

University of  
Torino

VII Seminario sul Software  
per la Fisica Nucleare,  
Subnucleare ed Applicata



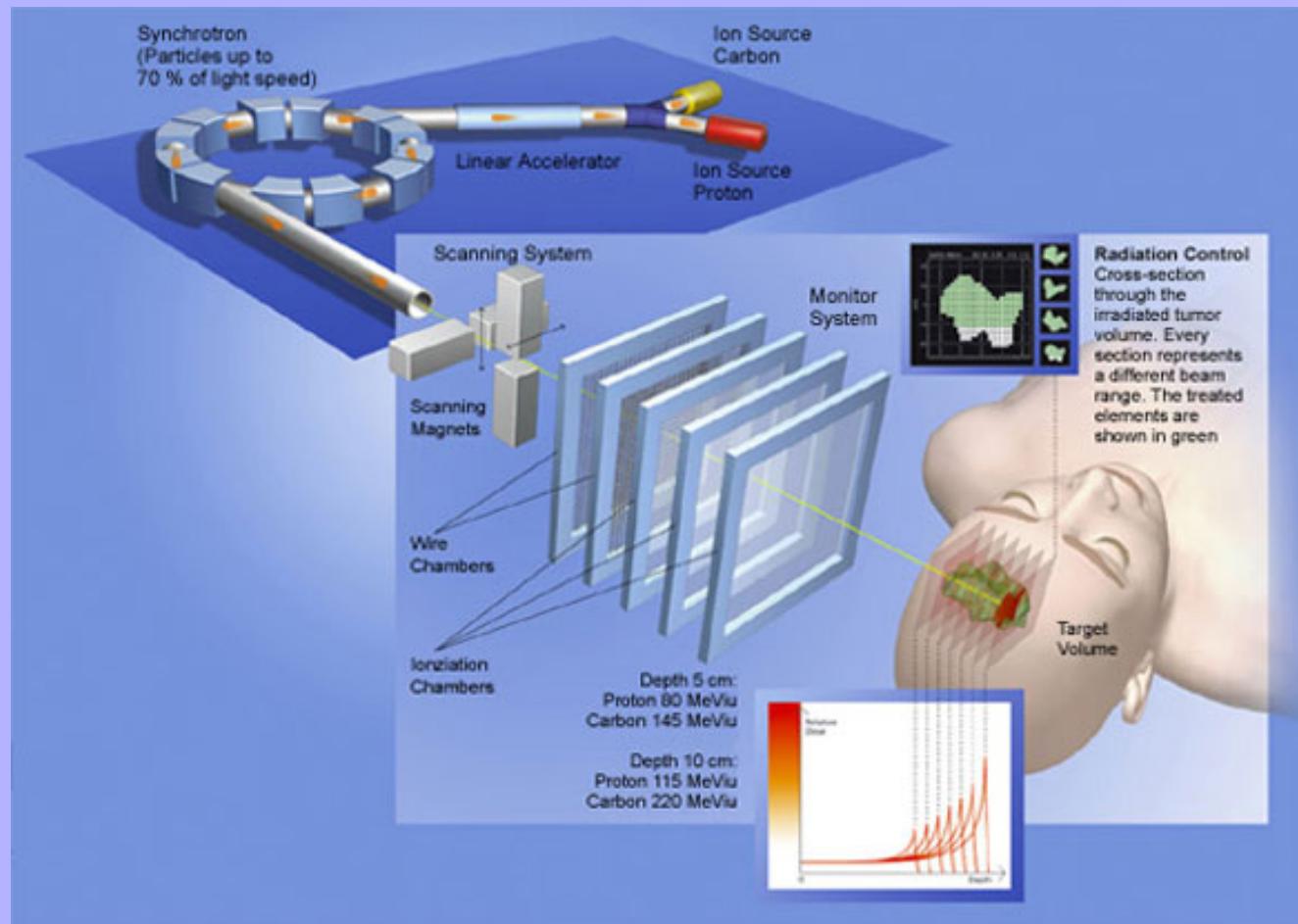
INFN-TPS  
project

# The development of a carbon ion Treatment Planning System

Germano Russo

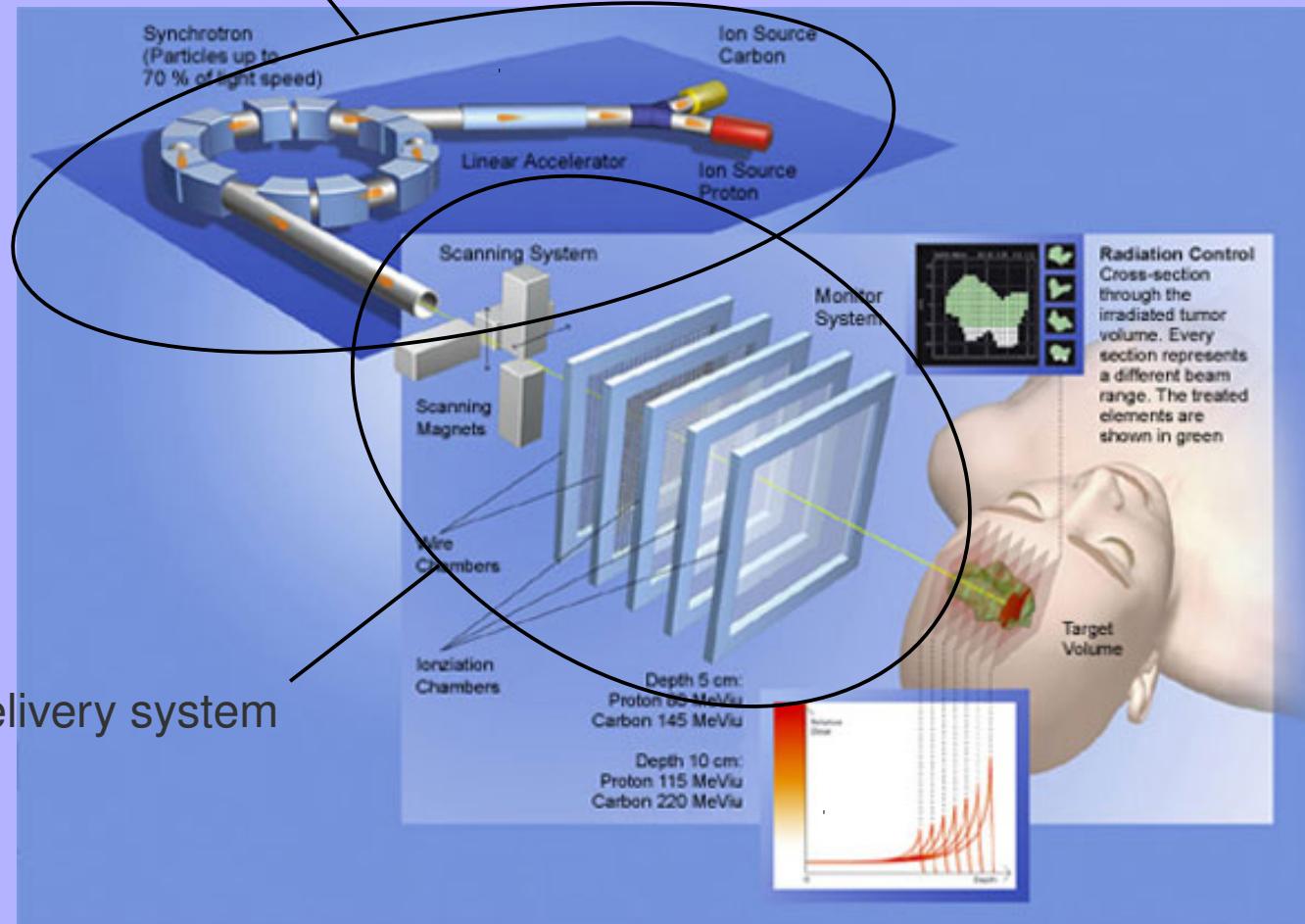
Alghero, 01/06/2010

# The principles of ion therapy



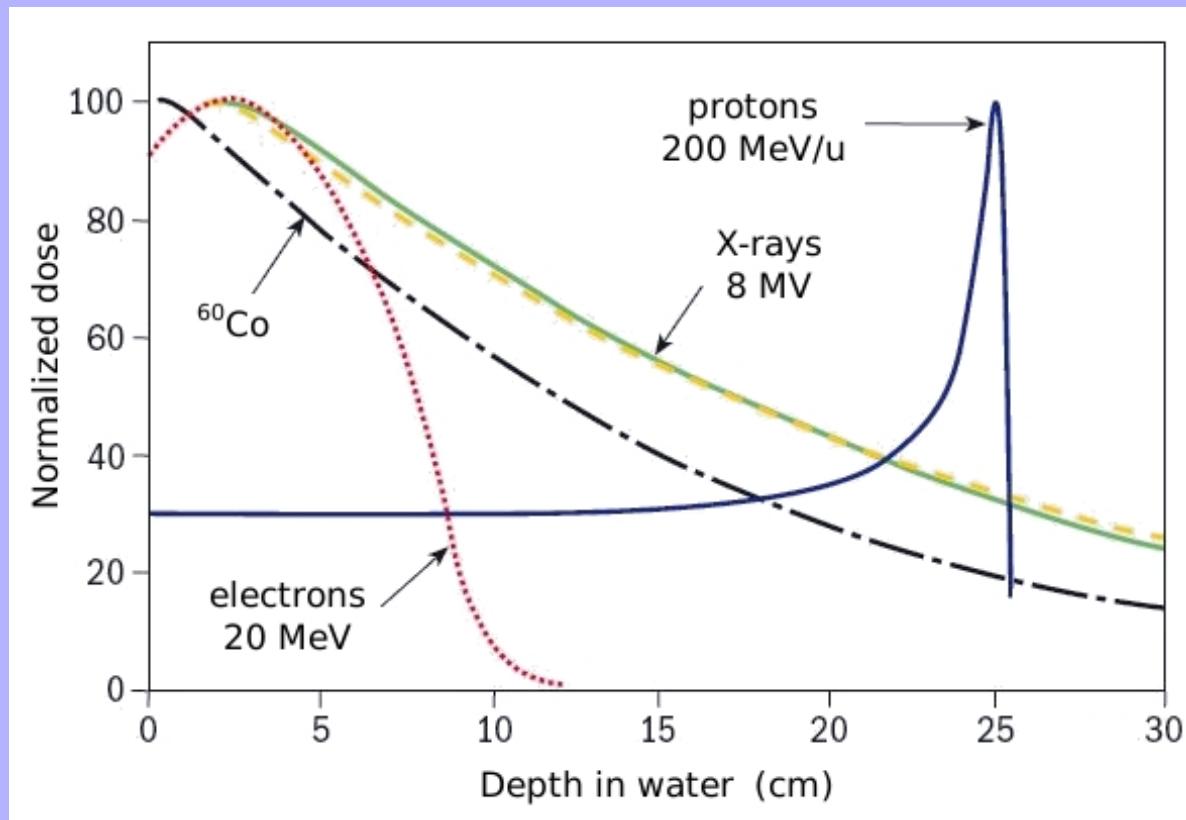
