

## BELGIUM 2007:

1. Clinical Study Protocol dated, 23 July 2007 (See attachment)

Initial feedback + targets based on Clinical Study Protocol, 23 July 2007 (which have never been implemented):

### HbA<sub>1c</sub><sup>14,18,20</sup>

5.5- 6.1%	Excellent
6.1-6.5%	Good
6.5-7.0	Suboptimal
7.0-8,9%	Moderate
≥ 9%	Bad

**Pre-set target for HbA<sub>1c</sub>: < 6.5%**

14. Global Guideline for Type 2 Diabetes. Chapter 6: Glucose control levels. Clinical Guidelines Task Force. International Diabetes Federation 2005. p.26-28

18. Guidelines on diabetes, pre-diabetes, and cardiovascular diseases: full text. The Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD). Lars Rydén et al. European Heart Journal. Doi:10.1093/eurheartj/eh261

20. Gaede et al. Multifactorial intervention and cardiovascular disease in patients with type 2 diabetes. New Engl J Med 2003;348: 383-93

### Blood Pressure<sup>17,18</sup>

< 130/80 mm Hg	Good
130/80 – 139/89 mm Hg	Borderline
≥ 140/90 mm Hg	Too high

**Pre-set target for systolic blood pressure: < 130 mmHg**

**Pre-set target for blood pressure: <125/75 mmHg in case of renal impairment, proteinuria > 1g/24h**

17. European guidelines on cardiovascular disease prevention in clinical practice. Third Joint Task Force of European and other Societies on Cardiovascular Disease Prevention in Clinical Practice. Guy De Backer et al. European Heart Journal (2003) 24, 1601-1610

18. Guidelines on diabetes, pre-diabetes, and cardiovascular diseases: full text. The Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD). Lars Rydén et al. European Heart Journal. Doi:10.1093/eurheartj/eh261

## Lipids<sup>16,18</sup>

	Very good	Borderline	Bad
<b>Total cholesterol</b>	< 175 mg/dl	175-250 mg/dl	≥ 250 mg/dl
<b>LDL-cholesterol</b>	< 100 mg/dl	100-130 mg/dl	≥ 130 mg/dl
<b>LDL-cholesterol for very high risk patients</b>	< 70 mg/dl		
<b>HDL-cholesterol</b>	> 50 mg/dl	40-50 mg/dl	≤ 40 mg/dl
<b>TG (fasting)</b>	< 150 mg/dl	150-200 mg/dl	≥ 200 mg/dl

**Pre-set target for LDL-cholesterol: < 100 mg/dl**

**For very high risk patients:< 70 mg/dl**

Very high risk patients are defined as patients with diabetes and coronary artery disease<sup>18</sup>.

16. Implications of recent clinical trials for the National cholesterol Education Programme Adult Treatment Panel III Guidelines. Grundy et al. for the Coordinating Committee of the National Cholesterol Education Programme. *Circulation* 2004; 110: 227-239

18. Guidelines on diabetes, pre-diabetes, and cardiovascular diseases: full text. The Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD). Lars Rydén et al. *European Heart Journal*. Doi:10.1093/eurheartj/eh261

## BELGIUM 2008:

2. After discussion the feedback and targets have been adapted in a Local Study Protocol Amendment Number 1 dated, 17 July 2008 (See attachment).

Revised Feedback + targets based on Local Study Protocol Amendment Number 1, dated 17 July 2008. This benchmarking feedback has been given to the GP's throughout the whole study period.

## HbA<sub>1c</sub><sup>14,18,31</sup>

≤ 7%	Excellent
7.1-7.5%	Borderline
>7.5%	Too high

**Pre-set target for HbA<sub>1c</sub>: < 7.0%**

14. Global Guideline for Type 2 Diabetes. Chapter 6: Glucose control levels. *Clinical Guidelines Task Force. International Diabetes Federation 2005. p.26-28*

18. Guidelines on diabetes, pre-diabetes, and cardiovascular diseases: full text. The Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD). Lars Rydén et al. *European Heart Journal*. Doi:10.1093/eurheartj/eh261

31. American Diabetes Association. Executive summary: Standards of Medical Care in Diabetes- 2008. *Diabetes Care* 2008; 31 Suppl 1: S5-S11

