwig, Stefan Lukanek, Martin Mägdefrau, Roman Mantaj, Martin Markreiter, Fares Martak, Toralf Marten, Angela May, Herbert Mayer, Uwe Meier, Stefan Meier, Eveline Meinecke, Uwe Meinung, Eckhardt Meisel, Michael Meibner, Ulricke Merbach, Harald Messner, Friedrich H. Methfessel, Bernd Metscher, Horst Meub, Brigitte Meyer-Bender, Ludger Meike, Andreas Mietaschk, Wolfgang Mohr, Siegfried Molzahn, Christina Mondorf, Roland Morell, Margarethe Moritz-Lippmeyer, Walter Müller, Uwe Müller-Bühl, Roman Mura, Ronald Naumann, Karl-Heinz Nedder, Andrea Neeff, Peter Nehrig, Alya Neu, Eberhard Neumann, R. Manfred Neumann, Hans-Peter Nikolaus, Lennhart Nissen, Rüdiger Nold, Ralf Oertel, Helmut Ofer, Rainer Offermann, Günter Opel, Thomas Opitz, Bernd Ostmann, Peter-Michael Pankow, Rüdiger Patschan, Andreas Pätz, Albrecht Pellens, Roswitha Perlwitz, Karl-Heinz Pfetsch, Horst Philippi, Nicola Piepenbrock, Joachim Pinterowitsch, Bärbel Pohle, Axel Poll, Christian Pomiersky, Bettina Poten, Ernst Prange, Annegret Preissner-Kiebling, Horst-Dieter Püls, Peter Puth, Rainer Püttbach, Holger Pütz, Rita Quosigk, Hubert Raab, Rami Rabahieh, Reinhard Raddant, Friedrich Ramm, Günther Rapp, Klaus P. Ratzmann, Michael Rau, Wolfgang Rautenberg, Thomas Reiff, Norbert Reike, Bernd Dieter Reinhard, Albert Reischl, Ute Rentz, Andreas Reul, Eberhard Rieker, Stefan Ries, Volker Rink, Claus Eric Rippl, Ulrich Rissel, Ulf Ritter, Silke Röhl, Hartmut Rohlfing, Monika Röhrich, Anette Rosenthal, Verena Roth, Michael Roth, Ursula Rotsel-Schäfer, Martin Rottenberger, Klaus Rudolph, Hermann Ruider, Dieter Ruland, Heidrun Rupp, Johannes Rüter, Verena Rütlein, Anita Sach, Ali Safavi, Peter Sagemüller, Uwe Sakrib, Arshad Sayegh, Thomas Schäfer, Helmut Scharrel, Gottfried Schellenberg, Wulf Schenk, Oliver Schifmann, Josef Schimek, Karola Schladitz, Jürgen Schlegel, Matthias Schlick, Hans-Joachim Schlüter, Gabriele Schlüter-Block, Günther Schmid, Sebastian Schmidtke, Kerstin Schmiedeberg, Georg Schneider, Klaus Schnittert, Michael Schnittert, Norbert Schöll, Matthias Scholz, Dirk Schön, Norbert Schön, Sabine Schöne, Wolfgang Schönecker, Joachim Schönen, Thomas Schönfelder, Eleonore Schönrock, Matthias Schreiner, Mark Schreiner, Johannes Schriek, Thomas Schröder, Bernd Schröder, Peter Schröder, Wolfgang Schröter, Doris Schulte, Klaus Schulten, Dietmar Schultz, Andreas Schumacher, Joachim Schuster, Manfred Schütz, Heinrich Schwadorf, Toralf Schwarz, Hans-Götz Schweighöfer, Lorenz Schweyer, Bernd Sczesni, Per Segebrecht, Bringfried Seidel, Karin Seifert, Hans-Peter Seifert, Anne-Monika Seiler, Christoph Seitz, Ingo Senfleber, Jörg Simon, Almut Sindl, Lutz Sinn, Ulrich H. Sinning, Ulrich Sliwka, Thomas Sommerlatte, Tirapol Sorncharoen, Wolfgang Sperle, Alfred Spitzer, Detlef Städt, Jens Stadtmüller, Angela Stahl, Andreas Stegner, Wolfgang Stein, Jörg Stein, Jörg Steindorf, Michael Steinle, Andrea Steinmeier, Gunter Stenzel, Klaus Stiegler, Bettina Stöcking, Hans-Georg Stohrer, Hans-Jürgen Stroh, Gerson Strubel, Janusz Swistowski, Angelika Täger, Jens Taggeselle, Gunnar Taubert, Sven Tauchert, Maria-Elisabeth Thamm, Gerhard Thiel, Manuela Thinesse-Mallwitz,

Joachim Thum, Martin Tietz, Karin Todoroff, Evelyn Traub-Bobrich, Steffen Tröger, Ulrich Tuchscherer, Bruno Tulaj, Andreas Turowski, Stefan Tymiec, Evelyn Udvari, Gertrud Ullerich, Christine Unger, Ingeborg Utz, Peter van Hasselt, Robert Villis, Achim Vogt, Cornelia Völckers, Jan Völker, Thomas Völler, Peter Baron von Bilderling, Stephan von Molitor, Andreas Voskamp, Annette Wagner, Bernd Wagner, Friedrich Walther, Csila-Maria Weider, Bernd Weier, Jens Weilacher, Cornelia Weirich, Rainer Weislogel, Götz Weissinger, Matthias Wenck, Jürgen Werner, Manfred Werner, Georg Weyers, Kurt Wiedemann, Marie-Luise Wiedemann, Susanne Wiegank, Eckhard Wilbrandt, Wolfgang Wildenauer, Birgit Willers, Wolf-Rüdiger Winter, Dieter Wirtz, Hermann F. Wissmüller, Claus-Henning Wolde, Mandy Woschek, Martin Wunderlich, Volker Zeese, Volker Zens, Klaus Zimmermann, Ado Zorn.

**Greece:** Georgia Asimi, Christos Bakalis, Charalambos Bakopoulos, Dimitrios Balis, Konstantinos Baltatzis, Athanasios Basdekidis, Ioannis Caraindros, Agni Chatsiou, Periklis Chatzigiannis, George Dakos, Georgia Dantsi, George Deligianinis, Athanasios Demiris, Ioannis Dermizakis, Chrisoula Dima, Christos Dimitriadis, Michael Fatsis, George Floros, Apostolos Garbis, Ilias Georgiadis, Nikolaos Georgiannis, Theodoros Groutsis, Lazaros Kapatianakis, Nikolaos Kapsoudas, Sofia Karabali, Dimitrios Karagiannis, Sylvia Karalioliou, Aggelos Klitsas, Nikolaos Kotsis, Paris Koulouzakis, Stilianos Ktistakis, Simeon Liberakis, Efthimia Mandalaki, Alekos Manolakas, Alexandra Maranga, Nikolaos Markoglou, Nikolaos Meramvoliotakis, Christos Milopoulos, Nikolaos Mimilas, Ioannis Moschonas, Ioannis Navrouzoglu, Panagiotis Panagiotopoulos, Dimitrios Papaconomou, Nikolaos Papatathanasiou, Irini Pappa, Dimitrios Parisis, Charalambos Petras, Ilias Petropoulos, Nikolaos Pontikakis, Charalambos Pontiki, Georgios Ragias, Spiros Rigas, Panagiotis Riza, Panagiotis Sabatakakis, Viron Sitis, Andreas Skanavis, Fotini Skirla, Michalis Sotiriou, Michael Stakiadis, Sonia Stilianoudaki, Anna Syrigou, Ioannis Tachmatzidis, Konstantinos Takis, Pagona Tassopoulou, Konstantinos Tekos, Antonis Theodorakis, Ilias Theodoropoulos, Theofrastos Tsakiris, Maria Tserkezou, Ioannis Varnavas, Pavlidou Venetia, Nikolaos Vrachnakis, George Ziros, Ioannis Zouberis.

**Hong Kong:** Chi Keung Au Yeong, Norman Chan, Kin Choi, Shu Lap Chow, Chor Lup Chu, Hau Kwong Chung, Victor Goh, Yim Fai Kong, Chi Sing Ku, Alexander C. K. Lam, Yuk Tong Lau, Chi Wing Lo, Wing Fai Ng, Peter Tong, Wing Kwong Tong, Chun Au Tsang, Hing Sing Tsui, Bun-Lap Wong, Wing Kwong Wong, Yu Kai Yu.

**Hungary:** Agnes Adam, Gabor Antalics, Vilma Balas, Erika Barfai, Zsolt Bartha, Monika Bata, Bela Bernath, Imre Bodnar, Imre Csomos, Melinda Csordas, Eva Czucz, Laszlo Darvai, Ilona Dulai, Gyorgy Eberling, Veronika Endre, Katalin Farkas, Gyongy Foldesi, Sandor Forgacs, Boldizsar Garai, Gyorgy Gergely, Istvan Gubucz, Ildiko Hajdara, Jozsef Hamvas, Peter Harcos, Agnes Hasitz, Gyula Hegedus, Marianna Hegyi, Zsuzsa Hermann, Katalin Jakob, Istvan Juhasz, Krisztian Juhasz, Gal Katalin, Andor Keresztes, Istvan Kosa, Agnes Kovacs, Jozsef Lakatos, Laszlo Lippai, Tibor Lovasz, Geza Lupkovics, Anna Magyar, Eszter Magyarosy, Tamas Major, Attila Makai, Rozalia Marton, Katalin Mede, Edit Metz, Marta Molnar, Aniko Muranyi, Zoltan Nagy, Maria Olasz, Katalin Paulo, Ildiko Penner, Zsuzsanna Revesz, Pal Roth, Szilveszter Rozsa, Csilla Sarkadi, Judit Semjen, Tas Attila Sipos, Eva Sitkei, Gusztav Strebel, Zsolt Sudar, Zoltan Szabo, Szabolcs Szepesvari, Geza Toth, Gabor Trapp, Arpad Zsigmond, Zoltan Zubercz.

**Indonesia:** John Adam, Achdiat Agoes, Ira Andaningsih-Rahardja, Robert Arjuna, Ahmad Asdie, Achmad Basyah, I. Gusti Ngurah Ketut Budiarsa, Djokorijanto Dirjaningrat, Robertus Djokomoejanto, Mochammad Fathoni, Billy Indra Gunawan, Margono Achyar Hendromartono, Laksmi Asanti Kadarjono, Harmani Kalim, Isfanuddin Nyak Kaoy, Sjukri Karim, Sutomo Kasiman, Dede Kusmana, Charles Limantoro, Robertus Arifin Limoa, Augusta Lukman Arifin, Lukman Hakim Makmun Mardianto, Djoko Maryono, Irmalita Mazwar, Jusuf Misbach, Paskalis Nangoi, Handoyo Pudjowidjanto, Hari Purnomo, I. Gusti Ngurah Putra Gunadhi, Dani Rahmawati, Sodikur Rifqi, Kiking Ritarwan, Anwar Santoso, Teguh Santoso, Suratno Sastrosukarno, Siti Setiati, Suroto Setijorumecko, Yanuar Soehartono, Djajang Suhana, Josef A. Hendro Susilo, I. Nengah Dwi Sutanegara, Aulia Syawal, Sutikno Tanuwidjaja, Trisulo Wasyanto, I. Wayan Wita, Hans Cahyadi Yeo.