# The principles of ion therapy

Accelerating system

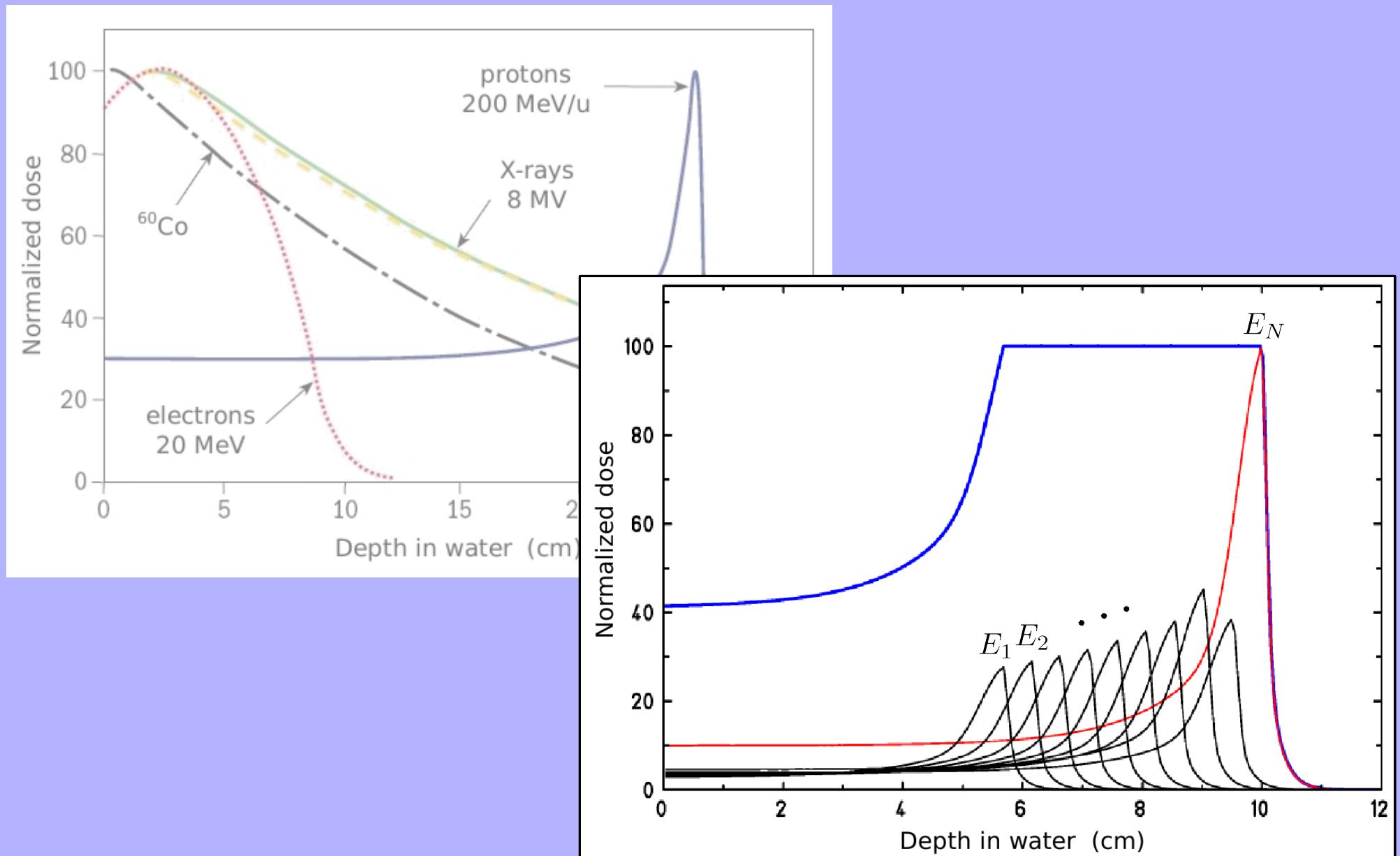


Delivery system

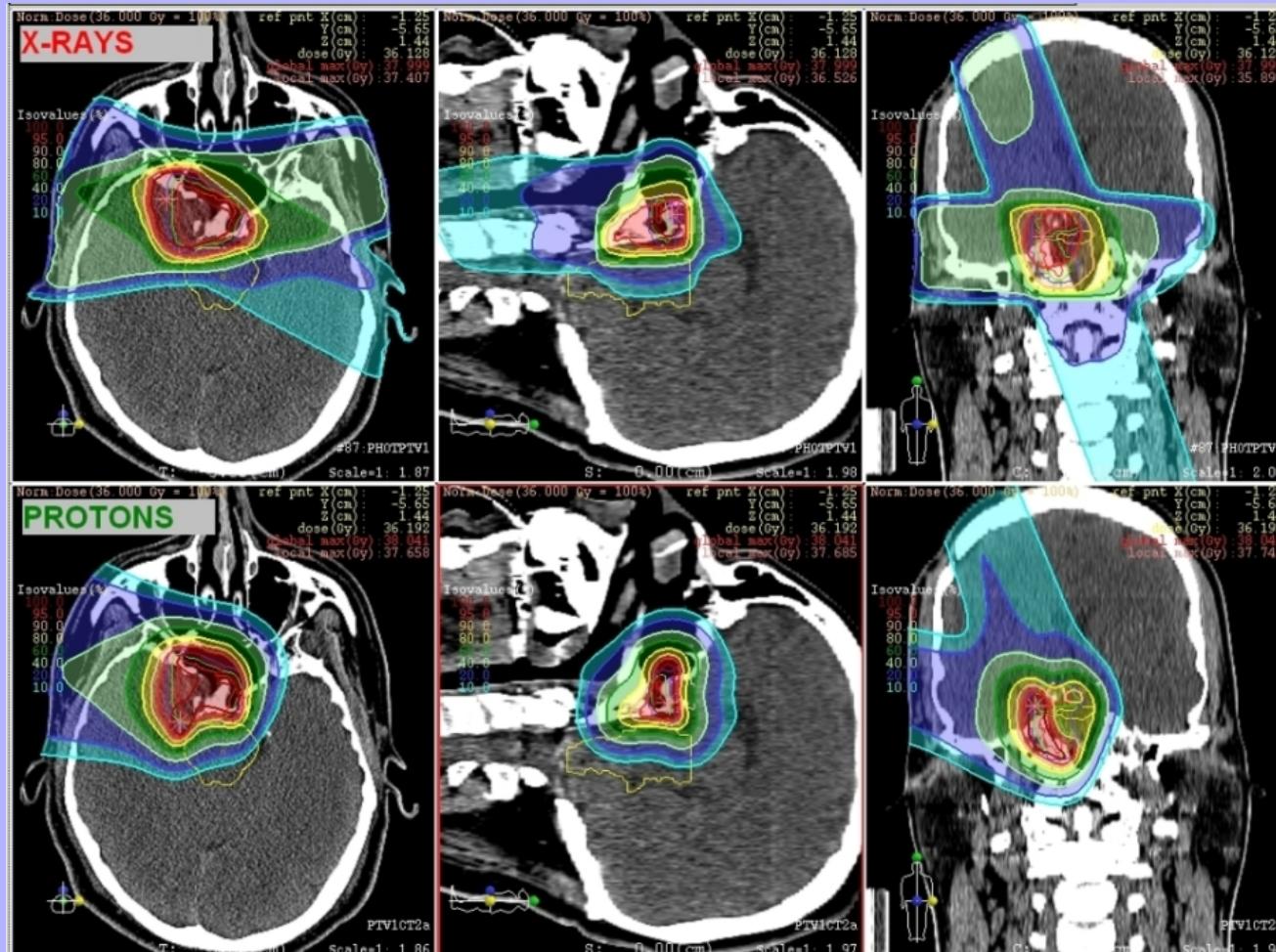
# The principles of ion therapy | Bragg Peak



# The principles of ion therapy | Spread Out Bragg Peak



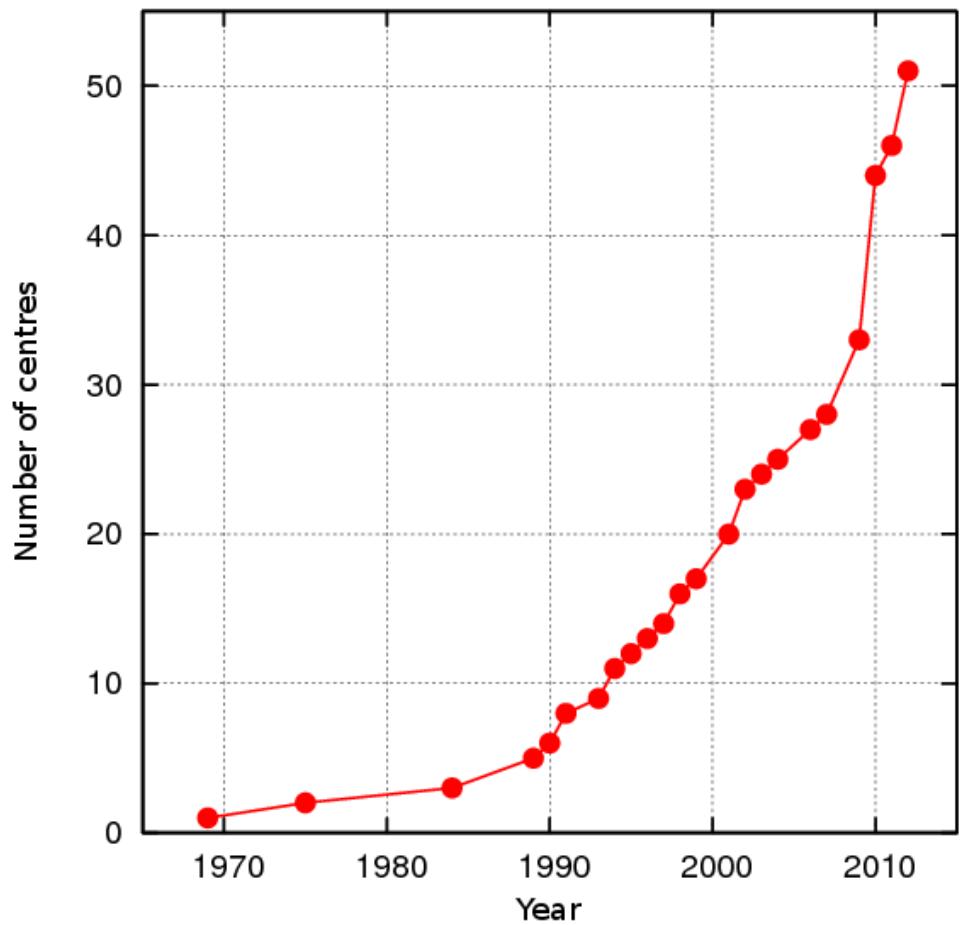
# The principles of ion therapy | Dose conformity



