Appendix B. Tables and Figures

**Table B1. Oral Hypoglycemic Agents: Summary Table**

|  | **Outcomes** |  |  |  |  | **Publication methods and results** |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study (name, year)** | **Change in A1c from baseline** | **% of patients with A1c <7.0%** | **% of patients with A1c <6.5%** | **% patients with decrease in A1c > specific value (specify)** | **Other A1c outcome** | **Change in primary and/or secondary outcome with respect to A1c between methods and results** | **Outcome in methods NR in results** | **Outcome in methods in-adequately reported in results** | **Outcome in results NR in methods** | **Change in analyses between methods and results** | **Subgroups reported in results that were not described in the methods section** | **Is SOR/ SAR present based on the publica-tion** | **ORBIT based on publication**  **(judgment 1)** | **Change in A1c outcome between original and current outcomes listed in registry** |
| Aschner, 2010 | Y | Y | Y | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | N |
| Bakris, 2006 | Y | N | N | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | N |
| Bunck, 2009 | Y | N | N | N | Y <7.1% | N | N | N | Y | N | N | Y | SOR/SAR but ORBIT does not apply | Y |
| Defronzo, 2009 | Y | Y | N | N | N | N | N | N | N | N | Y | Y | B, D, NA | N |
| Defronzo, 2010 | Y | N | N | N | N | N | N | Y | Y | N | N | Y | B; SOR/SAR but ORBIT does not apply | Y |
| Garber, 2009 | Y | Y | Y | N | N | N | N | N | N | Y | Y | Y | D; SOR/SAR but ORBIT does not apply | N |
| Goldberg, 2005 | Y | N | N | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | N |
| Goldstein, 2007  Williams-Herman, 2009 | Y | Y | Y | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | Y |
| Gupta, 2009 | Y | N | N | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | Y |
| Hamann, 2008 | Y | N | N | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | N |
| Jadzinsky, 2009 | Y | Y | Y | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | N |
| Kaku, 2009 | Y | N | Y | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | N |
| Nauck, 2007  Seck, 2010 | Y | Y | Y | N | N | N | N | N | N | N | N | Y | E | N |
| Nauck, 2009 | Y | Y | Y | N | N | N | N | N | N | N | N | Y | A | N |
| Perez, 2009 | Y | Y | N | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | N |
| Pratley, 2010 | Y | Y | Y | N | N | N | N | N | N | N | Y | Y | SOR/SAR but ORBIT does not apply | N |
| Raskin, 2009 | Y | Y | Y | Y | Y <7.5% | N | N | Y | N | N | N | Y | A | N |
| Raz, 2008 | Y | Y | N | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | N |
| Rigby, 2009 | Y | Y | N | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | N |
| Robbins, 2007 | Y | Y | Y | N | N | N | N | N | N | N | Y | Y | SOR/SAR but ORBIT does not apply | N |
| Rosenstock, 2006 | Y | Y | Y | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | N |
| Scott, 2008 | Y | Y | N | N | N | N | N | N | N | N | Y | Y | D | N |
| Seino, 2010 | Y | Y | Y | N | N | N | N | N | N | N | N | N | NA, no SOR/SAR | N |
| van der Meer, 2009 | Y | N | N | N | N | N | N | N | Y | N | N | Y | SOR/SAR but ORBIT does not apply | NA |