**Interlatina:** Ana Cecilia Arango, Jorge Arauz Chavarria, Aron Benzaon Cohen, Jose Cabrera, Boris Castillo, Edith Haydee Chavez Huelpella, Chih Hao Cheng Ku, Ernesto Diaz Alvarez, Rosa Eliana Dina Jimenez, Hernan Espinosa, Sandra Natacha Espinoza Cedeño, Carlos Eduardo Heredia Rivera, David Hernandez, Jorge Hernandez, Julia Lucy Madrid Alvaro, Felix Medina, Jose Alberto Minchola Haro, Miguel Mini, Guido Molina, Javier Moya, Miguel Esteban Ortiz, Alexander Parajeles, Clemente Alberto Ramos, Edgar Rodriguez, Gustavo Luis Saravia Risso, Jose Mario Sprok, Diego Ricardo Tapia Villagomez, Jaime Tortos-Guzman, Victor Urrutia, Dario Veras Sanchez, Jean Paul Vercauteren Dupont, Pablo Villa-Garcia Martinez, Mary Vinocour.

**Israel:** Aviva Abramovitz, Sharon A. Amar, Ram Avrahami, Aya Biderman, Nataly Davidov, Dana Faibel, Oro-Nory Flechner, Frida Glikberg, Marion Hefer, Yaakov Henkin, Edith Klain, Roza Kleiman, Batya Kornboim, Tatiana Lev, Pircha Levie, Abu-Katash Mahmoud, Ayelet Mendelson, Lea Mor, Zvi Chalom Moran, Gila Nitay, Irine Ostrovski, Yaakov Pshetizki, Ayala Reinitz, Hanna Reiss, Raisa Rivkind, Larisa Roch-Klipper, Dorith Rosner-Kamana, Tilda Sabah, Maya Schulman, Eran Segal, Irena Shtraikher, Bernadiner Sophia, Ilan Strausberg, Michael Umansky, Selma Wainsztock, Eli Wertmann, Dorota Wrobel-Zaher, Cherna Zeltzer, Constantin Zhuravlove, Grigory Zibuleusky.

**Japan:** Koji Abe, Nobuyuki Abe, Masayoshi Adachi, Hisashi Adachi, Hideaki Akiyama, Yoshichika Anami, Masahiko Aoshiki, Teruhiko Aoyagi, Rika Araki, Atsuko Ashiba, Keita Atou, Kojiro Awano, Nobuyoshi Azuma, Akihiro Azuma, Hideaki Bujo, Keiji Chida, Haruhiko Date, Toshiyuki Degawa, Kenichi Doniwa, Kenji Ebihara, Genshi Egusa, Yutaka Eki, Masamitsu Endo, Tsuyoshi Enomoto, Takashi Fujii, Hitoshi Fujimori, Yoshihisa Fujimoto, Kazuteru Fujimoto, Harutoshi Fujimura, Nobuaki Fujio, Motohiro Fujita, Toshiyuki Fujiwara, Atsushi Fukuda, Yoshiharu Fukuda, Ryuzo Fukunaga, Takatoshi Furuya, Shigeru Fuse, Takahisa Fuse, Jun Goto, Katsumasa Goto, Rikuzo Hamada, Tomio Hamada, Shin Hamamoto, Tadashi Hanabusa, Toshiaki Hanafusa, Nobuo Handa, Kazuhiro Hara, Yoshiaki Harada, Seiichi Haruta, Toshikazu Hashizume, Akira Hattori, Masamichi Hayashi, Yasuo Hayashi, Kazuyuki Hida, Kiichiro Higahi, Susumu Higaki, Yoshihisa Higashi, Masafumi Higashidate, Tetsuya Hiramoto, Koji Hirano, Kenichi Hirata, Katsuhiko Hiratani, Osamu Hirono, Atsushi Hirotani, Ichiro Hisatome, Hideki Honda, Jin Hoshino, Tsutomu Hosoi, Naohisa Hosomi, Setsuro Ibayashi, Toshio Igaki, Tatsuyuki Iijima, Kiichiro Ikuni, Hiroshi Ikenouchi, Katsuji Imai, Kenji Imai, Takeo Imai, Shigehiro Imamura, Tetsuya Inatsu, Isao Inoue, Ikuro Inoue, Shun Ishibashi, Toshiyuki Ishibashi, Kazufumi Ishida, Shiro Ishida, Naoki Ishige, Masayuki Ishihara, Hisamitsu Ishihara, Yoshiyuki Ishii, Yasuaki Ishimaru, Hiroshige Itakura, Tatsuro Ito, Tatsuya Ito, Norio Iwaki, Masahiro Iwamoto, Tetsu Iwao, Takashi Iwase, Yuichi Izumi, Yosuke Jinnouchi, Hideto Joki, Noboru Kagawa, Hiroshi Kaieda, Takashi Kajikawa, Tatsushi Kamiya, Haruo Kamiya, Kotaro Kaneko, Yoshifumi Kanemaru, Atsunori Kashiwagi, Hitoshi Kato, Kenichi Kato, Hiroshi Katsume, Toshihiro Kawabata, Tadashi Kawaguchi, Kazuya Kawahara, Toshiharu Kawamoto, Yasuo Kida, Mikihiro Kihara, Takashi Kimura, Hironori Kimura, Atsushi Kinoshita, Tetsuya Kitagawa, Kazuo Kitagawa, Kazuyuki Kitamura, Hirokazu Kitamura, Tomoki Kitano, Hiroaki Kitaoka, Kyoko Kobayashi, Yasutaka Kobayashi, Hisashi Kobayashi, Yoshio Kobayashi, Masayoshi Kobayashi, Nobuo Kohara, Junko Koide, Junji Koizumi, Hiroshi Komachi, Hidehiko Konno, Yukihiro Koretsune, Tatsuo Koriyama, Seiichi Koseki, Satoshi Kotori, Kazunori Koyama, Michiya Kubo, Masazumi Kume, Masanari Kunimoto, Makoto Kunisaki, Ryuji Kunitomo, Yukio Kuniyoshi, Keiichi Kuroki, Masafumi Kuzuya, Masahiro Makino,

Yasuhiro Manabe, Katsuya Maruyama, Taro Maruyama, Motoko Masaki, Ryoichi Masuda, Masahisa Masuda, Susumu Matsubara, Junichi Matsubara, Masanobu Matsuda, Makoto Matsumura, Takeshi Matsuo, Tatsuru Matsuo, Teruhiko Matsushima, Yoshifusa Matsura, Hiroyuki Matsuyama, Hajime Memezawa, Shinsuke Mii, Kunihiko Mitsuo, Hironobu Miyai, Yosuke Miyakawa, Susumu Miyamoto, Kazuo Miyatani, Yoshihiro Miyazaki, Yukihito Miyazawa, Hiroshi Mochizuki, Shin-Ichi Momomura, Yutaka Mori, Hisao Mori, Noriyasu Mori, Keisuke Morimoto, Ichiro Morita, Hiroshi Moriyama, Katsuhiko Motokawa, Tomoyuki Mukai, Makoto Murahashi, Satoshi Murao, Tsutomu Nagamitsu, Takehiko Nagao, Kazuya Nagata, Yasuhiko Nakada, Tomoko Nakagami, Joji Nakagawara, Kenichi Nakahara, Taku Nakajima, Yasuhiro Nakamura, Toru Nakamura, Yoshiki Nakamura, Yukio Nakamura, Takashi Nakamura, Masio Nakamura, Masaichi Nakamura, Hiroshi Nakane, Tatsuki Nakato, Masao Nakatsuka, Seiichi Nakayama, Tsuyoshi Nakazato, Kishio Nanjo, Manabu Narimiya, Teruhiko Negishi, Toyoharu Nemoto, Mitsuro Niinomi, Kazuhiko Nishigaki, Hideo Nishikawa, Hideo Nishimura, Masao Nitta, Masahiro Nitta, Koichi Noda, Hiroshi Noda, Koji Noma, Hachiro Obata, Yoshiki Ochi, Toya Ochi, Yuji Ogawa, Takuo Ogawa, Akira Ogawa, Atsushi Ogo, Shinya Ohagi, Yoshifumi Oishi, Kaiyo Oiwa, Masataka Ojira, Kazunori Okada, Kenji Okada, Motoi Okada, Yasushi Okada, Masaya Okamoto, Yukiharu Okamoto, Shinya Okamoto, Masamichi Okubo, Satoshi Okuda, Tomoyuki Onishi, Naomi Ono, Tatsuyuki Onodera, Toshihiro Onohara, Koji Osumi, Takashi Ota, Masakatsu Otani, Nozomu Otani, Haruo Ozaki, Hideki Ozawa, Hiroshige Sairenji, Kenichi Sakai, Kikuo Sakai, Susumu Sakamoto, Ryuichi Sano, Akira Sato, Hiroshi Sato, Jo Sato, Koichi Sato, Ryoji Sato, Shoji Sato, Norio Sawamura, Kazuhiko Segawa, Takao Seki, Teisaburo Sekiya, Takayoshi Senda, Yoichi Shibasaki, Mikio Shida, Toshiaki Shigeyama, Norihiko Shiya, Ichiro Shimada, Shoji Shindo, Kiyohito Shino, Isanori Shinohara, Uichiro Shintani, Teruo Shiraki, Kazutaka Siomi, Makoto Sonobe, Katsunori Sugisaki, Hiroaki Sugiyura, Naoyuki Suto, Tomoya Suwa, Kazuhiko Suyama, Shin Suzuki, Masahiro Suzuki, Seiji Suzuki, Michiyasu Suzuki, Akifumi Suzuki, Masao Suzuki, Atsushi Tabuchi, Masami Tada, Naoko Tadokoro, Shuichi Taguchi, Soichi Taguchi, Yuji Tajiri, Tetsuya Takahashi, Toshihiro Takata, Yasuo Takeda, Manabu Takei, Naoki Takeichi, Hidehiro Takekawa, Yasunori Takemoto, Masakashi Takenaka, Toshiharu Takeuchi, Noriyuki Takeyasu, Motohiro Takita, Shunya Takizawa, Norio Tanahashi, Kimitaka Tanaka, Katsuhiko Tanaka, Satoshi Taniguchi, Toshihiro Tanzawa, Kazuhiko Tashima, Hirokazu Tashiro, Yoshihisa Tatsuo, Koji Tenda, Tamio Teramoto, Muneshige Tobita, Ryohei Todo, Ryuji Tominaga, Makoto Tomina, Atsufumi Tomohiro, Hirotaka Toshimori, Toshio Tsukubura, Takuya Tsuchihashi, Tetsuya Tsukahara, Kengo Tsukahara, Hiroshi Tsutsui, Naomichi Uchida, Hirokazu Ueda, Daisuke Uematsu, Hiroshi Uenohara, Makoto Ujihara, Takuya Umemoto, Masaaki Uno, Masaharu Urakaze, Yoshifumi Wada, Yukio Wakuta, Kazunori Wasada, Kiyoshi Watanabe, Tsuyoshi Watanabe, Takao Watarai, Toshikazu Yabe, Zenju Yamada, Kenichi Yamada, Atsuo Yamada, Takeshi Yamada, Tetsuhiko Yamada, Hajime Yamagata, Tatsuyuki Yamaguchi, Kazuhiko Yamaguchi, Kazuo Yamaguchi, Shuhei Yamaguchi, Masahiro Yamamoto, Yasumasa Yamamoto, Hiroshi Yamanari, Kanji Yamane, Midori Yamano, Masahiro Yamasaki, Kenji Yamasaki, Katsuhiko Yamashita, Masafumi Yamashita, Iwao Yamashita, Kazumasa Yamatani, Yoshimitsu Yamazaki, Kaoru Yanagihara, Takumi Yasugi, Shozo Yasuoka, Hidehiro Yokochi, Norihiko Yokomori, Hiromitsu Yokota, Hitoshi Yokota, Naoto Yokota, Noboru Yokota, Toru Yokotani, Hiroyuki Yokoyama, Shigeru Yokoyama, Kazuya Yonezawa, Yoshihiro Yonezawa, Minako Yoshida, Masaki Yoshikawa, Koichi Yoshimura, Rikiya Yoshimura, Kimihiko Yoshimura, Shinichi Yoshimura, Kenichi Yoshioka, Narihito Yoshioka, Toshihiro Yūdō.

