Roche Diabetes Care Participation in the Continua Health Alliance – *A Members Perspective*

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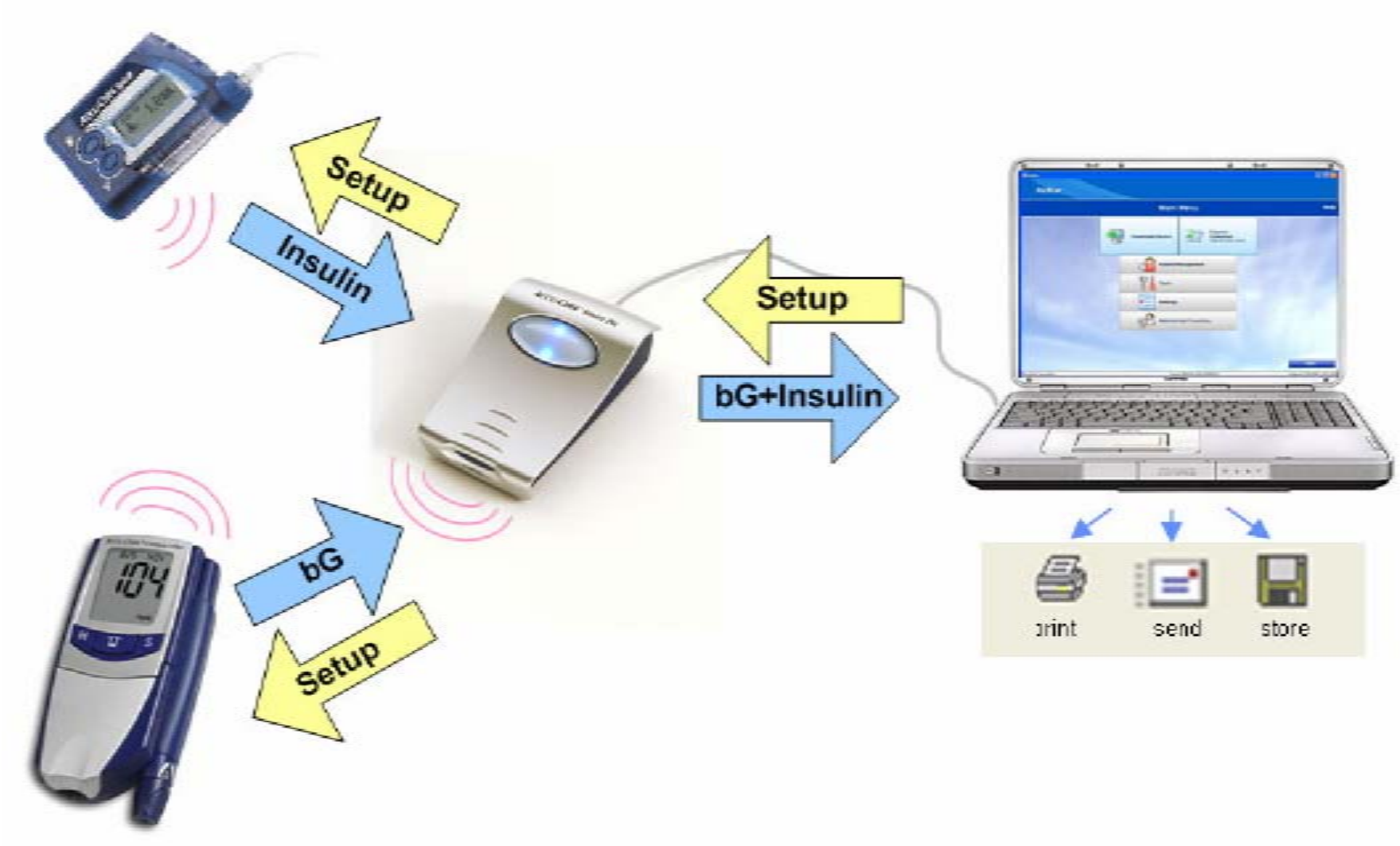
Roche Diabetes Care Product Portfolio

- Serving People w/ Diabetes & Professionals



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Many Innovations Start with a Problem ...