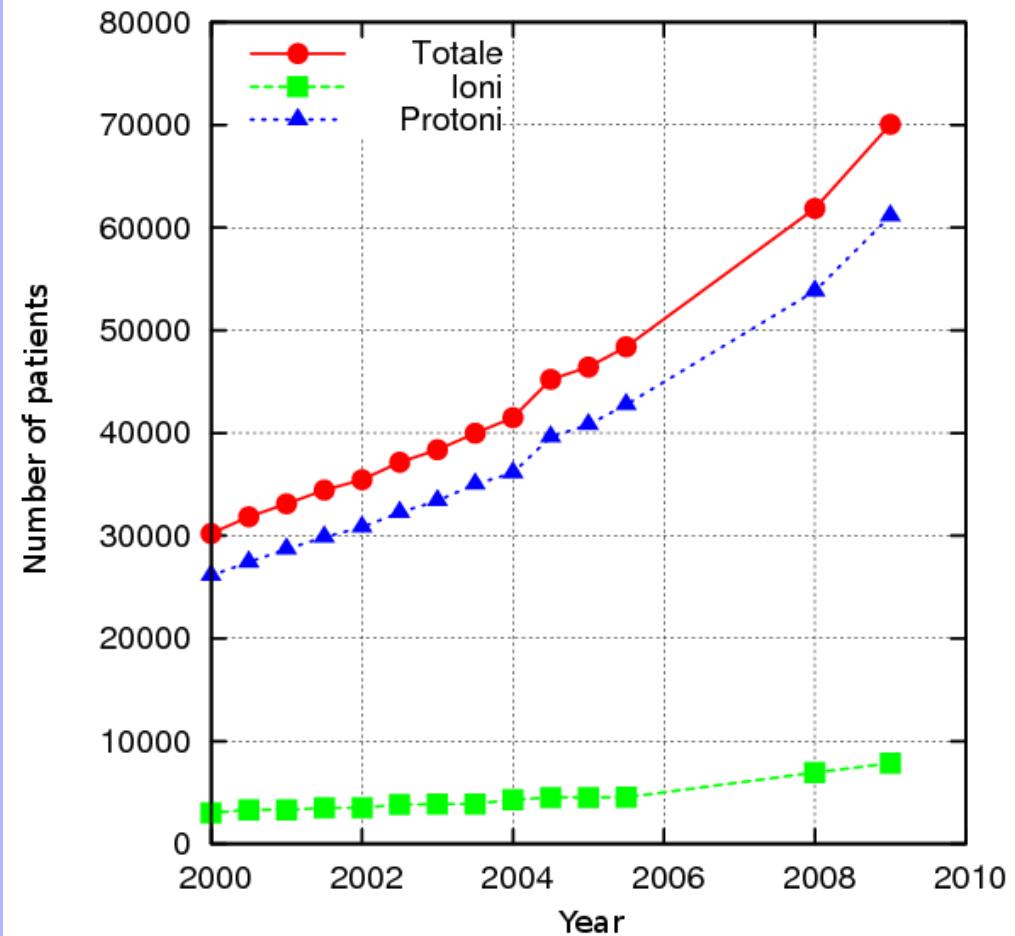
Courtesy of the Rinecker Proton Therapy Center, Germany

# The principles of ion therapy | Spread

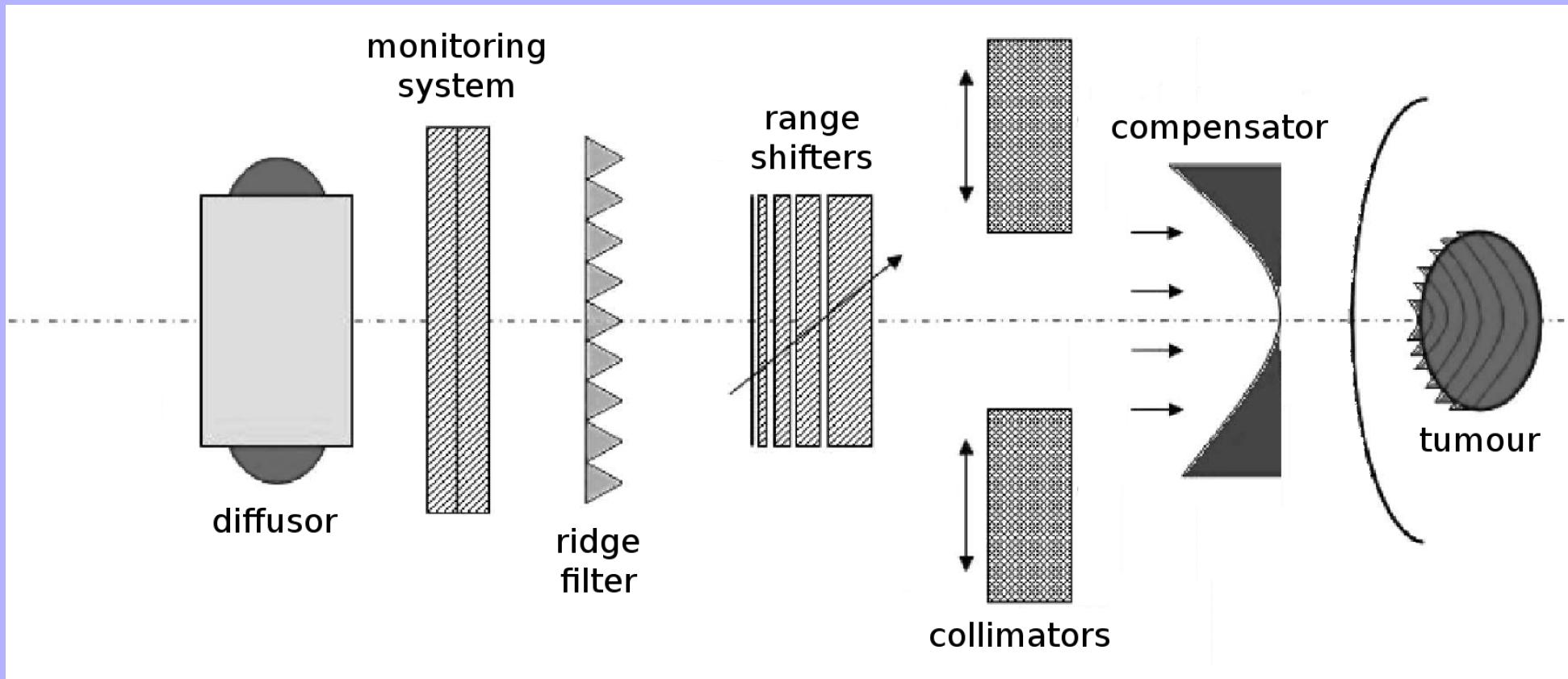
Hadrontherapy centres around the world



Treated patients around the world



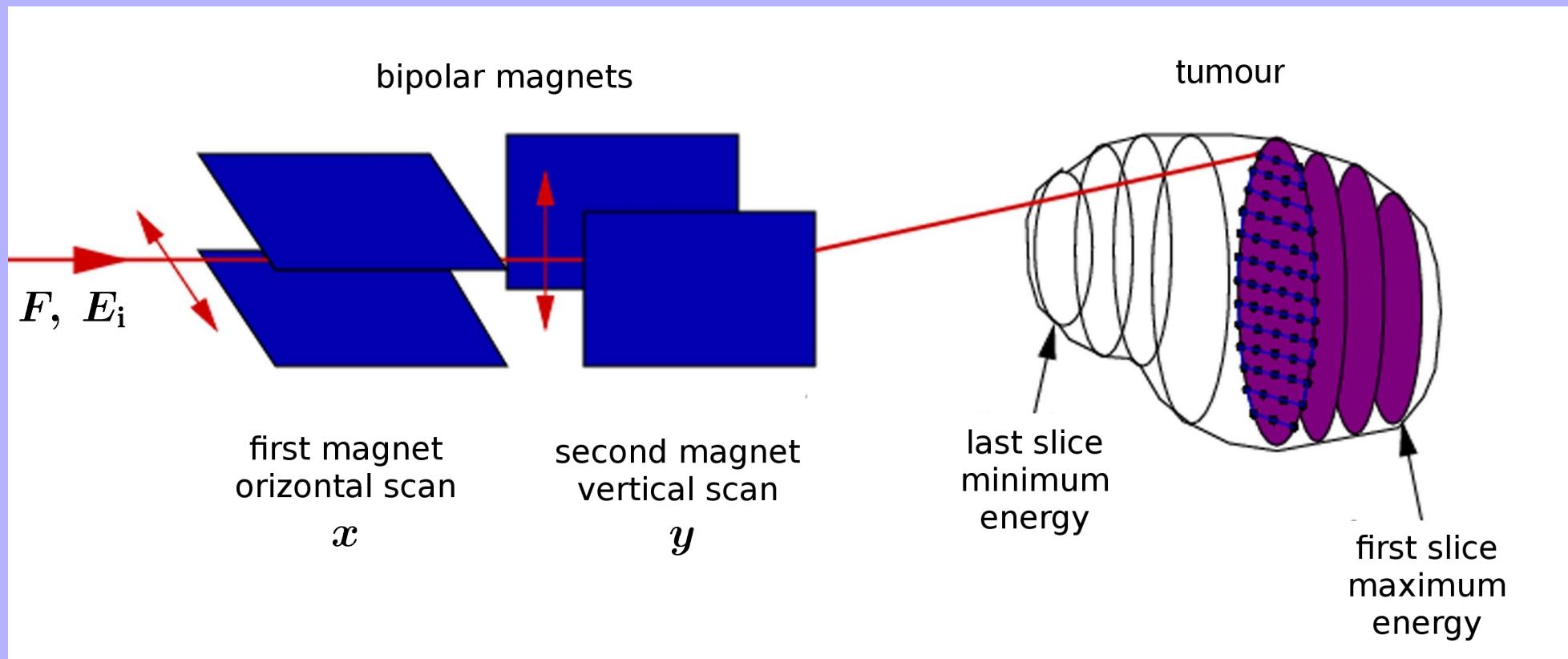
# The principles of ion therapy | Passive delivery



