



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/CAT Workshop on Cell-based Therapies for Cardiac Repair

EMA London 14.-15.5.2014

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CAT Vice-Chair
CAT-DGTI-GSCN Workshop, 11 September 2014, Dresden

An agency of the European Union





Agenda (1) CAT Workshop – Cardiac Repair

Quality – Manufacturing technologies

- Non-manipulated (non-selected and selected) cell-based medicinal products (CBMPs) derived from bone marrow or apheresis
- Expanded CBMPs (e.g. MSCs, cardiac stem cells)

Non-clinical models

- Non-clinical issues and animal models for cardiac repair



Agenda (2) CAT Workshop – Cardiac Repair

Clinical issues – part 1

Focus on Acute Myocardial Infarction and Chronic Heart failure

Clinicians` experience from clinical trials with

- non-manipulated, non-sorted bone marrow or apheresis cells
- sorted BM or apheresis cells
- expanded cells (MSCs, cardiac stem cells...)

Clinicians` experience with Imaging Techniques

- Efficacy assessment by imaging
 - Cell tracking and retention, morphology, function



Agenda (3) CAT Workshop – Cardiac Repair

Clinical issues – part 2

Focus on Acute Myocardial Infarction and Chronic Heart failure

Discussion on

- Target population
- Timing of administration
- Cell dose, route and schedule of administration
- Design of pivotal trials

Round table and general discussion

Conclusions