**Kingdom of Saudi Arabia:** Hussein Algahtani, Ashraf Hammouda, Waleed Khoja, Mostafa Abdel Ghany, Abdul Aziz Al Zamzami, Mohammed Ali Ali, Mostafa Ali Ahmed Alshamiri, Saeed Bohlega, Fayed El Shaer, Yousif Elmaleeh, Ibrahim Wasfy Gamal, Abdulhalim Kinsara, Mohammad Kurdi, Ahmed Mabrouk, Asif Malik, Hassan Raslan, Ashraf Shaaban, Hesham Taha, Radwan Zaidan.

**Korea:** Tae-Hoon Ahn, Sei Hyun Baik, In-Ho Chae, Ki Hyun Cho, Woong Hwan Choi, Yong Kil Choi, Kyung-Choon Chung, Ji Hoe Heo, Yangsoo Jang, Myung Ho Jeong, Dae Soo Jung, Heung-Sun Kang, Sun Woo Kim, Jong Sung Kim, Kyung-Soo Kim, Sung Koo Kim, Yong Ki Kim, Kee-Sik Kim, Dae Hie Lee, Kwang Ho Lee, Kwang-Soo Lee, Byung-Chul Lee, Inkyu Lee, Kyong Soo Park, Jeong Euy Park, Seong-Wook Park, Sung Woo Park, Chong-Yun Rhim, Ki-Bae Seung, Ho-Young Son, Jeong-Taek Woo, Sang-Doe Yi, Byung-Woo Yoon.

**Lebanon:** Hassan Abdallah, Joe Abi Raad, Grace Abi Rizk, Michel Abu Salbi, Khalil Ashkar, Farida Atallah, Pierre Awwad, Elie Chammas, Mostafa El Nakib, Kamel Ezzeddine, Adel Ghaddar, Beatrice Khater, Salem Maaliki, Malek Makarem, Michel Matar, Hanna Mattar, Riachi Mounir, Umayya Musharrafieh, Claudine Nasr, Naji Riachi, Mouner Saleh, Elie Stephan, Georges Tabet.

**Lithuania:** Nijole Bodindorfiene, Vytautas Docka, Laima Jankauskiene, Jurate Kojeliene, Milda Kovaite, Zaneta Petrulioniene, Ignas Tamosiutis, Birute Terbetiene, Danute Zaronskiene.

**Malaysia:** Raiha Abdul Kahar Abd Gapar, Nah Abdul Khalid, Hjh Aziah Ahmad Mahayiddin, Tun Fizi Ambrose, Choon Kiat Ang, Zainal Ariffin Azizi, Raymond Azman Ali, Hamid Basri, Wei Ling Chan, Siew Pheng Chan, Sau Kong Chang, Kok Han Chee, Yook Chin Chia, Yoon Sin Chong, Choon Hooi Choong, Santhi Datuk Puvaranajah, Yin Khet Fung, Eng Leon Goh, Hanif Hussein, Omar Ismail, Zulkeflee Ismail, Shaiful Bahari Ismail, Naimaton Ismail, Nor Azmi Kamaruddin, Norshinah Kamarudin, Balachandran Kandasamy, Soon Khai Lee, Yew Pung Leong, Houg Bang Liew, Chee Khoo Liew, Phanindranath Mahadasa, Choon Soon Mak, Julia Shahnaz Merican, Masni Mohamad, Chirk Jenn Ng, Hasral Noor Hasni, Tiong Kiam Ong, David Kwang Leng Quek, Vijayasingam Rajasingam, Kui Hian Sim, Ramesh Singh Veriah, Jeyaindran Sinnadurai, Kay Sin Tan, Lian Kim Tee, Soon Wee Tiang, Wan Bebakar Wan Mohamad, Zurkarnai Yusuf.

**Mexico:** Arturo Abundes Velasco, Geronimo Aguayo, Marco Antonio Alcocer Gamba, Graciela Alexanderson, Melchor Alpizar, Luis Enrique Amaya, Antonio Arauz, Armando Astorga, Jose Ramon Azpiri, Fernando Barinagarrementeria, Enrique Bernal Esbrada, Hector Manuel Brisenio Ramirez, Cesar Calvo, Carlos Cauto, Hector Colorado, Jorge Cortes, Jorge Cossio, Manuel Odin De Los Rios Ibarra, Rodrigo De Zatarain, Carlos Diaz, Luis Eng, Jesus Esparragoza, Luis Espinosa Sierra, Carlos Espinoza, Pedro Fernandez Bonetti, Elias Garcia Cantu, Rodrigo Garcia Martinez, Alejandro Garza Guerra, Felipe De Jesus Gonzalez Camid, Francisco Guerrero Pasqueira, Ismael Hernandez, Andrei Kostine, Jose Luis Leiva, Leonardo Llamas-Lopez, Berenice Lopez, Julio Lopez Cuellar, Mauricio Lopez Meneses, Antonio Marcos, Sergio Najera Lopez, Jacobo Nettel, Fernando Ortiz Galvan, Rogelio Peralta, Juan Carlos Perez Garcia, Alejandra Ranero, Ricardo Rangel-Guerra, Joel Rodriguez, Ildelfonso Rodriguez Leyva, Jose Alberto Rojas, Aldo Romero, Gustavo Rubio, Jose Luis Ruiz, Alberto Sagastegui, Oscar Talamas, Monica Tapia, Jose Luis Antonio Toriz Melchor, Artemio Uribe, Jorge Vazquez, Jose Antonio Velasco, Erich Carlos Velasco Ortega, Raul Gerardo Velasco Sanchez, Jorge Villarreal.

**the Netherlands:** Wouter Barendregt, Jacob Buth, John Cheng, Anita Dall'Agata, Jeroen De Haan, Jaap Deckers, Jan Driesen, Zoran Erjavec, Albert Funke Küpper, Gwan Ho, Josephus Jutte, Koos Keizer, Jan Koning, Steef Kranendonk, Arno Oomen, Evert Sanders, Han Sie, Niek Valk, Ben van Brussel, Marc van Dale, Eric van de Pavoordt, Rob van der Heijden, Laura van Dortmont, Jan van Iersel, Hero van Urk, Wim Verhagen, Adrie Withagen.

**Philippines:** Elizabeth Aguilar, Maria Ellen Grace Alferos, Maria Grace Ang, Veeda Michelle Anlacan, Maria Antonette Lourdes Aportadera, Abdias Aquino, Celine Aquino, Joel Ernest Araniego, Alberto Atilano, Fe Bacsal, Yul Balleza, Benny Barbas, Roy Joseph

Barcinas, Noel Belonguel, Jenny Beltran, Deborah Bernardo, Florenz Eubil Bilocura, Ester Bitanga, Amelita Brillantes, Leonor Cabral-Lim, Emerito Calderon, Warner Camarao, Maria Lourdes Canto, Raymond Jude Changco, Carlos Chua, Marietta Crisostomo, Joven Cuanang, Edna Cuasay, Rex Decolongon, Manuel Del Moro, Erwin Del Rosario, Eduardo de los Reyes, Alejandro Diaz, Carissa Paz Dioquino, Jane Doctora, Marcelito Durante, Del fin Encarnacion, Roy Entienza, Cesar Estalilla, Renato Evangelista, Erman Fandialan, Carmelita Fernandez, Roy Ferrer, Francisco Fuentes, Marie Simonette Ganzon, Florimond Garcia, Ruby Go, Manolete Guerrero, Lerrie Gutierrez, Alina Fatima Hojilla, Ranulfo Javelosa, Sjoberg Kho, Rogelio Libarnes, Marcelo Lim, Aileen Cynthia Llaraena, Johnny Lokin, Marilou Maglana, Francisco Maleza, Elma Maranon, Maria Conception Marcelo, Apistar Matias, Clarissa Mendoza, Rommel Montes, Jose Navarro, Reynaldo Neri, Orlino Pacioles, Patricio Palmes, Joel Paz, Rene Punsalan, Felix Eduardo Punzalan, Francis Marie Purino, Maria Lina Renales, Eugenio Reyes, Clara Rivera, Godfrey Robeniol, Raymond Rosales, Reynaldo Rosales, Romulo Rommel Rosita, Diana Jean Roxas, Artemio Roxas, Elson Sedilla, Johnny Shia, Edgar Tan, Aurora Tanzo, Dennis James Torres, Ramonito Tria, Wilson Tulmo, Tommy Ty Willing, Luciene Lourdes Villacin.