And the problem is …

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Changing Health Care Environment calls for Efficiency Improvements

	Cost and Quality Pressures	Example: Type 2 Epidemic
Trends	• Payors more aggressively targeting expenses for chronicle diseases • Increasing demands on HCPs for quality control – ***Pay for Performance*** • Rising computerization of PwD and practices	• Future health care cost significantly driven by pre-diabetics and Type 2s • Type 2s have to deal with diabetes along with comorbidities • PCPs and nurses gatekeepers to Type 2 population
Needs	• Improve practise efficiency • Facilitate patient self-management • Digitalization and interoperability	• Enable treatment by nurses and PCP's • Provide optimal therapy, avoid trial& error ("Watch Dogs", Prognosis Models)

Potential Solutions

- Easy device & non device data capturing, storing
- Data concentration, analysis & integration (into DMS, EHR, PHR)
- Information concentration sharing & exchange
- Remote patient monitoring
- Telehealth / telemedicine incl. instant decision support

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User Issues: Capturing & Integrating of Diabetes Information

- **Top challenges for health care providers (HCP)**
  - Single, automated method and interface for uploading blood glucose and insulin data
    - Cost, power and size considerations lead to simple proprietary, connectivity implementations
  - Capturing of diabetes related data (blood pressure, weight scale data, carbohydrate intake, etc.) – direct data upload from home-use devices
  - Integration of diabetes related data into EMR / EHR.
    Note: Diabetes is more than one disease (cardio vascular, renal disorder, stroke, nerve damage, obesity, etc.)
    - Diabetes management applications are often not part of the IT infrastructure
    - Diabetes management applications are typically standalone and lack data exchange with other systems e.g. practice managemnt systems, EMR, DMS
    - Today's EMR interfaces are non-standard and highly customized. Interfacing cost and maintenance prevents data exchange.

Industry Challenge: Regulatory Environment

- **Situation**:
  - IVDD/ MDD in Europe, FDA in the US regulate the interaction (data exchange) between medical / in-vitro diagnostics devices and data recording / data management systems.
    - New MDD considers medical software as “Medical Device”
- **Requirement**:
  - Interfaces between devices and software require formal validation
  - Regulatory bodies expect proper complaint handling to protect users from harm
- **Consequence:**
  - Validation effort to implement & support connectivity for 3rd party devices or applications becomes a significant burden. Proprietary nature of device / applications communication compound the issue
  - Interoperability between industries and/or manufacturers is costly and very difficult to manage

* IVDD = Invitro Diagnostics Device Directive, MDD = Medical Device Directive of the European Union

Continua Health Alliance

Opportunity:

- Continua Health Alliance is an industry consortium targeting the telehealth and remote monitoring markets with the stated intent of

  "Bringing together standards and diverse technology….to enable better personal health care for people worldwide."

- More than 130 companies have joined including: AstraZeneca, Bayer, Boston Scientific, Cisco, GE, HDI, IBM, Intel, Kaiser Permanente, LifeScan, Medtronic, Motorola, Novo Nordisk, Partners Healthcare, Panasonic, Philips, Pfizer, Samsung, Sharp, Siemens.

Current Status:

Roche participating as a founding member to drive & influence the development of emerging markets for interoperability, remote monitoring / telehealth. Our participation includes:

- Dedicating diabetes care subject matter expertise to ensure that the requirements of our customers are addressed in the Continua guidelines
- Investing technical resource to ensure that Continua specifications reflect the requirements of our devices / applications and that our product portfolio is Continua compliant
- Contributing regulatory knowledge with the goal to achieve endorsement of the Continua standard by regulatory bodies

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Expected Benefits of Participation in the CHA

- Establish standardization of medical device communication and application data exchange based on state-of-art connectivity technologies and standards.
  - Standardization drives technological implementation of interoperability
  - Interoperability solutions drive efficiency and promote tele-medical approaches
  - Efficiency gains are pre-requisite for reimbursement
  - Reimbursement is precondition of business opportunities
- Reduce regulatory barriers to interoperability through standardization and compliance certification in close cooperation with regulatory bodies
- Drive and ultimately achieve reimbursement of telehealth / telemedical services

- *Fosters interaction between industries and health care providers assisting in adoption of beneficial solutions.*
- *Interaction between industries fosters creativity, enables partnerships and propels innovation*

Continua Health Alliance

The Right Time

The Right Place

The Right Size

The Right Combination

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Issues relevant to EHR/meter integration?

- Healthcare Providers often voice 2 common wishes:
  - a single, automated method and interface for uploading bG data
  - a single graphical format for charting bG data for use in Diabetes Management

- Standalone diabetes care applications most often aren't supported by HIT departments
  - Applications like Camit Pro or 360 get "stranded" on a PC "island", not on the network
  - Note: HIT apps that *<u>are</u>* integrated imply on-going service-level support from vendors

- EHR vendors aren't FDA regulated - and they'd prefer to stay that way
  - Direct integration with a medical device begs the question: "Who is liable?"

Tim Stitely, CIO of the FDA says[1] *"As the ability for direct capture evolves, the current direction FDA is heading is* ***the medical record becomes part of the device.*** *I don't think now [EHRs] as defined will be regulated by the FDA. It is not a medical device, food, drug or other thing we regulate."* The types of devices the FDA may regulate could include blood pressure or cardiogram devices that send the data directly into a database.

[1] FDA to Oppose Rule on Health Records - Miller, Government Health IT, June 5, 2007