



## Reasons for poor asthma control

### 4: The challenge for clinical trials

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**It is difficult to capture and therefore demonstrate subjective benefit in clinical trials. Results from trials that can be applied to real world patients are needed.**

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#### Limitations of current trials

Treatment recommendations in asthma management guidelines are guided by results of clinical trials. However, most clinical trials, as currently designed, are limited in focus and therefore limited in what can be expected from the results.

Factors driving current clinical trials include:

- Regulatory requirements,
- The needs of industry,
- History (what's been done in the past and is therefore still expected),
- Ease of measuring certain endpoints,
- Available technology to measure these endpoints,
- The need to focus on short-term events of asthma,
- The limited number of agents available for treating asthma, and
- The need to remove all possible confounding factors to allow assessment of the intervention studied.

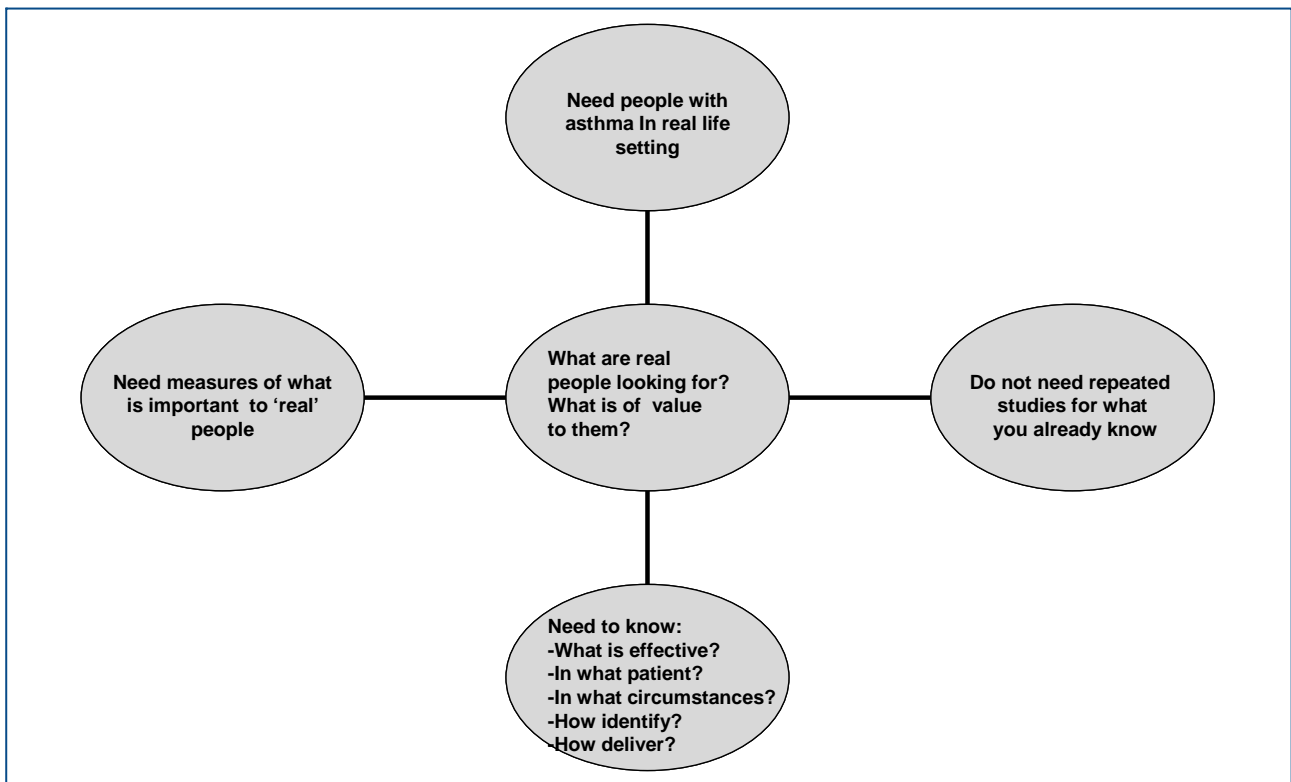
#### The need for trials that apply to real world patients

Only a small percentage (<10%) of patients with asthma seen in primary care would be eligible for enrolment in the typical double-blind randomised controlled trial.<sup>1,2</sup> We need trial results that can be applied to real world patients.

Drawn from an international panel discussion held in Aberdeen in September 2007 and published in Respiratory Medicine: Haughney J, Price D, Kaplan A, Chrystyn H, Horne R, May N, Moffat M, Versnel J, Shanahan ER, Hillyer EV, Tunsäter A, Bjermer L. Achieving asthma control in practice: understanding the reasons for poor control. *Respir Med.* 2008;102:1681-93

We need:

1. Clinical trials enrolling patient populations reflecting the real world diversity in patients seen in primary care, including
  - wide age ranges,
  - presence of comorbidities,
  - current smoking,
  - differing ethnic origins, and
  - cultural diversity.
2. Study of specific asthma phenotypes, such as patients with intermittent asthma attacks, to identify optimal treatment.
3. Measurement of outcomes that are important to patients, as well as their families, such as the ability to lead a normal life.
4. Assessment of the cost-effectiveness of interventions for asthma using outcomes that matter to patients, measures that reflect impact on family and social networks and on personal issues, such as loss of opportunity.



#### References

1. Herland K, Akselsen JP, Skjonsberg OH, Bjermer L. How representative are clinical study patients with asthma or COPD for a larger "real life" population of patients with obstructive lung disease? *Respir Med.* 2005;99:11-9.
2. Travers J, Marsh S, Williams M, et al. External validity of randomised controlled trials in asthma: to whom do the results of the trials apply? *Thorax.* 2007;62:219-23.