**Portugal:** Luis Bimbo, Rui Duarte, Augusto Ferreira, Jorge Ferreira, Correia Junior, Filipe Macedo, Rui Medon, Joao Morais, Duarte Noronha, Jose Osorio, Carlos Perdigo, Paulo Pessanha De Andrade, Jorge Puig, Elisabete Rodrigues, Jose Sampaio, Manuel Viana Costa, Edgar Wellenkamp.

**Romania:** Valeria Carmen Albu, Daniela Cristina Anghel, Florina-Anca Antochi, Eduard Apetrei, Marina Catalina Arsenescu, Valeria Gloria Badiu, Ovidiu Alexandru Bajenaru, Rodica Ioana Balasa, Viorica Bangau, Constanta Banica, Carmen Barbulescu, Gabriela Bicescu, Elena Bobescu, Gabriel Boeru, Ruxandra Stefana Bogdan, Valentin Bohotin, Adrian Constantin Bucsă, Mihaela Bustan, Adrian Catalin Buză, Ana-Varvara Campeanu, Radu Capalneau, Andrei Carp, Ovidiu Chioncel, Cristian Chiriac, Ruxanda-Dana Chirileanu, Mircea Cinteza, Aurora Constantinescu, Elena Constantinescu, Elvira Craiu, Carmen Cristea, Roxana Cruce, Dan Iulian Cucureanu, Ioana Cristina Dăhă, Anca Dan, Gheorghe-Andrei Dan, Roxana-Oana Darabont, Dan Deleanu, Doina Ruxandra Dimulescu, Cristian Dina, Mihail Diniesch, Maria Dorobantu, Andreea Dragulescu, Stefan Iosif Dragulescu, Bogdan Dumitriu, Amalia Ene, Cristian Falup-Pecurariu, Teodor Stefan Fischer, Angela Mirela Gavenea, Susana Geleriu, George Georgescu, Ioan Teodor Gheorghe, Leonida Gherasim, Ioana-Adriana Ghiorgiu, Carmen Ginghina, Alina Giuca, Ioan Laurentiu Gutiu, Anca Hancu, Diana Nicoleta Hodorog, Bogdan Ignat, Adina Ionac, Dan-Dominic Ionescu, Florina Violeta Isai, Octavian Istratoae, Dragos Catalin Jianu, Emilia Lungu, Cezar Macarie, Liviu Macovei, Ioan Constantin Marginean, Mihaela Marian, Doina Carmen Marinescu, Liviu Matcau, Costel Matei, Daniela Maria Maximov, Constantin Miliaru, Ioan-Dan Minea, Adriana Mitre, Mircea Moldovan, Ecaterina Moraru, Carmen Manuela Muresan, Bogdan Mut-Vitu, Gabriela Monica Niculescu, Maria Mihaela Opris, Cristina-Aura Panea, Ion Pascu, Daniela Mariana Patru, Marcel Pereanu, Lacramioara Perju-Dumbrava, Florin Petria, Maxim Petrica, Sanda Hortensia Petrutiu, Viorel Poalelungi, Mihaela-Ruxandra Popescu, Andreea-Catarina Popescu, Damian Popescu, Dinu Cristian Popescu, Maria-Rodica Prodan, Tudor Protopopescu, Mariana Radoi, Maria Rotaru, Mihaela Rugina, Horatiu Rus, Anca Paraschiva Rusu, Radu Andy Sascau, Marinela Serban, Adela Serban, Costel-Sorin Stamate, Delia Maria Stanca, Liana Stanescu, Cristian Statescu, Felicia Stefanache, Cristina Mihaela Tanaseanu, Marina Tîcmeanu, Diana Tint, Cristina Tirziu, Cristina Tiu, Ildiko Toldisan, Luminita Toma, Nicoleta Andreea Tovornac, Simona Octaviana Treidler, Luminita Tudor, Valerica Tudorica, Daniela Turdeanu, Sorin Tuta, Vitalie Vacaras, Ioana Varga, Marin Vasile, Radu-Gabriel Vatasescu, Crisanda Vilciu, Dragos Vinereanu, Marius Marcian Vintila, Gabriela Vulpe, Cornelia Zaharia, Simona Zaharia, Lucian Zarma.

**Russian Federation:** Fail Ageev, Dariga Akasheva, Gregory Aroutounov, Boris Bart, Boris Bondarenko, Vladimir Chernyavski, Irina Demidova, Oxana Drapkina, Natalia Egorova, Anatoly Evdokimov, Igor Fomin, Marina Freydlina, Albert Galyavich, Maria Glezer, Nikolai Gratsiansky, Yury Grinstein, Nikolai Horev, Alla Ivleva, Michael Karpenko, Yuri Karpov, Ludmila Katelnitskaya, Perch Kazantchian, Roman Khokhlov, Oleg Khrustalev, Andrew Kiritchenko, Zhanna Kobalava, Irina Kolina, Andrey Komarov, Lioudmila Korenko, Valery Koshkin, Sergey Kotov, Natalya Koziolova, Ekaterina Kropacheva, Valery Kukharchuk, Pavel Laguta, Petr Lebedev, Alexander Lipchenko, Veronika Lopukhova, Valentin Markov, Anatoly Martunov, Irina Mironova, Vladimir Naumov, David Nebieridze, Igor Novitsky, Iana Orlova, Nikolay Pavlov, Anatoly Pokrovsky, Victor Rapovka, Oleg Rodnenkov, Anastasiya Sankova, Sergei Shalae, Igor Shaposhnik, Marina Shestakova, Vladimir Shmirev, Alexander Shpektor, Vladimir Shulman, Boris Sidorenko, Alexey Sizov, Andrey Skvortsov, Veronika Skvortsova, Ivan Sokolov, Michail Statsenko, Gennady Storozhakov, Leonid Stratchounski, Tatyana Sukhinina, Vitaly Sulimov, Nina Syssoeva, Marine Tanashyan, Konstantine Tebloev, Victor Tutunov, Alexander Upnitsky, Natalya Yarovkino, Ludmila Yeliseyeva, Vladimir Zadionchenko, Alara Zakirova, Yekaterina Zharova.

**Singapore:** Poh Kit Ang, Sivathanan Cu maraswamy, Bernard Chan, Nang Fong Chan, Hui Meng Chang, Christopher Li Hsian Chen, Thomas Cherian, Kok Hoong Chia, Piang Ngok Chong, Sui Meng Chua, Pong Kuan Chua, Mark L. A. Da Costa, Deidra Anne De Silva, Binayak Deb, Mukund Doshi, Peter Eng, Robert Gan, Khee Hock Goh, King Hee Ho, Gunasegaran Kurugulasigamoney, Peng Chin Kek, Philip Siam Soon Koh, Adrian Thong Kiang Koh, Seng Long Koo, Chee Chong Koo, Chon Sham Lee, Tang Yin Lee, Stanley Liew, Ah Kiong Liew, Ing Haan Lim, Michael Lim, Chin Hock Lim, Su Chi Lim, Jayaram Lingamanaicker, Lip Ping Low, Suresh Mahtani, Koon Hou Mak, Sebastian Mathew, Richard Mong Hoo Ng, Ramani Narayanaswamy Venketasubramanian, Peter Teck Hwee Ng, Sarani Omar, Jason Pang, Raymond Chee Seong Seet, Vijay Sharma, Kim Bin Siah, Charles Siow, Lui Cheng Sng, Huay Cheem Tan, Ru San Tan, Melvin Tan, John Choon Heng Tan, Yong Teck Tan, Vincent Tan, Jam Chin Tay, Hock Luen Teoh, Hoo Ing Tong, Thean Seng Tong, Jane Tran, Albert Wee, Teck Wee Wong, Meng Cheong Wong.

**Spain:** Manuel Abeytua, Maria Dolores Adarriaga, Antonio Agarrado, Eduardo Jesus Alias, Fatima Almagro, Guillermo Alonso, José Luis Alonso, Nelson Maria Alvarenga, Luis Javier Alvarez, Amparo Alvarez, Juan Andreu, Jose A. Anton, Juan Carlos Arias Castano, Ignacio Artigues, Emilio C. Baldo, Joaquin G. Bautista, M. Nieves Bellera, Juan Bello, Oscar Beloqui, Jose Maria Bermudez, Miguel Blanco, Juan Carlos Bohorquez, Alfonso Bolaños, Vicente Brossa, Jordi Bruguera, Antonio Cabarcos, Purificacion Cabellos, Marc Cairols, Carlos Calvo, Ignacio Camacho, Joaquim Canoves, Pere Carbonell, Maria Cruz Carreno, Ignacio Casado, Jose Ignacio Catalan, Paz Catalan, Aranzazu Caudevilla, Jose Cerda, Pilar Raquel Chamarro, Alfredo B. Charles, Berta Claramonte, Vicente E. Climent, Juan Colas, Pere Comas, Jesus Juan Corrochano, Carlos Culebras, Meliton Francisco Davila, Javier de Andres Novales, Maria del Pilar de Luis, Felix Diaz Perez, Ignacio Duran, Jose Antonio Egido, Jose-Bernardo Escribano, Juan Manuel Escudier, Antonio Espinosa, Raul Espinosa, Jose Ramon Fernandez, Ovidio Fernandez, Fabriciano Fernandez de la Cigofia, Marta Ferrero Ros, Antonio Flores, Rosa Maria Folgado, Francesc Formiga, Carlos Franco, Joaquin Franco, Evaristo Freire, Moises Galan, Jesus Galiana, Iluminada Garcia, Francisco Garcia, Juan Pedro Garcia, Bartolome Garcia, Gonzalo Garcia, Jose Maria Garcia, Fernando Garcia de Burgos, Bernardo Garcia de la Villa, Juan de Dios Garcia Diaz, Juan Carlos Garcia-Mongo, Daniel Eduardo Geffner, Ricardo Gesto, Juan Miguel Giron, Ignacio Goicolea, Fernando Gomez, Jorge Francisco Gomez Cerezo, Emilio Gonzalez, Carlos Gonzalez, Alonso Gonzalez, Maria Isabel Gonzalez, Manuel Gonzalez, Manuel Gracia-Naya, Gabriel Gusi, Gabriela Guzman, Jose Sergio Hevia, Maria Luisa Hidalgo, Pedro Horcajo, Maria Ibanez, Ana Idoate, Miguel Idoate, Jaume Illa Gay, Maria Irurita, Javier Iser, Guillermo Izquierdo, Sergio Jansen, Catalina Jimenez, Blas Jimenez, M. Dolores Jimenez, Elisabet Juñca, Francisco Laynez,