*HIBMC*

**HIMAC**

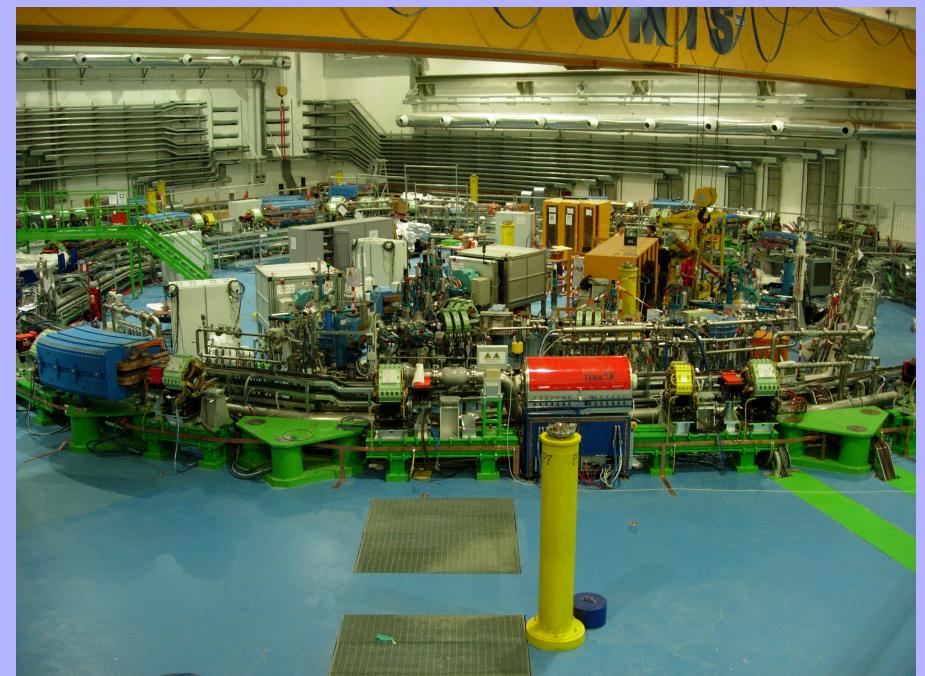
# The principles of ion therapy | Active scan



# The principles of ion therapy | Active scan

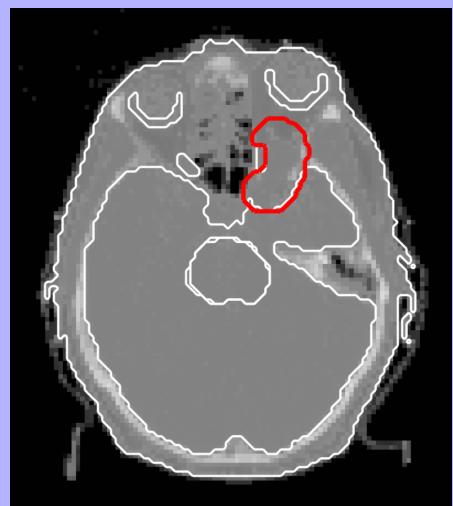


Building of the Centro Nazionale di Adroterapia Oncologica (CNAO), Pavia, Italy – under construction

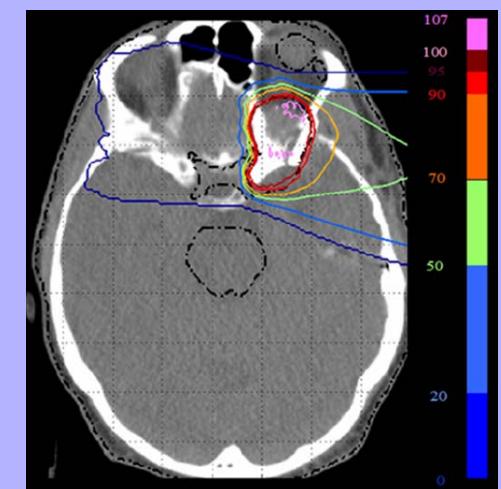


Accelerating ring of the CNAO

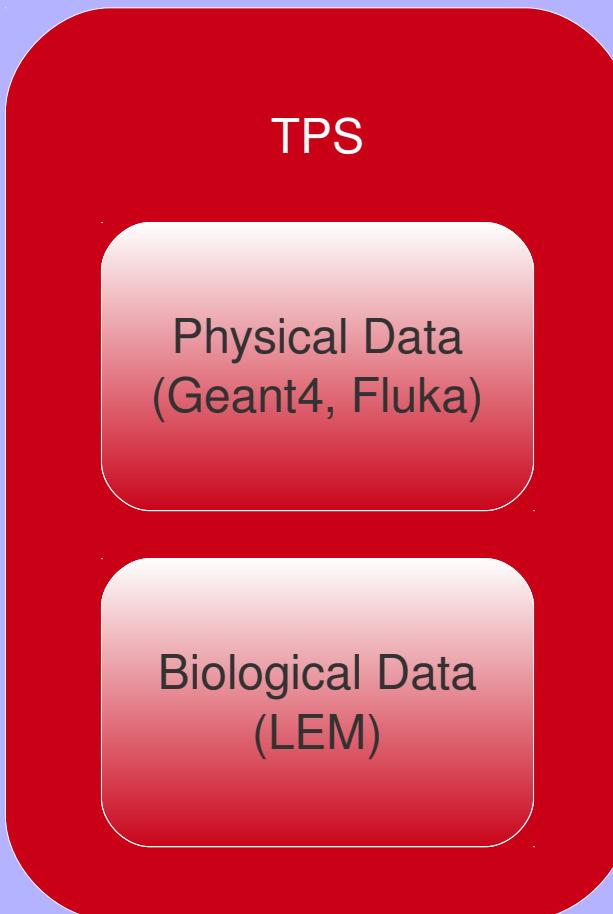
# The principles of ion therapy | TPS



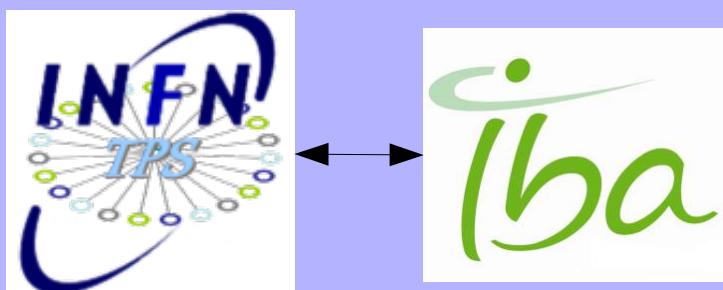
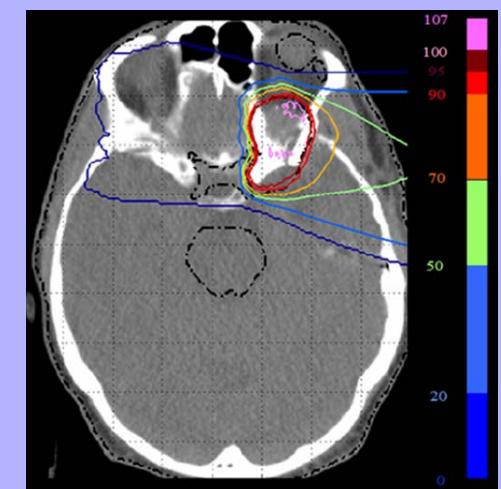
$$\rightarrow \{E_i, F, x, y\}$$



