

Busta 1

1. Quali caratteristiche devono avere le formulazioni dei farmaci destinate ai bambini
2. Quali sono le caratteristiche strutturali di una unità di fase I
3. Quali sono i principi etici su cui si basano le GCP

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Towards reducing inequalities: European Standards of Care for Children with Cancer[☆]

1. Introduction

Significant progress has been made in the treatment results of children with cancer across Europe. This progress was achieved due to the close collaborations amongst paediatric oncology professionals, within and across the different Member States.

Despite these efforts, disparities in survival rates and significant long-term side-effects in many survivors across Europe are a fact [1,2]. The majority of these disparities are due to the different approach of treatments, the organisation of care and availability of resources across Europe [3–5]. This situation must and should be improved to prevent unnecessary young citizen's suffering and deaths. One of the most important conditions to obtain comparable results and equitable outcomes is that each of the centres delivering the complex treatments required by children and young people with cancer should meet certain minimum standards and provide access to continuously updated 'best practice'. This objective can be achieved only if each centre takes an active part in research or in a network that provides access to 'State of the Art' treatments. To address these inequalities, the European Society of Paediatric Oncology (SIOPE) has carried out a joint study in order to investigate the current situation and the Standards of Paediatric Oncology Centres across Europe, in partnership with ICCCP, the International Confederation of Childhood Cancer Parent Organisations [6].



all. 2 verb. 4

Busta 2

1. Problematiche nella somministrazione dei farmaci endovenosi in età pediatrica
2. Che training è necessario per le persone coinvolte nelle sperimentazioni cliniche pediatriche
3. Peculiarità nella conduzione degli studi clinici nei bambini rispetto a quanto avviene negli adulti



Busta 2

Towards reducing inequalities: European Standards of Care for Children with Cancer[☆]

These standards include both the infrastructure for diagnosis and treatment as well as common work practices and training for health professionals, including participation in clinical trials.

Significant progress has been made since the Warsaw Conference in 2009 which launched this project and partnership between paediatric oncologists, patients, parents, nurses, psychologists, counsellors, play therapists and physiotherapists.

The implementation of the Standards at national level, possibly through national cancer plans, would be a vital 'next step', improving the Quality-of-Care for children with cancer, increasing survival rates and enhancing the Quality-of-Life for childhood cancer survivors. Applying harmonised Standards of Care would guarantee more accurate diagnosis and risk stratification and application of 'state-of-the-art' treatments and follow-up practices, particularly important for young patients with life-threatening diseases like cancer who receive intensive treatments at an early stage in their life [5].



all. 3 verb 4

Busta 3

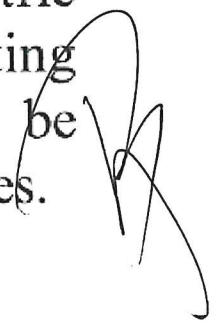
1. Differenze nella farmacocinetica nelle diverse fasce di età pediatriche
2. Quando va preparato un pediatric investigation Plan
3. Peculiarità del consenso informato in età pediatrica



Towards reducing inequalities: European Standards of Care for Children with Cancer[☆]

2. The European Standards of Care for Children with Cancer – Document overview

Delivery of Therapy: treatment of cancer in children and young people is constantly being refined and the inclusion of the patient in clinical trials is widely recognised as the best ‘standard of care’ even for newly diagnosed patients. Treatment protocol recommendations need to be regularly updated, so to remain consistent with the latest research findings. Optimal treatment should be widely encouraged by the national childhood cancer research network. Depending on the country, drugs are covered either by an insurance company or the State. Standard chemotherapy drugs are often administered ‘off label’ to children with cancer purely due to the lack of relevant paediatric studies in the application for the marketing authorisation. Such ‘off-label’ drug use must be covered by the usual national health procedures.



Busta 4

1. Come si calcolano le dosi dei farmaci in età pediatrica
2. Quando è necessario creare un clinical trial quality team
3. Secondo lei quali sono le caratteristiche di un team dedicato agli studi clinici in età pediatrica rispetto a quanto avviene nell'adulto

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Busto 4

Towards reducing inequalities: European Standards of Care for Children with Cancer[☆]

2. The European Standards of Care for Children with Cancer – Document overview

2. A Childhood Cancer Register is required at national level, based upon the internationally-recognised classification – International Classification of Childhood Cancer ver.3 (ICCC-3). In this regard the peculiarities of adolescent cancer need to be taken into account.
3. Requirements of a Paediatric Haematology and/or Oncology Unit: each paediatric haematology and/or oncology unit requires a number of standard facilities to cater for patients and their families as well as approved clinical protocols. Link-ups with other specialised units should be in place in case the need for further consultation should arise and/or to offer some procedures ('shared care') to patients living close by.