Jose Manuel Ligeró, Jose Maria Lis, Secundino Llagostera, Carmen Lloret, Alfredo Llovet, Juan Carlos Lopez, Luis Lopez, Aquilino Lopez de la Osa, Pablo J. Lopez-Ibarra, Francisco Lozano, Maria De Los Reyes Luna, Jose Luis Macingirar, Juan Manuel Maraver, Jose Maria Marey, Jose Marin, Alejandro Martin, Juan Carlos Martin, Elvira Martin de la Torre, Alberto Martinez-Berganza, Manuel Martinez-Perez, Ramon Martos, Jaime Masjuan, Antonio Mateos, Vicente Medrano, Jordi Merce, Angel Merchante, Shaghim Mir Davood, Carlos Mirete, Felipe Molina, Jose-Manuel Molto, Marcelino-Jesus Montero, Manuel Montero, Marian Montero, Pedro Maria Montes, Francisco Jose Monzon, Mirem Morillas, Pedro Jose Morillas, Antonio Munilla, Ricardo Nicolas, Pedro Niembro, Rosa Numancia, Enrique Nuño, Fernando Olaz, Nieves Oller, Juan Ortega, Javier Ortega, Ernest Orts, Ana Otero, Antonio Paules, Marco Antonio Paz, Jose Luis Peña, Jose Luis Perez, German Perez, Alfonso Perez Molino, Gonzalo Pia, Josefina Pinedo, Angel Plaza, Inmaculada Plaza, Juan Manuel Pons, Jose Carlos Pontes, Antonio Portolés, Francisco Poveda, Maria-Ignacia Prat, Enrique Puras, Josefa Rasel, Jose Tomas Real, Sandra Redondo, Miguel Angel Rico, Andreu Rius, Josep Maria Roca, Enrique Rodilla, Jose Angel Rodriguez, Melchor Angel Rodriguez, Javier Rodriguez, Angel Ciriaco Roldan, Antonio Romero, Jaime Roquer, Julia Roure, Tomas Rubio Vela, Jose Ignacio Ruiz, Mariano Ruiz, Joaquin Ruiz de Castroviejo, Martin Ruiz Ortiz, Oscar Saavedra, Jose Saban, Josep Sadurni, Luis Saez, Jose Antonio Saenz de Quevedo, Jesus Salas, Antonio Salvador, Jose Maria Sanchez, Pedro Sanchez, Sonia Santos, Julia Saura, Jesus M. Sedeno, Tomas Segura, Francisco Javier Serrano, Pedro Javier Serrano, Javier Solis, Cristina Soriano, Jose Francisco Sotillo, Ana Isabel Soto, Carmen Suarez, Mercedes Suarez, Luis Miguel Tamargo, Luis Teigell, Jose Maria Trejo, Jordi Trulla, David Tura, Miguel Urtasun, Eliseo Val, Mariano Valdes, Javier Vaque, Fernando Vaquero, Luis Varona, Antonio Vazquez, Francisco Vega, Alfredo Velasco, Tomas Vicente, Juan Antonio Vidan, Blanca Vilaseca, Ricardo Vilchez, Irama Villar, Javier Viñas, Guido Volo, Manuel Jesus Zarauza.

**Switzerland:** Gilbert Abetel, Franco Ackermann, Nicola Alexander-David, Piero Andreoli, Michel Badan, Bruno Boillat, Hans-Juerg Bopp, Ruedi Bosshardt, Heinrich Budmiger, Reto Cadisch, Philippe Chapuis, Haw-Tzer Chen, Yves Colliou d-Robert, Josy-Philippe Cornut, Jean-Pascal Croci, Philippe Delorme, Roberto Gianni Di Stefano, Urs Duerst, Dominique Durrer, Urs Enggist-Ruesch, Marco Facchini, Heinrich Ch Flueckiger-Keller, Antoine Frangos, Felix Fust, Markus Gallati, Didier Genond, Alfred Gerber, Alberto Ghirlanda, Didier Giroud, Willy Gross, Christian Haeuptle, Philippe Haldy, Michael Hany, Elie Hecker, Christophe Henny, Markus Hug, Blaise Ingold, Gereon Jachertz, Olivier Jaques, Sébastien Jotterand, Urs Keller, Franz Kieliger, Aldo Kramis, Mariusz Kraszewski, Andreas Kuske, Martin Landolt, Markus Lanz, Thomas Limacher, Jean-Francois Luthi, Pierre-Andre Martin, Juerg Niesper, Karl Nuesch, Hanspeter Oechslin, Albert Pfaeffli, Alexander Pinzello, Michel Pithon, Michael Richter, Thomas Schneider, Hans-Rudolf Schwarzenbach, Philippe Staubli, Hans Stricker, Lou is Tjon -A-Meeuw, Pierluigi Togni, Enrico Tschurr, Paolo Tutta, Barbara Vogel Wigger, Irene Von Planta, Daniel Vuilleumier, Nikolaus Waldis, Jean-Marc Wandler, Yves-Marie Wasem, Josef Widler, Christian Widmer, Stephen Woolley, Bernhard Zauner, Andreas Zbrun.

**Taiwan:** Lung Chan, Chao-Shun Chan, Chi-Jen Chang, Hung Yu Chang, Chiung-Chih Chang, Ku-Chou Chang, Pan Chen Chang, Rei-Yeuh Chang, Jun-Yih Chang, I-Chung Chen, Chi-Li Chen, Yu-Wei Chen, Jia-Ren Chen, Chih-Wei Chen, Cheng-Yun Chen, Yung-Ping Chen, Tsang-Shan Chen, Wei-Hung Chen, Yu-Hung Chen, Zhih-Cherng Chen, Kuo-Chin Chen, Mei-Hsiu Chen, Tain-Junn Cheng, Chih-Hui Chin, Chiung-Zuan Chiung, Li-Ping Chou, I-Tseng Chu, Wen-Ting Chung, Chin Shih Fong, Chih-Ping Hsia, I-Chang Hsieh, Yuankai Hsieh, Jen-Che Hsieh, Ron-Bin Hsu, Ming-Chin Hsu, Chin-Fu Huang, Chin-Wei Huang, Yu-Yau Huang, Jiann-Shing Jeng, Chien-Chen Ko, Wen-Kai Kuo, Wen-Ter Lai, Chen-Chin Lee, Tsong-Hai Lee, Kuan-Hua Lee, Li-Ming Lien, Shinn-Kuang Lin, Ruey-Tay Lin, Tin-Kwang Lin, Kao-Chang Lin, Rue-Tsuan Liu, An-Bang Liu, Huey-Ming Lo, Dee Pei, Shan-Jin Ryu, Mao-Lin Sung, Sung-Chun Tang, Shiang Tang, Wen-Lung Tsao, Kwo-Chang Ueng, Tzung-Dau Wang, Shi-Yi Wang, Ko-Yi Wang, Cheng-Yu Wei, Ting-Yu (Dean) Wu, Jung-Chou Wu, Wen-Shiann Wu, Shang-Shan Yang, Shouu-Jeng Yeh, Chung-Hsin Yeh, Shih-Bin Yeh, Ping-Keung Yip, Bak Sau Yip.

**Thailand:** Yupin Benjasuratwong, Watana Boonsom, Wacin Buddhari, Pongamorn Bunnag, Nijasri Charnnarong Suwanwela, Adhisabandh Chulakadabba, Chaicharn Deerochanawong, Suchat Hanchaiphilboolkol, Sapon Jirasiritham, Rungsrit Kanjanavanit, Weerayut Khositsakulchai, Songsak Kiatchoosakun, Pornchai Leelanipon, Nithi Mahanonda, Samart Nidhinandana, Sirichai Niramaxsakul, Sumana Nopparat, Arintaya Phrommintikul, Chumpol Piamsomboon, Pavit Pienvichit, Paisith Piriyawat, Niphon Pongvarin, Wilai Puavilai, Disya Ratanakorn, Tongprakob Siriwanij, Kajorn Suntrapiwat, Swangit Suraamornkul, Saranyou Suwanugsorn, Sompongse Suwanwalaikorn, Viroj Tokavanich, Damras Tresukosol, Gumpant Veerakul, Apichati Vichayanrat, Visuit Vivekaphirat.

**Ukraine:** Kateryna Amosova, Svetlana Andriyevskaya, Igor Bereznyakov, Mykola Bezyuk, Olexandr Dyadyk, Georgiy Dzyak, Ludmila Dzyak, Boris Goloborodko, Nataliya Grytsay, Igor Kobza, Oleg Korkushko, Olena Koval, Volodymyr Kovalenko, Svetlana Kuznetsova, Tamara Mishchenko, Nataliya Mishchuk, Vasyli Netiazhenko, Alexandr Nikonenko, Vadim Nikonov, Alexander Parkhomenko, Tetyana Pertseva, Sergey Polyvoda, Yuriy Rodin, Anatoliy Rudenko, Victor Rudenko, Yuriy Rudyk, Oleg Sergeyev, Yuriy Sirenko, Yevgeniya Svyshchenko, Sergey Sychov, Victor Tashchuk, Igor Vakalyuk, Stepan Vynychuk, Vadim Vizir, Vladimir Volkov, Leonid Voronkov, Andriy Yagensky, Valentina Yavorskaya.

**United Arab Emirates:** Aboobaker Abdul Rahuman, Sherif Bakir, Nooshin Bazargani, Azzan Binbrek, Galal Eldin Elkilany, Jihad Inshasi, Deeb Maxwell Kayed, Christian Lange, Adel Wassef, Tayseer Zein Elabdin.

**United Kingdom:** Malcolm Addlestone, Rajendra Agarwal, Richard Barker, Anthony Barnett, Balasubramaniam Baskaran, David Bowen-Jones, Andrew Brooks, James Ronald Courtney, Philip Cummin, Richard Donnelly, Michael Duckworth, Jeremy Dwight, Thomas Egerton, Ian Farker, James Ferguson, Ahmet Fuat, Tim Getzen, Jonathan Hamling, John Hole, Shervanthi Homer Vaniasinkam, Ivor Hughes, Paul Husselbee, Martin James, George Kassianos, Martin Kent, Barbara King, James Kingsland, Michael Kirby, Robin Lalsarin, Richard Lawrence, Ping Siang Lee, Mary MacLeod, Gillian Manning, Ross Martin, Carol McKinnon, David Douglas McKeith, Dalpatram Mistry, Susan Morgan, Sarah Morgan, Michael Page, Basil Francis Penney, Stephen Rowlands, Jagtesh Sharma, Cliff Shearman, Lionel Sherman, Manish Singh, William Thorburn, David P. B. Watson, Alastair Watt, Robert Weir, Peter Sidney Wiggins.

**United States:** Coordinating Committee : Larry Brass, Marie Brown, John Cooke, Bruce Coull, Mark Creager, Michael Criqui, Greg Fonarow, William Golden, Philip Greenland, Michael Jaff, Pavel Levy, Pat McBride, Mary McDermott, Elizabeth Ofili, Charles Reasner, Ralph Sacco, Elijah Saunders, Jeffrey Saver, Peter Sheehan, Karol Watson.