# The principles of ion therapy | TPS



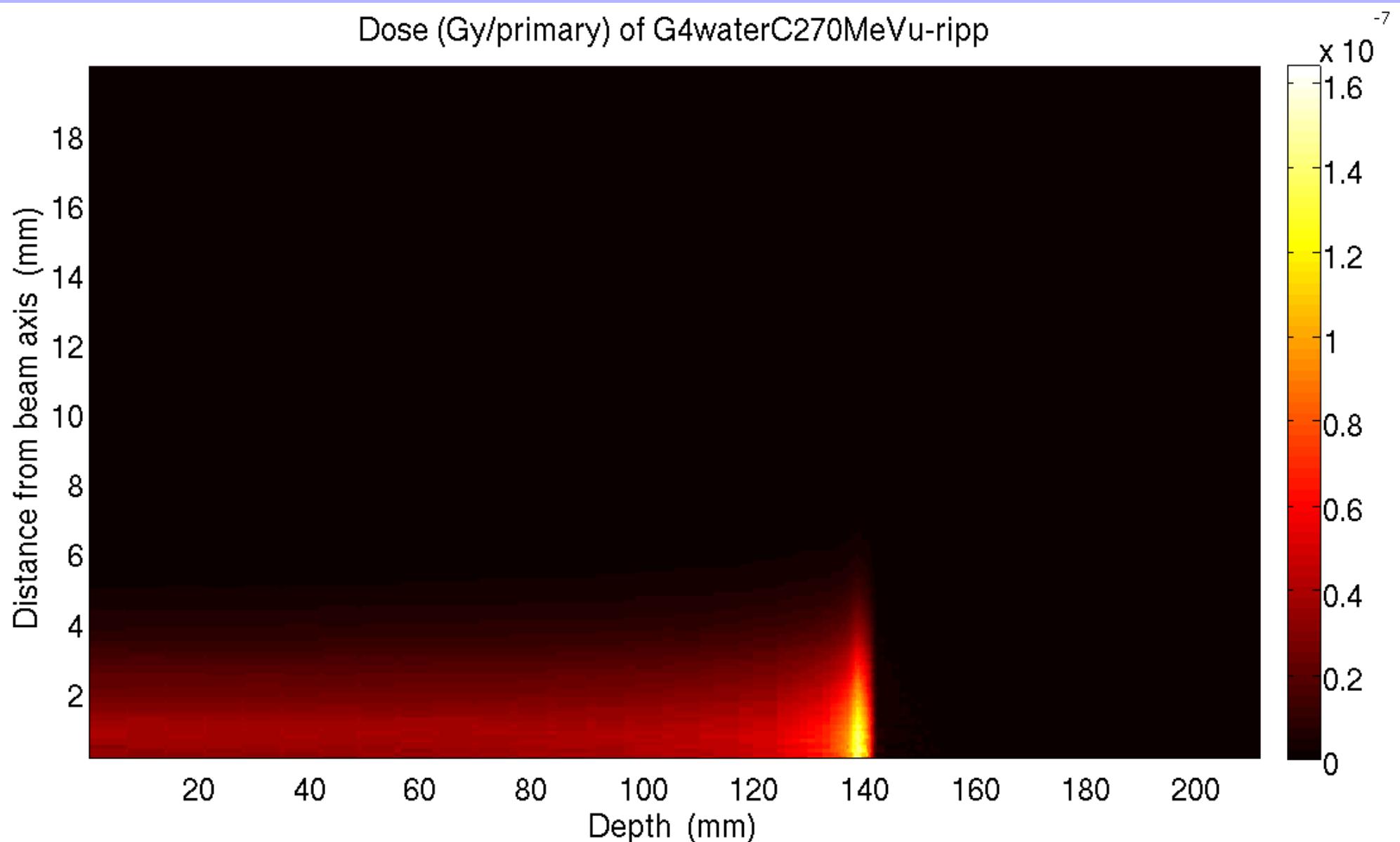
$$\rightarrow \{E_i, F, x, y\}$$



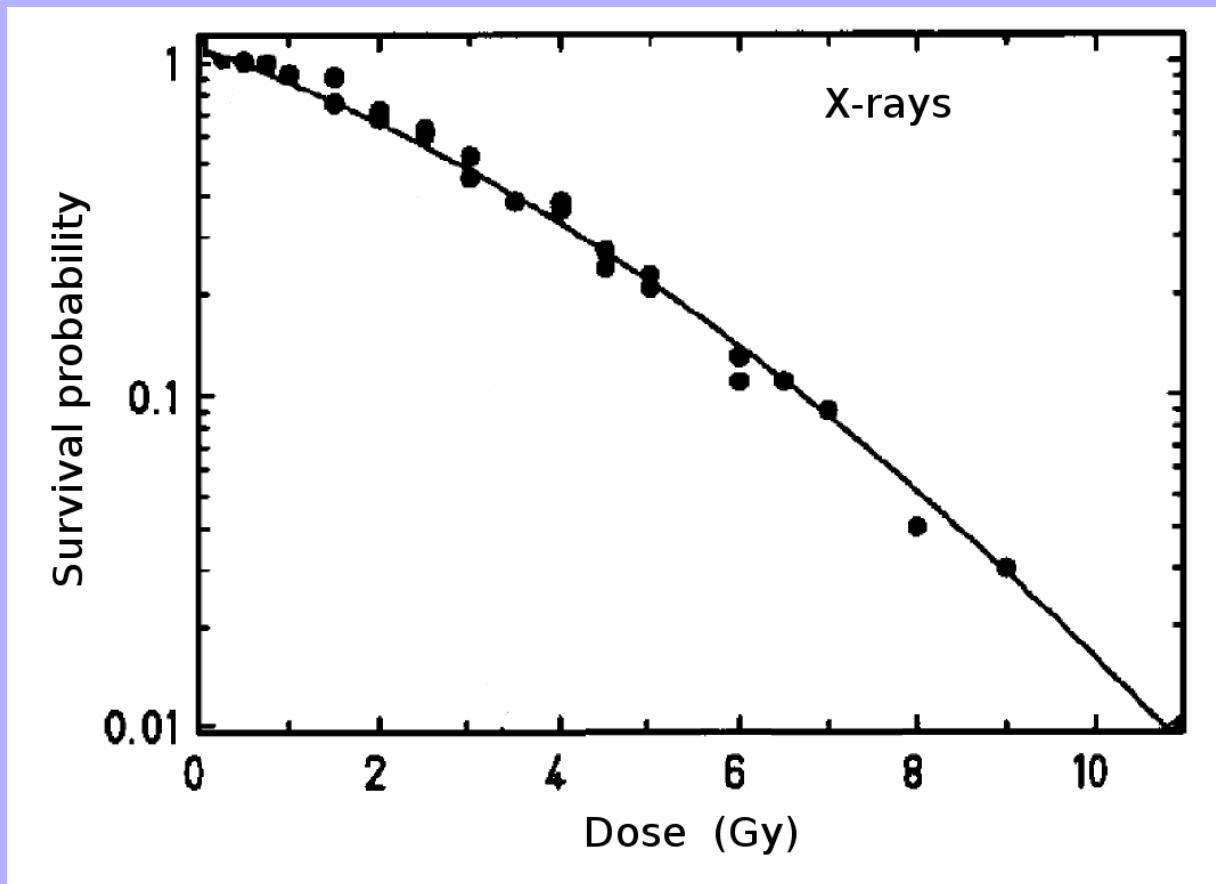
Cooperation Agreement  
for the development of  
a commercial carbon ion TPS  
signed on June 2009

# TPS Physical Data

Dose (Gy/primary) of G4waterC270MeVu-ripp



## TPS Biological Data | Survival curves

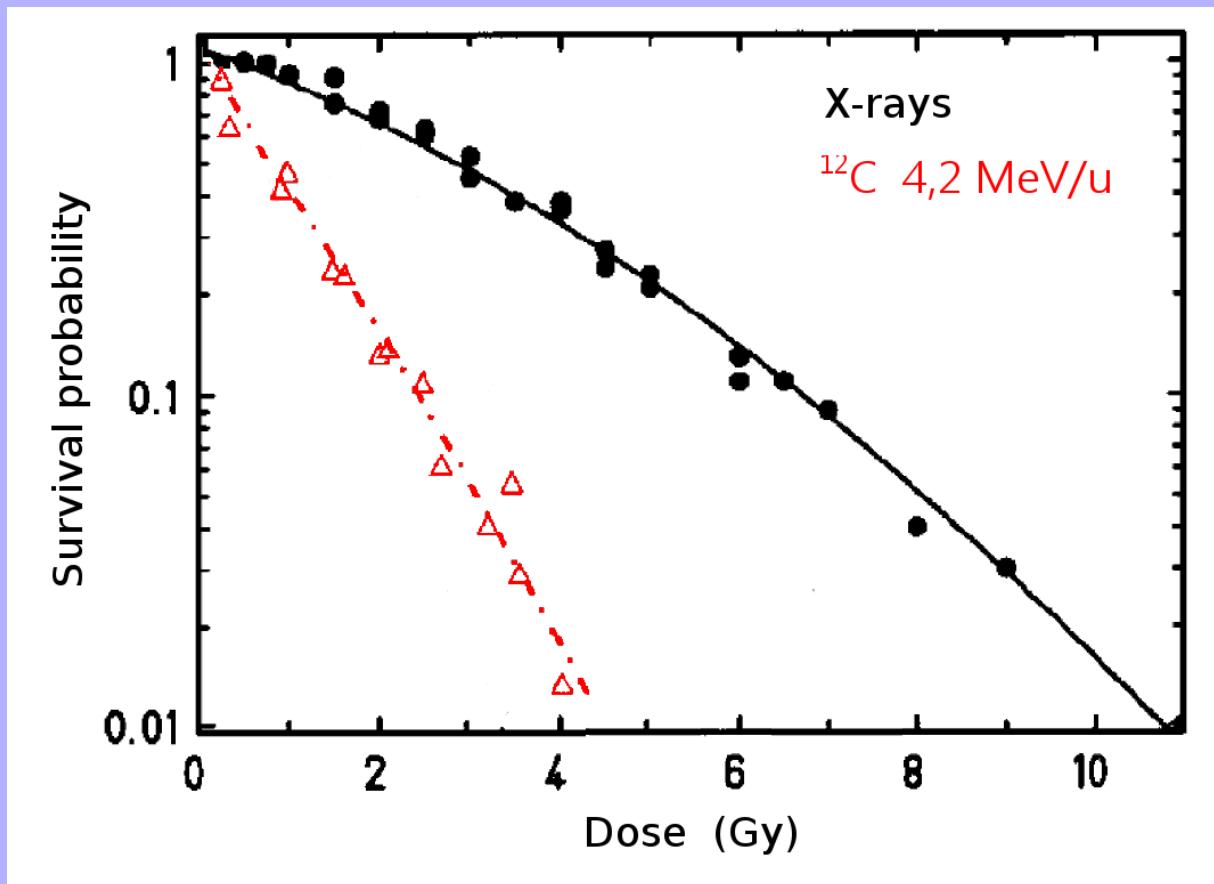


The biological effect depends on:

- 1) tissue type:
  - cell line;
  - oxygenation level;
  - growing environment.
- 2) beam characteristics:
  - dose released;
  - radiation type.

$$S(D) = e^{-\alpha_x D - \beta_x D^2}$$

## TPS Biological Data | Survival curves



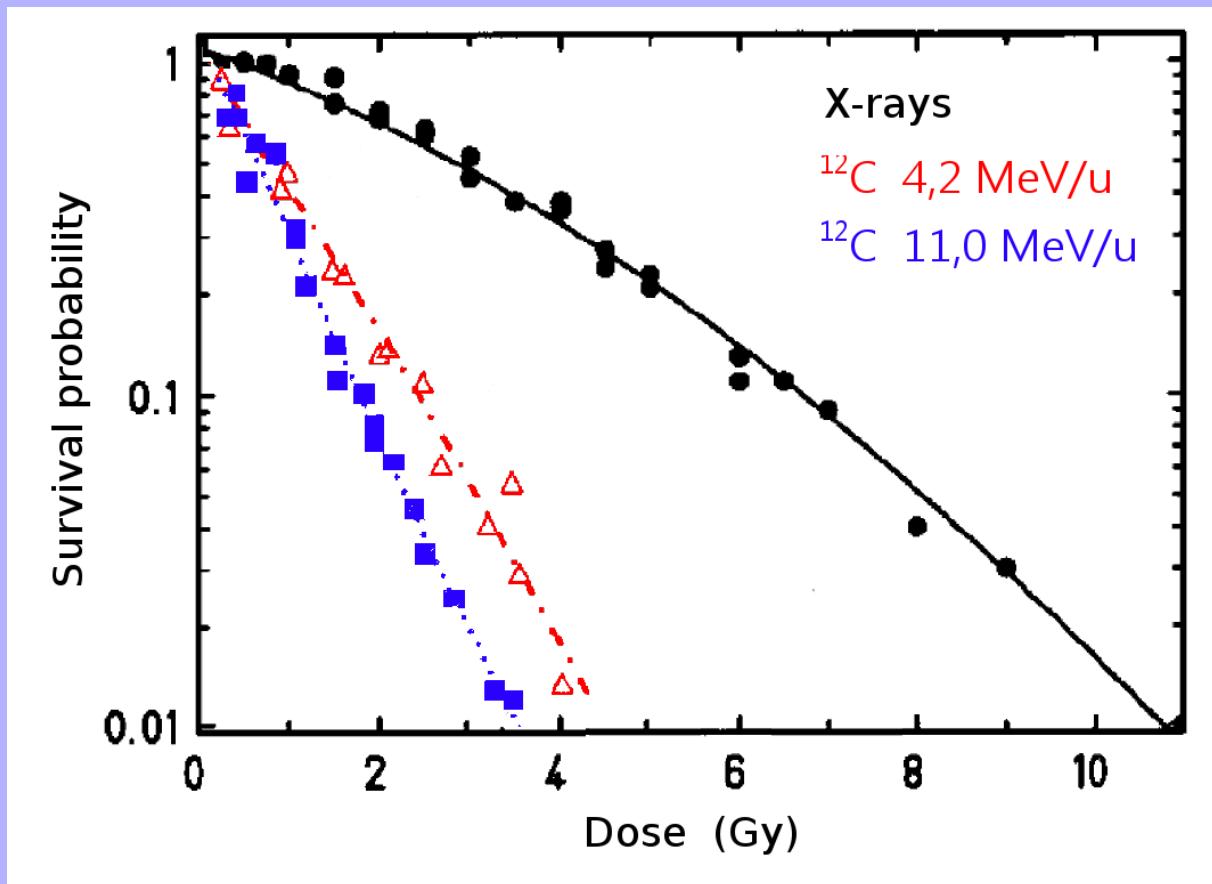
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$$S(D) = e^{-\alpha_x D - \beta_x D^2}$$

$$S(D) = e^{-\alpha D - \beta D^2}$$

# TPS Biological Data | Survival curves



The biological effect depends on:

