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<b>TITLE:</b>	<b>Agenda for the Joint Initiative Open Forum Session on Software as Medical Devices, scheduled for Sunday 10-th October between 16:30 — 18:30 PM</b>
<b>SOURCE:</b>	<b>CEN/TC 251 secretariat</b>
<b>ACTION REQUIRED:</b>	<b>For your information</b>

## Joint Initiative Open Forum Session on Software as Medical Devices

*Educational session at CEN/TC251 and ISO/TC215 JWG meeting in Rotterdam*

**2010-10-10: 16:30 – 18:30**

Open to all JWG attendees

**1. Forum welcome and introduction, <10min**

*Kees Molenaar, JIC Chair*

**2. A Regulator view, <10 min**

*Jos Kraus, NL*

**3. An Industry view, <10 min**

*Martin Ellis, Intellect*

**4. A 'Provider' view - 1, <10 min**

*Neil Gardner, Canada*

**5. A 'Provider' view - 2, <10 min**

*Jeremy Thorp, UK*

**6. A 'Provider' view - 3, <10 min**

*Björn-Erik Erlandsson, Sweden*

**7. EU CEN/CLC JTF Software as Medical Devices (SAMD) status, <10 min**

*Melvin Reynolds, SAMD Co-chair*

**8. ISO/IEC 80001 in context, <10 min**

*Todd Cooper, JWG ISO Co-chair*

**9. Open Forum with Speaker Panel Q&A, >35min**

Moderator, *Kees Molenaar*

In addition to the opportunity to make verbal comments and questions, short written contributions are welcomed.

If pre-notified to Melvin Reynolds <[MelvinR@AMS-Consulting.co.uk](mailto:MelvinR@AMS-Consulting.co.uk)> and Don Newsham <[DNewsham@coachorg.com](mailto:DNewsham@coachorg.com)>, and depending on their number, there may be time to schedule written contributions into this open period of the meeting.

Any such written contributions will be collected together for the benefit of national experts and any subsequent work on this topic.

**10. Forum Summary / Actions, <5min**

*Don Newsham, JIC-OF/H WG Co-chair*

18:30 Forum Close