**Investigators :** Rahat Abbas, Lisa Abbott, David Abdehou, Issa Abedmahmoud, David Abisalih, William Abraham, Kenneth Ackerman, John Addo, Angela Adelizzi, Satinder Aggarwal, Maher Agha, Thordur Agustsson, Bashiruddin Ahmad, Anwar Ahmad, Sheikh Ahmed, Dilawar Ajani, Fabricio Alarcon, Cesar Albarracin, Kim Albright, Cesar J. Aleman, Ruben Aleman, Jeffrey S. Alexander, Michael Alexander, Steven Alexander, Abdul Ali, Hussamaddin Al-Khadour, Deana Al-Khateeb, David Allan, Richard Allen, Ronald Alley, Michael D. Allison, Manohar Alloju, Barnet Alpert, Irfan Altafullah, Reynald Altma, Venkatreddy Alugubelli, Frank Alvarez, Hernando Alvarez, Sandra Alvarez, Gustavo Alza, Saleem Aman, Chimezie Amanambu, Salah Amer, Jatin Amin,

Kausmik Amin, Narendra, J. Amin, Yogeshcha Amin, Maged Amine, David Amos, David L. Anders, Charles P. Anderson, William Anderson, Peter B. Anderson, Bruce Andrea, Luis Anez, Satish Angra, Shamshad Anjum, Salwan Anton, Juan Apon te, Vincent Aquino, Dercy Aranador, Peter Arcuri, Abraham Areepanthu, Lisa Arian, David Arkin, Jodh Arora, Ansermo Arthur, William J. Artz Jr, Palaniapp Arumugham, Siva Arunasalam, Tanya Arvan, E. David Ascarelli, Ralph Ascher, Letterio Asciuto, Wail Asfour, Mohammed Asgar, Susan Ashley, Gerald Asin, Mansour Assar, Hatem Ataya, John Atkinson, Frank Attenello, Larry Atwood, Ducarmel Augustin, Than Aung, Barry Austin, Howard Axe, Alexander Axelrod, George Aycock, Oluropo Ayeni, Bryce Ayers, MuhammadAzam, Nabil Azar, Harvey Azarva, Sueann Babb, Kevin Babin, Oswald Bacani, Umeshkuma Badami, Timothy S. Bailey, Paula Bailey-Walton, Gary Baiocchi, Donald Baird, James Baker, Ladan Bakhtari, Robert Bala, Gobivenka Balaji, James Baldys, Jose V. Ballesteros, Pratap Balusu, Chaim Banjo, Ahmad Banna, Tobia Barbato, Frederick Barber, Harris Barrett, Anthony Bartkowiak, Thomas Barkley, Sara Bartos, Basel Batarseh, Neera Bathija, Ali Bazzi, James L Beach, Thomas Beamer, Michael Beane, William C. Beck, Howard Becker, Richard Becker, Steven Becker, Teresa Becker, Gary Bedel, Harjaneet Bedi, Richard Beham, Steven Belt, J. William Benge, Dana Bennett, Charles Bennett, Nathan Bennett, Paul Benson, Michael Berard, Zoya Berenson, Richard E. Berger, Oran Berkenstock, Gregory Berland, Gary Berman, Yuri Bermudez, Seth Bernard, Jay Bernstein, John F. Berry, Robert Beville, Ravi Bhagwat, Adarsh Bhat, Harry S. Bhatia, Dinesh Bhatia, Anil Bhatia, Divyesh Bhatt, Jayantilal Bhimani, Paul Bicek, Sandy Bidner, Robert Bierman, Dan Bieser, John Biggers, Barbara Biggs, Smita Bijlani, Ilya Bilik, Alan Bilsky, Karla L. Birkholz, Ishak Bishara, Veita Bland, Benjamin Blank, Kenneth Blaze, Michael Bleiman, Scott Bleser, Daniel Blizzard, Ronald Blonder, Craig M. Bobson, Donald Bodemann, Stephen Bodemann, Timothy Boehm, Nancy Bohannon, Paul Boinay, Gregory Bojrab, Anu Bommareddi, William M. Bond, Dana Bonezzi, Jonathan Bornfreund, Joseph F. Bornheimer Jr, David T. Borowski, Robert Borrego III, Peter Bottar, Alix Bouchette, Craig Boudreaux, Max Boune, Jean-Claude Bourque, Robert L. Bowling, Cherry Brandstater, Gary Breen, Ray Breitenbach, Arnold J. Brender, Peter Bressler, Donald Brideau, Timothy J. Bright, Alan J. Briker, Chandra Britt-Armstrong, Harry Brodie, Michael Brodowski, Neil Brodsky, Barry Bronstein, George A. Brooks, Carman Brooks, Gilbert T. Brovar, James Brown, Kevin Brown, Gary Brunkow, John E. Brunner, Michael Buben, Hector Buch, Robert Buckingham, Ernesto Buencamino, Ronald Buening, Angela Bully, Richard Bultman, Noor Bunney, Brian Buoscio, John Burch, Max Burger, John Burkard, James Bush, Richard Butcher, Susan Butler-Sumner, Robert J. Buynak, Joseph G. Cacchione, Alvin Cacho, Daniel Cadigan, David Cahn, Robert Caifano, Roy Caivano, Beverly Calkins, Daniel Cameron, Sumner Camisa, Deborah Camiscoli, Jeanne Campbell, David R. Campbell, Robert Campbell, Martin Caperton, James P. Capo Jr, Angelo Cappiello, Anthony Caputo, Richard A. Caputo, John Caras, James E. Carley, Leonor Carluen, David Carmouche, Richard Caro, Kent Carpenter, Kyle Carter, Glenn Carter, Steven Carver, Terrance Castor, Samuel D. Caughron, George Cavanaugh, Patricia Caverio, Lee Celio, Robert Cevasco, Vijay Chadha, Jyoti Chakravarty, Donna Chambers, Becky L. Chandler, Michel Chapnick, Arthur Charmatz, Maria Charron, Michael Chaskes, Ignacio Chaves, Opkar Chawla, Kuan-Cheng Chen, Chung-Kwang Chen, Eric Cheng, Tien Cheng, Yuri Cherny, Indira Chervu, Thomas Chesar, Salomon Cheson i, David Chess, Peter Chhabria, Michael Chidester, Anthony Chieffalo, Oscar L. Chien, Danny Chin, Angel o Chini ni, Donald Chisholm, Oletia Chisolm, Ronald H. Chochinov, Suk Choi, Myunghae Choi, Jatinder Chopra, Nakchin Chung, Robert Ciemiega, Michael Cirilli, Ronald Ciubotaru, Frank A. Civitarese, Louis A. Civitarese, Daniel Clark, Dennis Clark, William Coburn, Steven L. Cochran, J. Louis Cohen, Loren Cohen, Shari Cohen, Susan Colbert-Threats, Ronald Cole, Gary Coleman, Scott L. Coleman, Maha Coles, James Comazzi, Barry Conlan, Michael Conrad, Sean Conroy, Sebastian Conti, Richard Cook, Nelson Cook, J. Paul Cook, Joseph Cook IV, David L. Cooley, Daniel Cooper, Michael Cooperman, Jerry Cope, Danny Corales, Bernard Corbett III, Edward Coreil, George Cornett, David Cossman, Susan L. Courtnage, Louis Cox, William Cox, Michael Cox, Yvette Crabtree, Johnetta M. Craig, John Crider, James Crider, Edgardo Crisostomo, Michael Cromer, Jon Cronin, Janna Crosnoe, Irene L. Cueto, Frank E. Cummins, Chackumkal Cyriac, Rebecca Dailey, Samuel J. Daisley, Gloria Damien, Keith Damsker, Bhuvaneww Dandapani, Tze-Yu Dang, Christine Darwin, Suresh Dasani, Leonard Dimriti Dasilva, Robert Dausch, Amita N. Dave, Kamlesh Dave, Roger Davidson, Gregg Davis, Kenneth Davis, Pamela Davis, Paul Davis, Regina Davis, Sakina Davis, William Davis, Hursie Davis Sullivan, Thomas M. Dawes, Mark Dawson, Dominador L. Dayon Jr, Praxedes M. Dayon Jr, Nirmal K. De, Armando de Fera, Mario de Meireles, Jose de Souza, Don Dearmitt, Susan Debin, Gordon Decker, Ernest Defazio, Ross del Fierro, Bernardo Delaguardia, Eli ezer R. Deleon, Christine Delgaizo, Salvador Delrosario, Joseph Deluca, John A. Demopulos, Michael Dempsey, Marvin Den, Michael Denker, Paul Denker, Kevin Denlinger, Garth Denyer, Shivinder S. Deol, Gustavo Depetris, Pankaj R. Desai, Jayaprakash Desai, Anthony Detulio, Denise Deveranez, Gary Devoss, Chrisette Dharma, Ricardo di Sarli, Richard Diamond, Steven Diamond, Sam Diasti, Franco Diaz, Martiza di Diaz, Susan Dickson, James Diethelm, Michael Dietz, Patricia Disharoon, John Dixon, Michael Dobish, Christopher Dobrose, Douglas Doctor, Heman B. Dodani, Larry Doehring, Frederick Doerfler, Paul Donnan, James Donovan, Larry Doroshov, John Dorsey, Natalie Doyle, Gerald Dreslinski, Netley D'Souza, Pamela Dugano-Daphnis, Narindar M. Duggal, Jennifer Dunbar, Katherine Dunleavy, Richard M. Dupee, Antonio Duazo, Theodore Eastburn, Andrew M. Ecker, Joseph Eckert, James Edwards, Troy Edwards, Richard Egan, Alan Egelman, Christopher Ehly, Joseph Eickmeyer Jr, Zamir Eidelman, Bruce M. Eisenberg, Gilbert Eisner, Richard A. Elias, Arthur Elkind, Russell Emerson, Jay Enders, Michael Englund, Richard Enns, Julio A. Enriquez, Thomas Epperson, Gurol Erbay, Kent Erickson, James Eisenmenger, Oliver Eshenaur, William Espinoza, Nordeli Estronza, Manoharan W. Eustace, Bryan Evans, Patricia Fahey, Fayaz Faiz, Alik Farber, Hussam Farhoud, Joseph Farmer, Mark Faron, Debra Fast, Stacey Fazenbaker, G. Thomas Fazio, Kathleen Fearon, Daniel P. Featherston, Michael Fedak, Hailing Fei, Brian Feingold, Greg Feinsinger, Bryan Feldman, Francis M. Felice, Afonso Ferreira, Dennis P. Fielding, Carolyn Fields, Ramon Figueroa, Alan Fine, Brian First, Jerome Fischer, Joel Fischgrund, Richard Fishman, Eugene Fishman, David B. Fittingoff, Kelleen Fitzgerald, Mark Fitzgerald, David Fitz-Patrick, Patrick Flamion, Thomas Flanagan, Susan Flanzman, Jerrold Flatt, Leslie F. Fleischer, Diane Flershem, Adolph Flowers, Pau K. Fong, Robert Foster, Dana Fouchi, Donald Fowler, David Fox, John Fox, Carol Frank, George Frank, Ronald Frank, Matthew Frankel, Michael Franklin, Elliott Franks, Jerome Franz, Daniel Freberg, Jeffery M. Freesemann, Donald Frein, John B. Freitas, Greg French, Craig Freyer, Jack Friedel, Richard Friedlander, Edward Friedman, Linda Freilich, Samuel Frumkin, David Fuentes, Joseph Fuller, Frank Fusco, Denise Fuson, Manu Gadani, Pravin Gadani, Nitin Gaikwad, Marc Gaines, Anthony Gaither, Peter Galvan, Melissa Gamponia, Arvind Gandhi, Jyoti Gandhi, Bhupendra Gandhi, Ramon M. Garcia-Septien, Jeffrey Garb, Shyrelle Gardner, David Garfias, Marcus Garfield, Ram Garg, James Garner, David Garretson, David Garrett, David Garza, Irvin J. Gastman, Simon Gebara, Lakhahai Gedia, James Gehant, Steven Geller, Willis Gelston, Mikhail Gendel, Shawn Gentry, William George, Matthew George, Robert Geronemus, Luis Gerstenmeier, Donald Giant, James E. Gibbs, Francisco Gil, David L. Gilbertson, Michael Gilinsky, Satpreet Gill, Roy Gillick, David Gilliam, Eugene Gillman, Mary Gindi, George Gindi, Linda A. Glaser, James Glass, Elyse Glazer, Boris Gliner, Jan Glowacki, Eugene Go, James Goetz, Ramnik Gokani, Burton H. Goldberg, Ronald Goldberg, Joshua Goldman, Stephen Goldner, Daniel Goldsmith, Arnold Goldstein, Francis Goldstein, Robert Goldstein, William A. Gonzales, Julian Gonzales, Miguel Gonzales, Diane Goodale, Peter Goodfield, Daniel Goodman, Anil Gosali a, John Gosling, Atul Goswami, Daniel Gottlieb, Otto Goyco, Neil Grabensetter, James Grady, Kurt Graves, Victoria Greblya, Randall