### Systolic Blood Pressure<sup>17,18</sup>

< 130 mm Hg	Excellent
130-139 mm Hg	Borderline
≥ 140 mm Hg	Too high

**Pre-set target for systolic blood pressure: < 130 mmHg**

**Pre-set target for blood pressure: <125/75 mmHg in case of renal impairment, proteinuria > 1g/24h**

17. European guidelines on cardiovascular disease prevention in clinical practice. Third Joint Task Force of European and other Societies on Cardiovascular Disease Prevention in Clinical Practice. Guy De Backer et al. *European Heart Journal* (2003) 24, 1601-1610

18. Guidelines on diabetes, pre-diabetes, and cardiovascular diseases: full text. The Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD). Lars Rydén et al. *European Heart Journal*. Doi:10.1093/eurheartj/eh261

### Lipids<sup>16,18</sup>

	Excellent	Good	Too high
Total cholesterol	< 175 mg/dl	175-250 mg/dl	≥ 250 mg/dl
LDL-cholesterol	< 80 mg/dl	80-99 mg/dl	≥ 100 mg/dl
LDL-cholesterol for very high risk patients	< 70 mg/dl		
HDL-cholesterol	> 50 mg/dl	40-50 mg/dl	≤ 40 mg/dl
TG (fasting)	< 150 mg/dl	150-200 mg/dl	≥ 200 mg/dl

**Pre-set target for LDL-cholesterol: < 100 mg/dl**

**For very high risk patients: < 70 mg/dl**

Very high-risk patients are defined as patients with diabetes and coronary artery disease<sup>18</sup>.

16. Implications of recent clinical trials for the National cholesterol Education Programme Adult Treatment Panel III Guidelines. Grundy et al. for the Coordinating Committee of the National Cholesterol Education Programme. *Circulation* 2004; 110: 227-239

18. Guidelines on diabetes, pre-diabetes, and cardiovascular diseases: full text. The Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD). Lars Rydén et al. *European Heart Journal*. Doi:10.1093/eurheartj/eh261

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**OTHER COUNTRIES 2008 (this includes Luxemburg, Spain, Greece, UK and Portugal):**

1. The Clinical Study Protocol, dated 23 July 2007, has been used as basis. This protocol has been discussed with the different participating countries.
2. A Global Clinical Study Protocol Amendment Number 1, dated 5 May 2008, was created after discussions with the different countries and the newer guidelines. The reference values have been adapted in order to be acceptable in all participating countries (See attachment).

Revised Feedback + targets based on Study Protocol Amendment Number 1, dated 5 May 2008. This benchmarking feedback has been given to the GP's throughout the whole study period for all countries (excluding Belgium).

**HbA<sub>1c</sub><sup>31</sup>**

≤ 7%	good
7.1%-7.5%	Too high
>7.5%	Too high

**Pre-set target for HbA<sub>1c</sub>: < 7.0%**

31. American Diabetes Association. Executive summary: Standards of Medical Care in Diabetes- 2008. *Diabetes Care* 2008; 31: Suppl 1: S5-S11

**Systolic Blood Pressure<sup>17,18</sup>**

< 130 mm Hg	good
130-139 mmHg	Too High
≥ 140 mmHg	Too high

**Pre-set target for systolic blood pressure: < 130 mmHg**

**Pre-set target for blood pressure: <125/75 mmHg in case of renal impairment, proteinuria > 1g/24h**

17. European guidelines on cardiovascular disease prevention in clinical practice. Third Joint Task Force of European and other Societies on Cardiovascular Disease Prevention in Clinical Practice. Guy De Backer et al. *European Heart Journal* (2003) 24, 1601-1610

18. Guidelines on diabetes, pre-diabetes, and cardiovascular diseases: full text. The Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD). Lars Rydén et al. *European Heart Journal*. Doi:10.1093/eurheartj/eh261

**LDL cholesterol**<sup>16,18</sup>

< 100 mg/dl	Good
100-110 mg/dl	Too high
>110 mg/dl	Too high

**Pre-set target for LDL-cholesterol: < 100 mg/dl**

**For very high risk patients: < 70 mg/dl**

Very high-risk patients are defined as patients with diabetes and cardiovascular disease<sup>18</sup>.

16. Implications of recent clinical trials for the National cholesterol Education Programme Adult Treatment Panel III Guidelines. Grundy et al. for the Coordinating Committee of the National Cholesterol Education Programme. *Circulation* 2004; 110: 227-239

18. Guidelines on diabetes, pre-diabetes, and cardiovascular diseases: full text. The Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD). Lars Rydén et al. *European Heart Journal*. Doi:10.1093/eurheartj/eh261