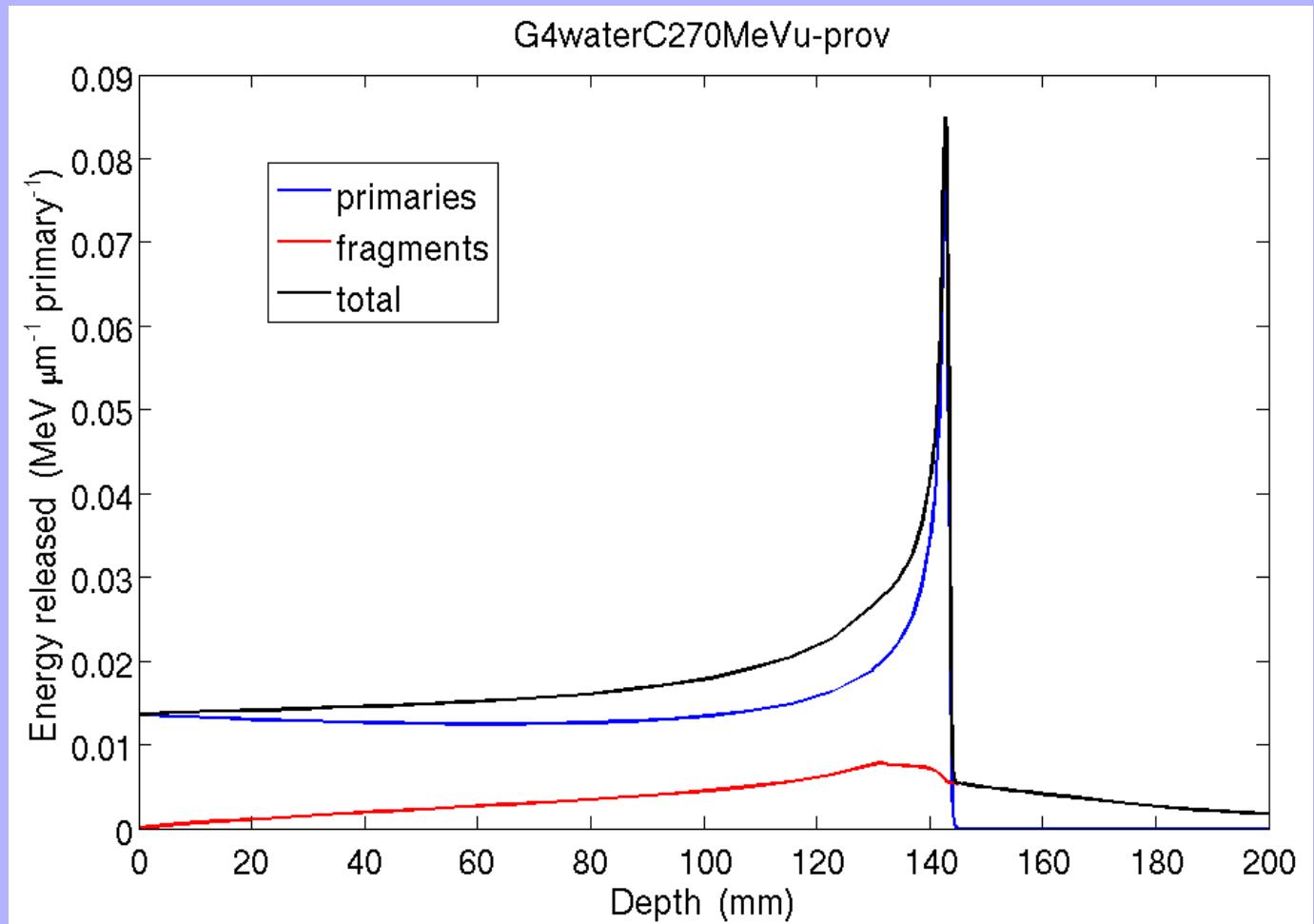
- 1) tissue type:
  - cell line;
  - oxygenation level;
  - growing environment.
- 2) beam characteristics:
  - dose released;
  - radiation type;
  - $p(e_c, \text{LET})$ .

$$S(D) = e^{-\alpha_x D - \beta_x D^2}$$

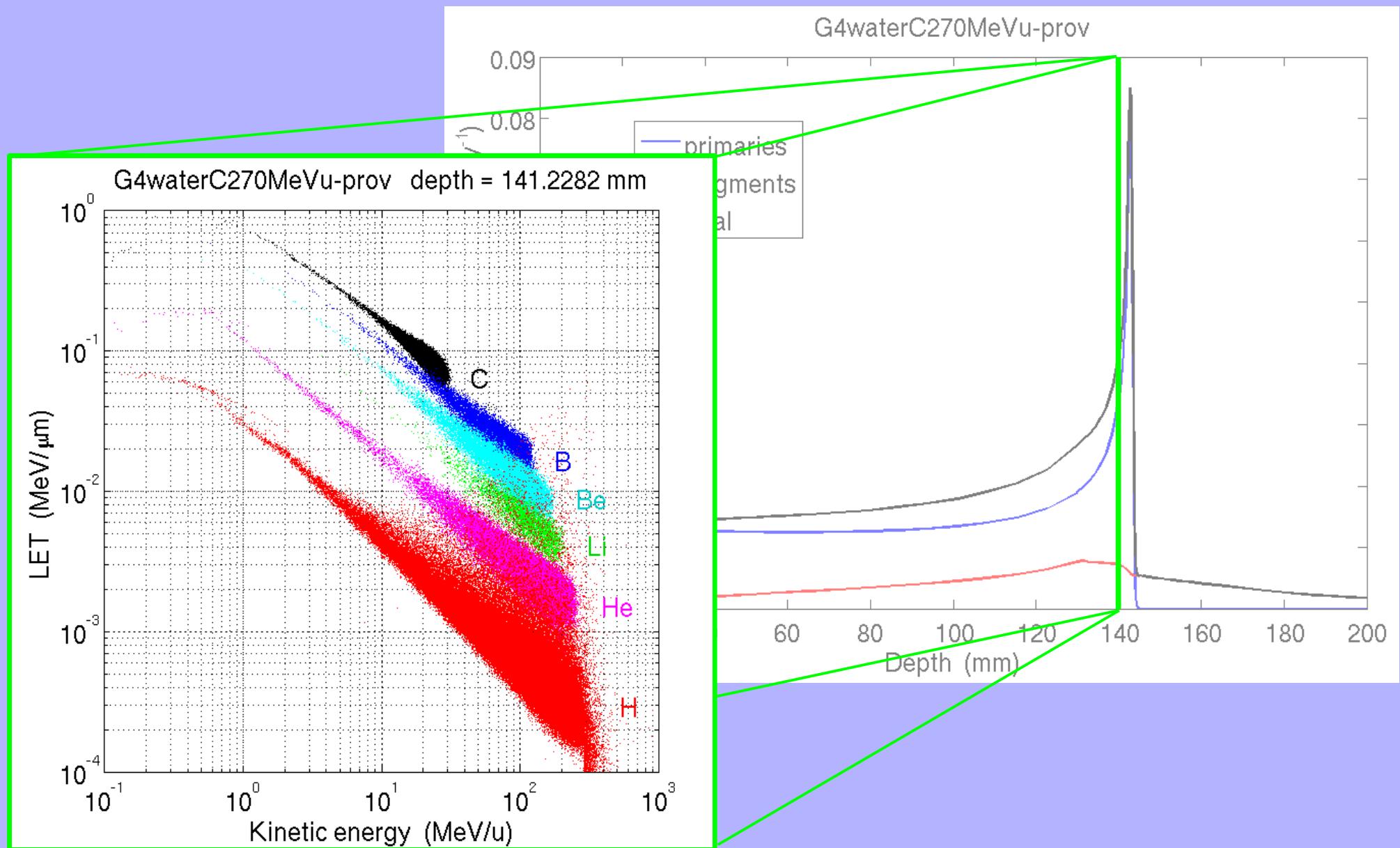
$$S(D) = e^{-\alpha D - \beta D^2}$$

$$S(D) = e^{-\alpha D - \beta D^2}$$

## TPS Biological Data | Mixed fields



## TPS Biological Data | Mixed fields



# Outline of following topics

The remaining part of this presentation will show:

how the Physical Data needed by TPS are created by means of  
**Geant4/Fluka Monte Carlo simulations**;

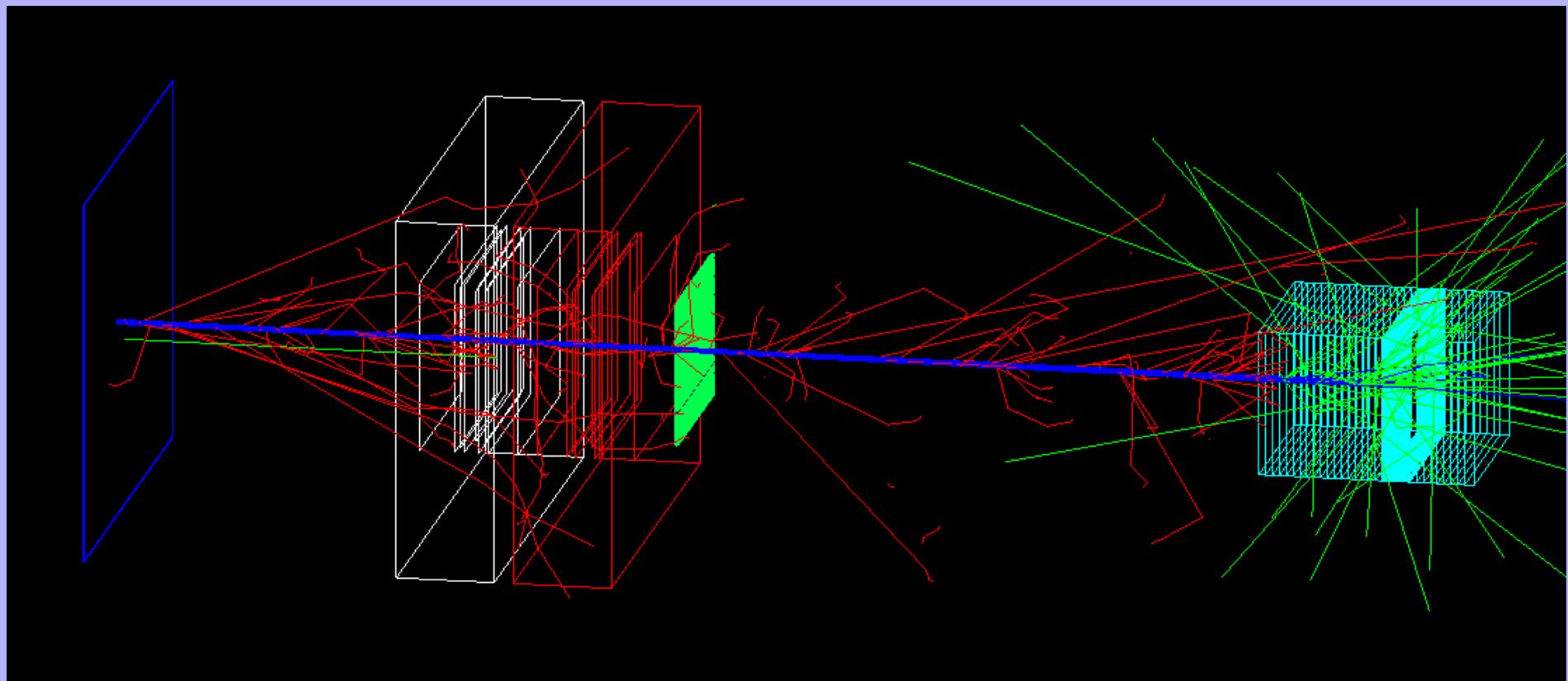
how the Biological Data loaded by TPS are obtained using an  
**implementation of the Local Effect Model (LEM)**;

the usage of **a relational database** for the storage and the analysis of physical and biological data;

