



AN EXPERIENCE IN ESTABLISHING A PRESENCE IN JAPAN

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JAPAN – BIOVALLEY : Demographic Differences



JAPAN – a unique culture



ESTABLISHING A PRESENCE - Three Key Success factors

1. Long-term commitment

- **Visible, local commitment to authorities and physicians**
- **Own feasible organisation or partnership**
- **Own organisation allows better adapted clinical development, followed by marketing**

'Actelion Japan' as preferred option

ESTABLISHING A PRESENCE - Three Key Success factors

2. Understanding of local regulatory environment

- **All NDA data submitted to Japanese health authorities have to meet local format requirements**
- **Chain of evidence must be complete (including raw data)**
- **Proven efficacy records elsewhere do not always count**

Submission in Japan is unique

ESTABLISHING A PRESENCE - Three Key Success factors

- 3. Personnel in Japan and HQ willing to adapt**
 - **Language barrier is an issue**
 - **Culture difference between Japan and HQ must be managed**
 - **Presence of an HQ representative in Japan**

Head-Count

End 2001: 7

End 2002: 25

Oct 07: > 100