**Table B1. Oral Hypoglycemic Agents: Summary Table, continued**

|  | **Registry without registry results** |  |  |  |  |  |  | **Results in registry** |  | **Comments** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study (name, year)** | **Change in 1º outcome between the registry and the pub** | **Change in status of A1c with respect to 1º and 2º outcome between the registry and the pub** | **Change in follow-up interval between registry and pub** | **Index outcome missing in the pub but in the registry** | **Index outcome reported in the pub but NR in the registry** | **Is SOR and/or SAR present based on both pub and registry? (Not including registry results)** | **ORBIT based on registry, not including registry results**  **(judgment 2)** | **Differences between registry results and pub results** | **ORBIT based on pub and registry, including registry results**  **(judgment 3)** | **Describe any "Y" responses** |
| Aschner, 2010 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | N | NA | 2. Categorical A1c not mentioned in registry methods but reported in publication results |
| Bakris, 2006 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | NA, no results | NA | 2. A1c not mentioned in registry methods but reported in publication results |
| Bunck, 2009 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | Y | NA, ORBIT classes do not apply | 1. Publication didn't adequately specify A1c outcomes 2. A1c not mentioned in registry methods but reported in publication results 3. Publication and registry results differ |
| Defronzo, 2009 | N | N | N | N | Y | N | NA, ORBIT classes don't apply | N | NA | 1. Publication reported subgroup results not mentioned in the methods section; Subgroups inadequately reported |
| Defronzo, 2010 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | Y | NA, ORBIT classes do not apply | 1. Exact P-value NR (P<0.05) in publication; "A1c" specified in methods of publication: results reported change in A1c at 20w 2. A1c added to registry (including results) after study completed  3. Publication reports additional between-group P-values compared to registry |
| Garber, 2009 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | N | NA | 1. Subgroups reported in publication but NR in publication methods; NI analysis proposed in methods of publication but NR in publication results or in registry 2. Categorical A1c not mentioned in registry methods but reported in publication results |
| Goldberg, 2005 | N | N | Y | N | N | Y | ORBIT G or H | N | NA | 2. Followup interval of 39w mentioned in registry but NR in publication  ORBIT based on registry was either G or H: clinical judgment NA to followup interval |
| Goldstein, 2007  Williams-Herman, 2009 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | N | NA | 2. A1c not mentioned in registry methods but reported in publication results |
| Gupta, 2009 | Y | N | N | N | Y | Y | NA, ORBIT classes don't apply | NA, no results | NA | 2. A1c not mentioned in registry methods but reported in publication results |
| Hamann, 2008 | N | N | N | N | N | N | NA. nor SOR/SAR | NA, no results | NA |  |
| Jadzinsky, 2009 | N | N | N | N | N | N | NA, no SOR/SAR | N | NA |  |
| Kaku, 2009 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | NA, no results | NA | 2. Categorical A1c not mentioned in registry methods but reported in publication results |
| Nauck, 2007  Seck, 2010 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | N | NA | 1. A1c <6.5% NR in results in Seck at 2-y F/U, but data were available 2. Categorical A1c not mentioned in registry methods but reported in publication results |
| Nauck, 2009 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | N | NA | 1. Results reported as not significant 2. Categorical A1c not mentioned in registry methods but reported in publication results |
| Perez, 2009 | N | N | Y | N | Y | Y | NA, ORBIT classes don't apply | N | NA | 2. Primary outcome changed in the registry from 24w to 24w or final visit after data collection was complete; Categorical A1c not mentioned in registry methods but reported in publication results; Additional between-group comparisons or monotherapies provided in registry but not publication |
| Pratley, 2010 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | N | NA | 1. Subgroup analysis not mentioned in the methods section but reported in the publication results 2. Categorical outcomes were added to the registry after the study was completed |
| Raskin, 2009 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | NA, no results | NA | 1. Results inadequately reported in the publication 2. Categorical A1c not mentioned in registry methods but reported in publication results ("sudden levels A1c") |
| Raz, 2008 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | N | NA | 2. Categorical A1c not mentioned in registry methods but reported in publication results  F/U interval specified in publication and registry as 18w, secondary outcome 30w (specified 4/10) (latter makes more sense clinically) |
| Rigby, 2009 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | N | NA | 2. Categorical A1c not mentioned in registry methods but reported in publication results |
| Robbins, 2007 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | NA, no results | NA | 1. Subgroups reported in results that were not specified in methods 2. Categorical A1c not mentioned in registry methods but reported in publication results; A1c not adequately specified in the registry including not specifying followup interval |
| Rosenstock, 2006 | N | N | N | N | N | N | NA, nor SOR/SAR | NA, no results | NA |  |
| Scott, 2008 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | N | NA | 1. Prespecified subgroups inadequately reported in the results of the publication 2. Categorical A1c not mentioned in registry methods but reported in publication results |
| Seino, 2010 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | N | NA | 2. Categorical A1c not mentioned in registry methods but reported in publication results |
| van der Meer, 2009 | N | N | N | N | Y | Y | NA, ORBIT classes don't apply | NA, no results | NA | 1. A1c not adequately specified in the methods section 2. A1c not mentioned in registry methods but reported in publication results |

Abbreviations: Y, Yes; N, No NA, not applicable; NR, not reported; pub, publication; 1º, primary; 2º, secondary.