Green, Robert Green, David Greenberg, Martin Greenfield, Robert M. Greenfield, Steven B. Greenman, Mitchell Greenspan, Paul Griffel, Daniel Griffin, Corinne Griffith, Howard Grill, William S. Gross, Teresita Guanzon, Michael Guice, Carolyn Guidot, Rohit Gulati, Franklin Guneratne, Suresh Gupta, Michael Hack, Everold Haffizulla, Farzanna Haffizulla, Jason Haffizulla, Joel Hagedorn, Jeffrey Haggenjos, Steven Hall, Roger Hallgren, Betty Halpern, Alan Hamilton, Maxine Hamilton, Todd Hammond, Jewell Hamner, Glenn Hamroff, Min-Yen Han, Forrest Hanke, Beth Hanrahan, Eric Hansen, Richard Hansen, Charles Hanshaw, Mike Harless, Michael D. Harris, Nita Harris, Roy W. Harris, Stephen Harrison, Matthew E. Hart, Paul Hartley, Daniel Haspert, Joseph Hassan, Irfan W. Hassen, Roger Hatharasinghe, Tabassum Hatimi, Martin Hautpschein, George C. Hawrot, Richard Hays, George Gilbert Head, Luis Heffess, Ole Heggeness, Jeffrey Hein, Philip Heinegg, Maryam Hekmat, Richard Hellman, Hal Hemme, Stephen Henderson, Gregory Henes, Mario Henriquez, David Henry, Aravind Herle, Paul Hermany, Adan Hernandez, Carlos R. Herrera, Moses Herrera, Robert Herrera, Stephen Herrington, Jeffrey Hershkowitz, Phillip Hertzman, Peter Herz, Steve Hiland, Stephen Hillis, Daniel Hilton, Edward Himot, Aref Hindawi, Ralph Hines, Susan Hirtz, David L. Hitz, George Hnatiuk, Marion Ho, Vincent Ho, Henry Hofbauer, Barbara Hoffman, Daniel Hoffman, Mark Hoffman, Joseph Holik, David Hollis, Kenneth Hong, Laura Hong, Peter Honig, Michael Hood, Bryan Hooker, David Hooks, Arnold Hopland, Stanley Horowitz, John House, Jerome Howard, Warren Hoyt, Ewa Hozakowska, Jui-Chinh Hsu, Yiling Huang, Daniel Hubbard, Yolanda Huet Vaughn, Michael Hugar, Garland Hughes, In Huh, Terrill Hulson, Richard Huntley, Joan Hurlock, Nizar Hussain, Amanda Huver, Anthony Iannamorelli, Syed Imam, Gregorio Imperial, Young In, Fred Ingram, Carlos Inocencio, Kam Ip, John Irvin, John Irvine, Armen Isaiaants, George Isajiw, Harold Isenberg, Gregory Isenberg, Tetsuo Ishimori, Gary Ishkanian, Rodney Ison, Ricardo Issa, Laxman Iyer, Henry Izurieta, Stephan Izzi, Mark Izzo, Nabil Jabbour, Byron Jackson, John Jackson, Michael R. Jackson, Richard A. Jackson, Robert Jackson, Prema Jacob, Walter Jacobs, Sushil Jain, Ashok Jain, Jaswant Jain, Herbert Jalowsky, Kassamali Jamal, Robert Jansen, Robert Jeanfreau, Ronald Jeffreys, George Jenckes III, Paul Jennewine, Albert Johary, Kenneth Johnson, Carol Johnson, David Johnson, Blaine Jones III, Rebecca Jordan, Elaine W. Joslyn, Jeffrey Kagan, Bruce Kahan, Scott Kahney, Amy Kaissar, Stephen Kajencki, Venu Kakarala, Sambamurthy Kalahasty, Nedzat Kalici, Luda Kamenetsky, Michael Kamiel, James Kammerling, Ramesh Kania, Ira Kaplan, Marc Kaplan, Richard Kaplan, Khalid Karim, George Karkar, David Karty, Randy Karu, Jerome J. Kastrul, Mulraj N. Katira, John Katsetos, Charles Katzenberger, Steven Katzman, Ronald Kaufman, Bruce Kauk, Morton Kavalier, Tahoor Kawaja, Susan Kawakami, Mark Kaylin, Marta Kazymyra, Allan Kelly, Richard Kelter, Nancy Kenney, David Kenton, Jayanth Keshavamurthy, Damoder Kesireddy, William Kessler, Clarita Ketels, Nasir Khalidi, Anila Khan, Misal Khan, Muhammad Khan, Waqar Khan, Yervant Khatcherian, Audisho Khoshaba, Rakesh Khosla, Samia Khwaja, Gary Kiefer, Peter Kiefer, Doug Kim, In Kim, Seong Kim, Alan Kimmel, Ganesh Kini, Mark Kipnes, Joseph Kipp, Nicholas T. Kipreos, William Kirby, Robert Kleinhans, Ken Kleinstaub, Martha Klipec, Alexander Klufas, James Knecht, Herman Knoll, Gloria Ko, Howard Koch, Stanley Koch, Peter P. Koenig, Charles Koepke, Keith Koepke, Valeri Koganski, Asha Kohli, Sanjeev Kohli, Gary Kolanchick, Kenneth Kollmeyer, Richard Kondan, Walter Koppel, Walter Koppenbrink, Bonnie Koreff-Wolff, Natalia Kovtun, Denise Kraft, Hal Kramer, Lawrence Kramer, Melvin Kramer, Michael Kramer, Sybil Kramer, Steven Krems, Marc Kress, Barry Kricsfeld, Anath Krishnan, Muthu Krishnan, Robert Kroopnick, Prathibha Kumar, Rakesh Kumar, Satesha Kumar, V. Hema Kumar, Anita Kundra, Michael Kunkel, Anthony Kurian, Richard Kurtz, Scott Kurzrok, Donald Kushner, Muthu Kuttappan, Tim Kval, Peter Kwon, Stella Kwong, Joseph Labuda, Bruce Lachterman, Anthony Lacorte, Jerome Lacy, David Lahasky, Vinodrai Lakhani, Habeeb Lakhani, Aristotel Laliotis, Chad Lamb, Jose Lami, Suman Lamsal, Carl Lang, Alan Langburd, Lorlyne Lange, Anthony Lanier, Rita Laracuate, Aurorita Lariosa, Joseph Lash, Alan Lau, Marshall Lauer, David Bruce Laughlin, Christopher Laverne, George Lawrence, Theodore Lawton, Milenko Lazarevic, Kadie Leach, Richard Leavitt, Marc Leblanc, Cristina Lecaros-Trinidad, John Ledbetter, Chok Lee, Dae Woo Lee, Joe Lee, John Lee, Karl Lee, Kenneth Lee, Nellie Lee, Tat-Sum Lee, Leonard Lefkovic, Anthony Leone, Eric Lerman, Keith Lerner, Stephen Leshin, Ying-Yan Leung, David Levenson, Phillip Levin, Marc Levine, Brian Levy, Meldon Levy, Richard Levy, Marc Lewen, Randal Lewis, Gary Lewison, Charles Li, Mark Li, Michael Li, Rogelio Liboon, David Lick, Laurence Lief, Cyril Light, Andrew Lim, Dee Beng Lim, Florian R. Limjoco, Shiann Lin, Jeffery Lindenbaum, Edward Linkner, David Liporace, Orrin Lippoff, Jeffrey Lipsky, Robert Lira, Daniel H. Lischwe, Scott Lisse, Jiang Ping Liu, Paul Liu, Hedy Loa, Cherry B. Lobaton, Francisco Lopez-Arostegui, Peter Lopresti, Juliette Louis-Charles, Joseph Lovato, Florentino Loya, Herbert Lubowitz, David Luck, Mark Lueg, Jorge Luengas, Manuel Luna, Jerry Luoma, Le Le Luu, Robert L. Lycksell, Lon Lynn, Gregory Lyon-Loftus, Sherry Ma, Shahrad Ma bou rakh, Michael Macadams, James Mackenzie, James Mackrell, Roger Madris, Richard Maffezzoli, James Magee, Robert Mahaffey, Aparna Mahakala, Yugal Maheshwari, Shaban Mahmoud, Gerald Mahon, Francisco Maislos, Prakash Makam, Louis Maletz, Manuel Malicay, Louis Malinow, Stanford Malinow, Steven Malkin, Ashith Mally, Jonathan Maltz, Martin Malz, Joselita Manalac, Richard Mandel, Barbara Mandell, George Manja, Steven Manuli, Raouf F. Maoud, Teresita Maqueda, Padmanabh Maramreddy, Isam Marar, David Margolis, James Margolis, Michael Margolis, Steven Margolis, Eric Marks, Stephen Marsh, Real Martin, Larry Martin, Danny Martin, Deogracias Martinez, Eduardo Martinez, Richard Martinez, Scott Massien, Nosrat Massih, Aziz Masud, Joseph Matheu, John Mathew, Mark Matthias, Elizabeth Mattson, Percy May, Eric Maybach, David A. Mayer, Miguel Mazariegos, Dervilla McCann, David McCarty, Brent McEntire, Patrick McLeroth, Steven McAllen, Edward McCarthy, Thomas E. McCauley, Thomas McClure, Jeremy McConnell, Boyd McCracken, Dee G. McCrary, Chandler McDavid, Camille McDonakl, Richard McEwan, John McGee, Ronald McGee, John McGettigan, Kent McGuire, Jerry M. McShane, Neil Meade, Richard Meadows, Andrew Mecca, William Mecca, Almas Mecklai, Edwin Medina, Hansa Medley, Stuart Medoff, Ravi Mehra, Minesh Mehta, Jose Meller, Joaquin Menendez, Antonio Menendez, Consuelo Mendez, Alexander Mendez, Mario Mendizabal, Concepcion Mendoza, John Menio, Raj Menon, Gregory Mercurio, John Merillat, Lawrence Merritt, Barry Meyer, Gary Meyers, Rene Meza, Anthony Miccio, Thomas Michelsen, Angelo Miele, Michael Mignoli, Jaroslav Mikus, Thomas Milko, Eugenia Miller, Jason B. Miller, Linus Miller, Michael Miller, Paul Miller, Randall Miller, Steven Miller, Guy Mintz, Milton Mintz, Bhagwan Mirchandani, Suresh Mishra, Sushil Mittal, Shalender Mittal, Jon Miyakawa, Amanda Modesta-Keyhani, Pratibha Modi, Tushar Modi, Rita Mody, Palghat Mohan, Syed Mohsin, Martin D. Mollen, Darren Molter, John Montana, David Montgomery, Dong Moon, Gregory Moore, Jeffrey Moore, Abdul Moosa, Joseph Moran, Sam Morayati, Chadia Morcos, James Moreci, John Moreland, Robert Moretsky, Matthew Morgan, William Morris, Bruce Morrison, James B. Moss III, Robert Moss, Thomas Moss III, J. Phillip Moyer, Kenneth Muckala, Ranajit Mukherjee, Suyra Munda, Valji Munjapara, John Munshower, Richard Murachanian, John Murashige, Ann Murphy, Ralph Murphy, Kevin Murray, Mustafa Musa, Derek Muse, Boyd Myers, Seymour Myers, Mark Nadaud, Laurie Nahum, Jayaram B. Naidu, Gnanasumathi R. Naini, Jyotirmay Nanda, Iqbal Nasir, Maher M. Nasser, Joseph Nassir, Judith Nations, Hector Navarro, Abdul Nayeem, Kenneth Nelson, Steven Nemirov, Rosa Neno, Frederic Neumann, Thomas Newton, Vuong Nguyen, Brian Nguyen, Khanh Nguyen, Thomas Niebeling, Earl Nielsen, Christopher Normile, Thomas Obarr Jr, Jose Oblena, Bikan Octain, Ola Odugbesan, Patrick Ogilvie, Akin Ogundipe, Timothy O'Keefe, Felix Olash, Robert Ollins, Agata Olszowska, Dennis O'Neill, Yee Ong, Osvaldo Orengo, Lavern Orlang, Donald Orth, Ben Oteyza, Baiyong Oung, Jeffrey Packer, Nak Paek, Robert Palandjian, Bryce Palchick, Arthur G. Pacia, Vipul Panchal, Dennis Pangtay, Gary Panik,