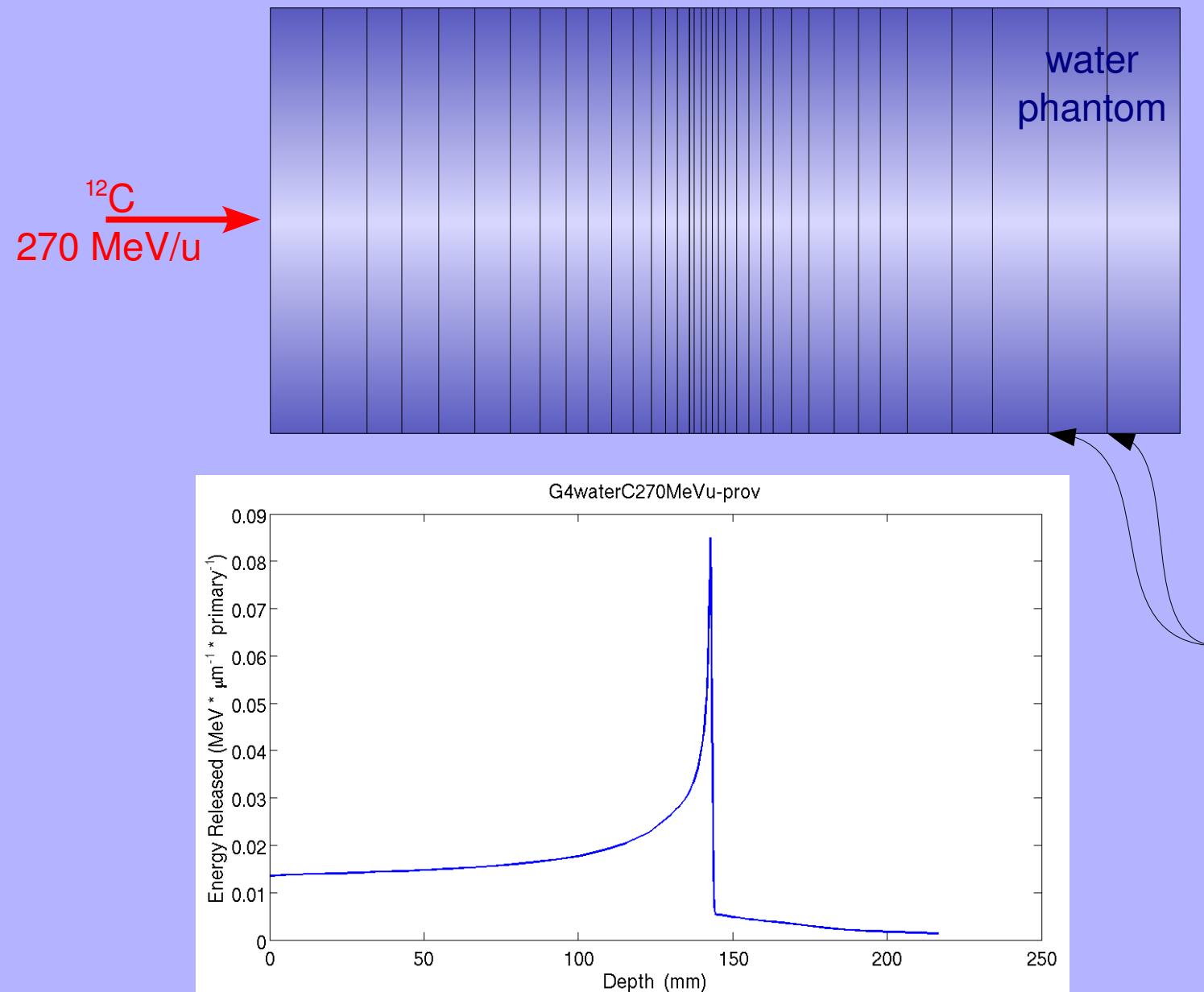
the way **the TPS Kernel** is structured;

the **establishment of the Quality Assurance** management procedures needed for the certification of medical device softwares.

# TPS Physical Data | Geant4 (Fluka) simulation

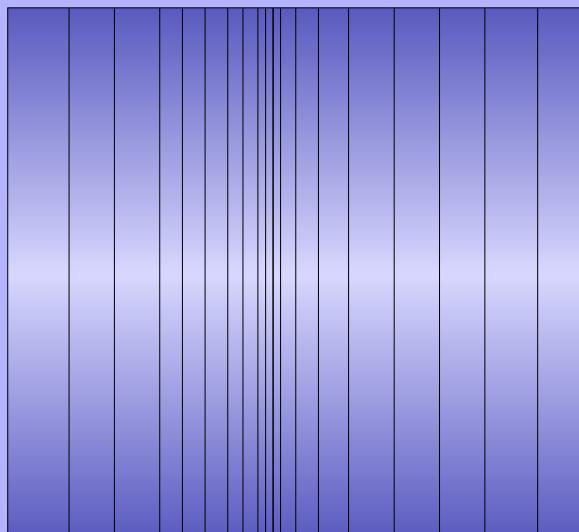


## TPS Physical Data | Geant4 (Fluka) simulation



Slices as  
SensitiveDetectors  
(10  $\mu\text{m}$  wide to be  
comparable to cell  
dimensions)

# TPS Physical Data | Geant4 (Fluka) simulation

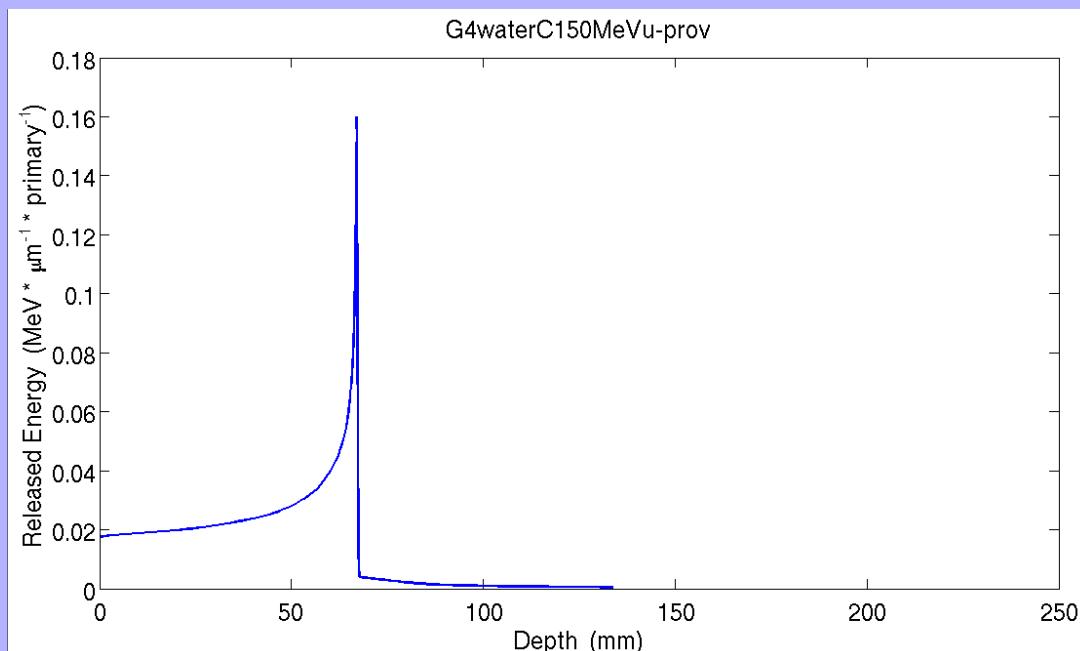


Adaptive geometry

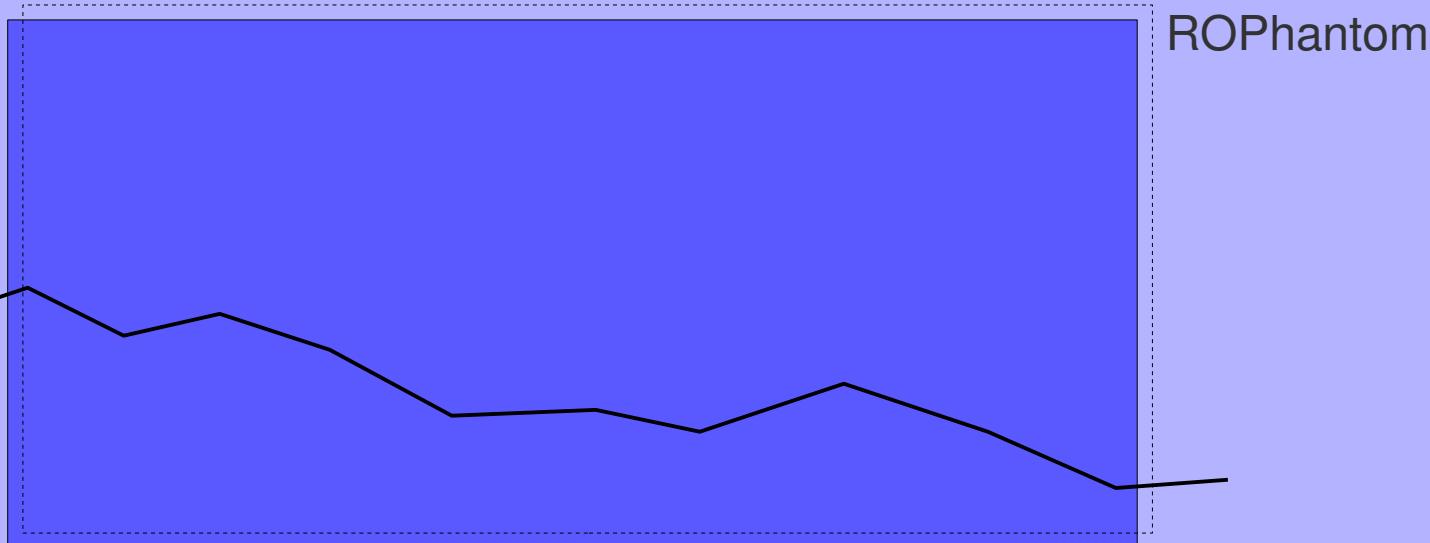
Fake run (0 events)  
for loading physics