Garret Parker, James Parker, David Parker, Keith Parmer, William Paronish, Cyrus Parsey, Surendra Paruchuri, Fred Pastermack, Ajit Patel, Anil Patel, Arun Patel, Chandravan Patel, Meenakshi Patel, Mohanlal Patel, Nadeem Patel, Piyush Patel, Pravin Patel, Ling Raj Patil, Sridhar Patnam, Henry Patton, Stephen Paulding, John Paulish, Fredrick Payne, Brenda Peabody, Mark Peacock, Gregg Pearson, Anthony Pearson, John Peet, Jose Pelayo, Carmen Perez, Nathan Persoft, Mark Peschiera, Koster Peters, Cornell Peters, Dennis Peterson, William Petit, Charles Pewitt, Tri Minh Pham, Charles W. Phelps, Gregory J. Phillips, Frank Pintauro, Kenneth Pittleman, Gerald A. Pitzl, Lester Ploss, Ethan Podet, David Pogue, Craig Polinsky, Jeff Pollock, Daniel Pomposini, Joseph Pongonis, Vicken Poochikian, Gary Post, Greg Potts, Kevin Pounds, Francis Powers, Amy Prack, Eric Prack, Jan Prasad, David Prelutsky, Larry Present, Jennifer Prescott-Coraggio, John Prosser, Rodolfo Protacio, Joan Prouty-Moore, Bernard Proy, Haresh Punjabi, Priya Punjabi, Alan Purdy, Raman Purighalla, Uma Purighalla, Anthony Purpura, Hoyte Pyle, Kamran Qureshi, Diana Rabad-Marar, Zenaida E. Racho, Amin Radparvar, Gordon Rafool, Prema Raghu, Chengalro Raghunathan, Suresh Raheja, Adeebur Rahman, Nader Rahmanian, Mohammad Rahnama, Marina Raikhel, Paavan Railan, Jon Rainey, Yoshana Rajaratnam, Ganesan Rajasekaran, Kumar Ramdas, Pedro Ramirez, Lucila Ramiro, Loakhnauth Ramkishun, Richard Randolph, Shashikant Rane, Mallapur Rao, Rafik Raphael, Joshua Rassen, Nita Rastogi, Max Rattes, Frank Rauzi, William Rawlings Jr, Sanjay Ray, Lori Reaves, Salvador Recio, Michael Redding, Nagaratna Reddy, Pankaj Reddy, Ramesh Reddy, Sukanya Reddy, Venkat Reddy, Gregory Reed, Jonathan Reimer, Paul Reinbold, Harvey Resnick, Wayne Reynolds, Bruce Richardson, Rifat Rifat, William Ritchey, Aleida Rivera, Manuel Rivero, Ghayass Rizk, Michael Rizzo, Mark Robbins, Robert Robbins, William Roberson, Barbara Roberts, Kenneth Roberts, Judith Robinson, Rod Robinson, Walter Robison, James Rocco, Robin Rodgers, Humberto Rodriguez, Barry Rodwick, Janelle Roethemeyer, Bernardo Rojas, Claude Romulus, Glen Rosen, Robert Rosen, David Rosenbaum, Steve Rosenbaum, Lauren Rosenberg, Matthew Rosenberg, Paul Rosenblit, Alfred Rosenthal, J. Edward Rosenthal, Benjamin Rosin, Anthony Ross, David Ross, Glenn Ross, Jack Ross, Richard Ross, Jeffrey Royce, Mylene Rucker, Goran Rudic, Edward Rufus, Robert Ruxin, Joseph Rybicki, Oswald Saavedra, Dusan Sabol, Deepti Sadhwani, Harish Sadhwani, Farid Sadr, Bradley Sakran, Kaori Sakurai, Peter Saliba, Ira Salom, Albert Salomon, Renolt Samaan, Thomas Samaras, Jay Sandberg, Jaime Sandoval, Anita Sanharival, Donato Santangelo III, Kesari Sarikonda, Chitto Sarkar, Louis Sasser, Robert Savory, Suman Sawhney, Mark Sawka, Paul Sawrey, Rajesh Saxena, Varun Saxena, Carlos C. Say, Ronald Schachere, Kenneth E. Schafermeyer, John F. Scheerer, Kevin Schendel, Richard Scherermann, Brent Schlapper, Jay Schmidt, Christian J. Schmitt, John Schoenberger, Charles Schuhmacher, Jeffrey Schultz, Verne Schwager, Daniel Schwartz, David Schwartz, Julio Schwartzman, Neil Schwartzman, David Schweizer, Mark Scialabba, Peter Scivoletti, Herbert Secouler, Edward Secunda, Melvin Seek, Elizabeth Seet, Andrew Segal, Georgina Sepapayak, Barry Seidman, Munni Selagumsetty, Howard Selinger, Marc Seltan, Pollachi Selvakumarraj, Usha Seth, Mohammed Sethi, Carlos Seuc, Zachary Gregg Seymour, Arthur Sgalilia, Dhiren Shah, Gaurang Shah, Mahesh Shah, Shrenik Shah, Vinod Shah, Mohammad Shaikh, Farihorz Shams, Martin Shansky, David Shapiro, Elton Shapiro, Rajendra Sharma, Susan Sharma, C. Richard Sharpe, Burton Shaw, George Shaw, Michael Shaw, Michael Sheaffer, Leon Sheer, Marc Shepard, Neil Shepler, Stephen Sherer, Yogesh Sheth, Stephen Shiffman, Mikhail Shik, Jocelyn Shimek, Edwin Shoaf, Matthew Shore, David Shore, Rosalind Shorestein, Michael Shorestein, Phillip Shou, Alla Shpaner, Dhana Shrestha, Krishanav Shroff, Alok Shukla, Stephen Siegel, Mark Siegelheim, Augusto Silva, Michael Silverman, William Silverman, Calvin Simmons, Robert J. Simon, Stephan Simons, Lawrence Sinatra, Gurcharan Sing, H. Paul Sing, Lakheram Singh, Sarupinder Singh, Vineet Singla, Prabhat Sinha, Hicham Siouty, Kanagarat Sivalingam, Walter Skowsky, Stan Slabic, Alex Slandzicki, Juris Slesers, Lance Sloan, Steven Smallow, Albert Smith, Gary Scott Smith, George Smith, Howard Smith, Jack Smith, James Smith, Janet Smith, Kenneth Smith, Muhammad Smith, Ruth Smothers, Bruce Sobel, Celeste Soberano, Todd Sobol, Barbara Socha, Carl Sofley, Nalin Soni, Om P. 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## **Angina and Future Cardiovascular Events in Stable Patients With Coronary Artery Disease: Insights From the Reduction of Atherothrombosis for Continued Health (REACH) Registry**

Alon Eisen, Deepak L. Bhatt, P. Gabriel Steg, Kim A. Eagle, Shinya Goto, Jianping Guo, Sidney C. Smith, E. Magnus Ohman, Benjamin M. Scirica and the REACH Registry Investigators

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