G4EmCalculator calc;  
 $r = \text{calc.GetRange}();$

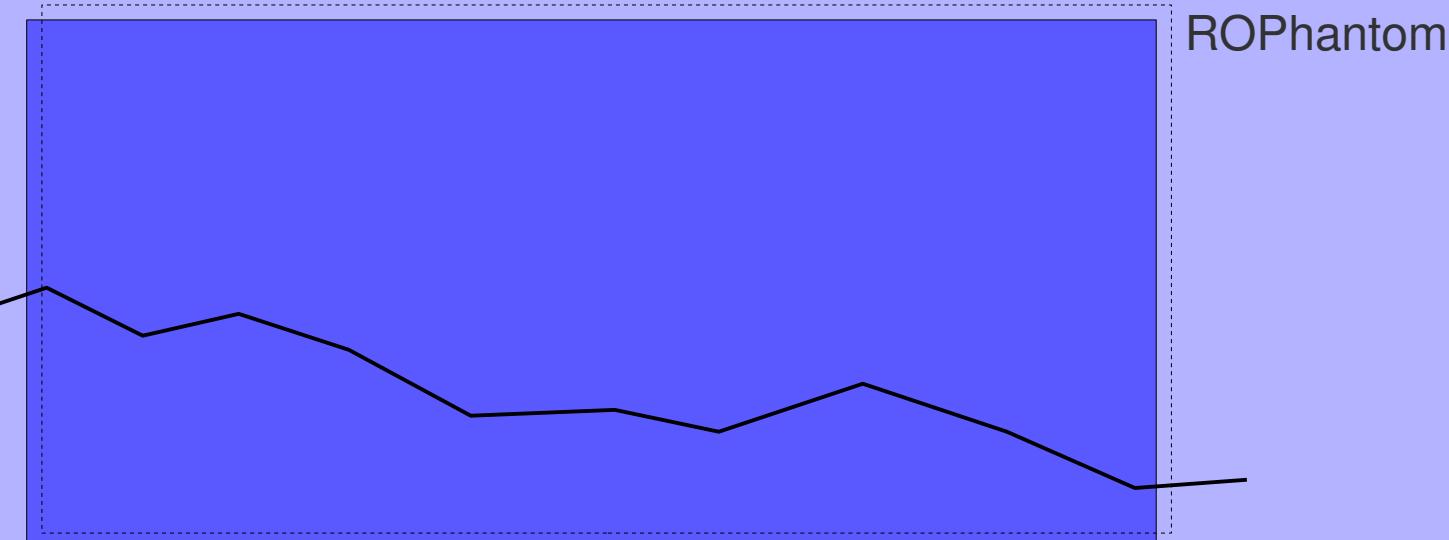
detector.SetSlices(r);



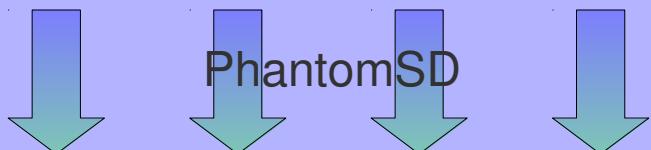
# TPS Physical Data | Geant4 (Fluka) simulation



# TPS Physical Data | Geant4 (Fluka) simulation

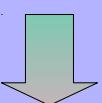


stepLimit: 6  $\mu\text{m}$



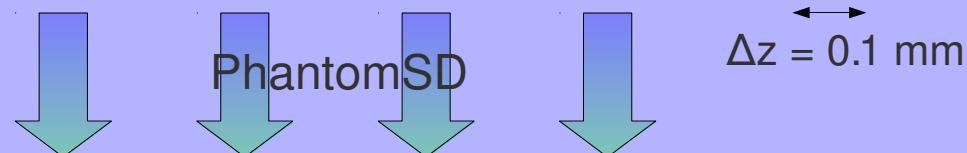
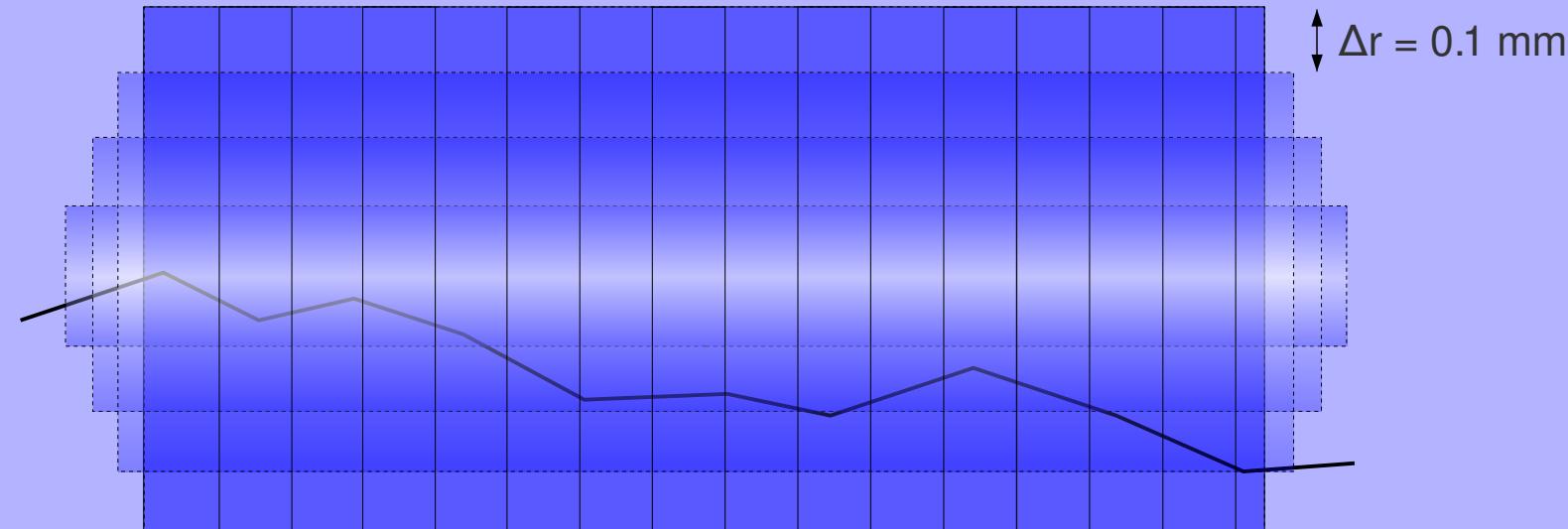
## Hits

slicelID, parentID, eventID, trackID,  
charge, restEnergy, e\_i, e\_d,  
(x\_i, y\_i, z\_i), (x\_f, y\_f, z\_f)



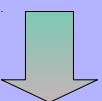
## Phantom HitCollection

# TPS Physical Data | Geant4 (Fluka) simulation

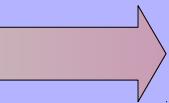
 $\Delta z = 0.1 \text{ mm}$ 

## Hits

sliceID, parentID, eventID, trackID,  
charge, restEnergy,  $e_i$ ,  $e_d$ ,  
 $(x_i, y_i, z_i)$ ,  $(x_f, y_f, z_f)$

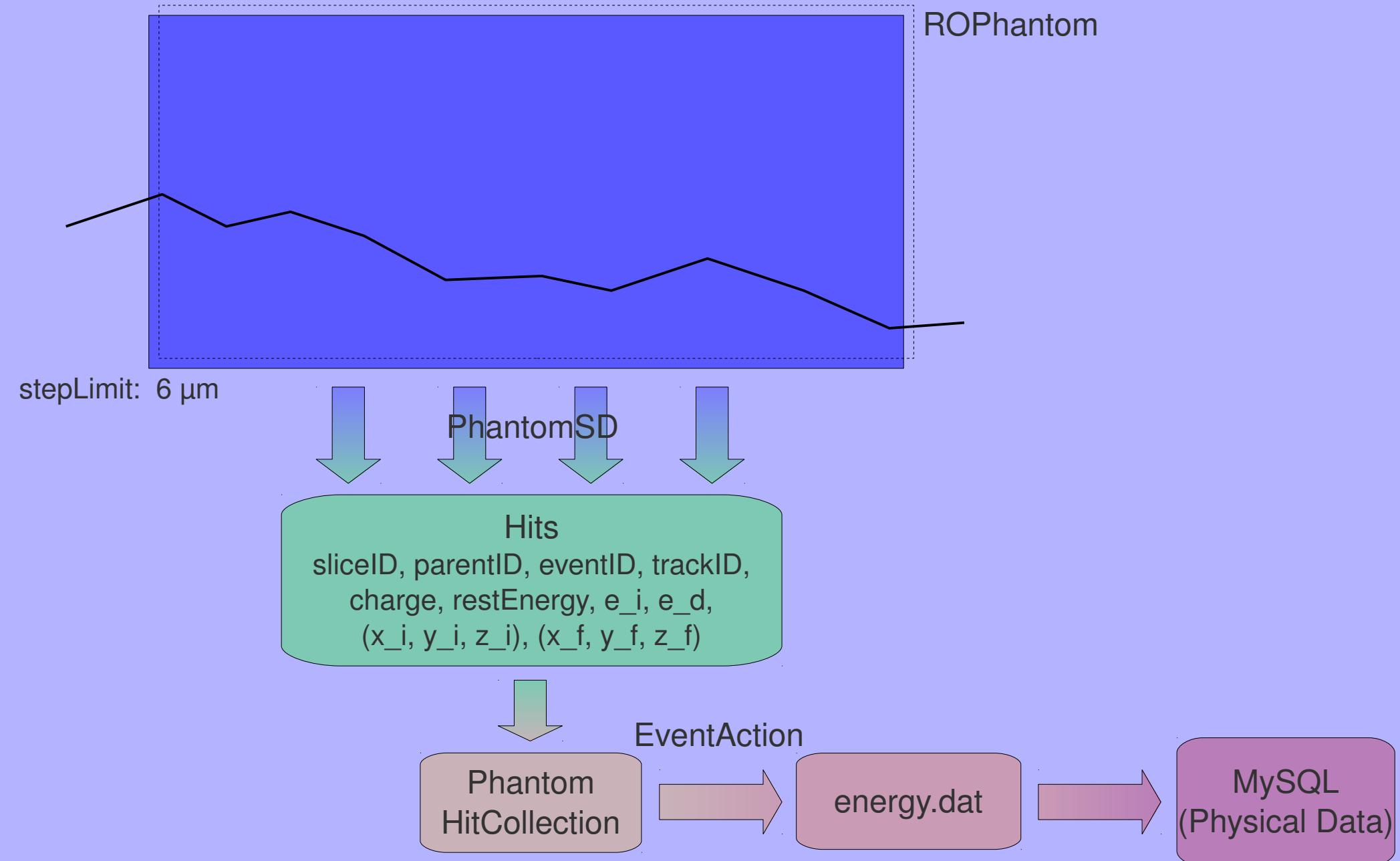


## EventAction

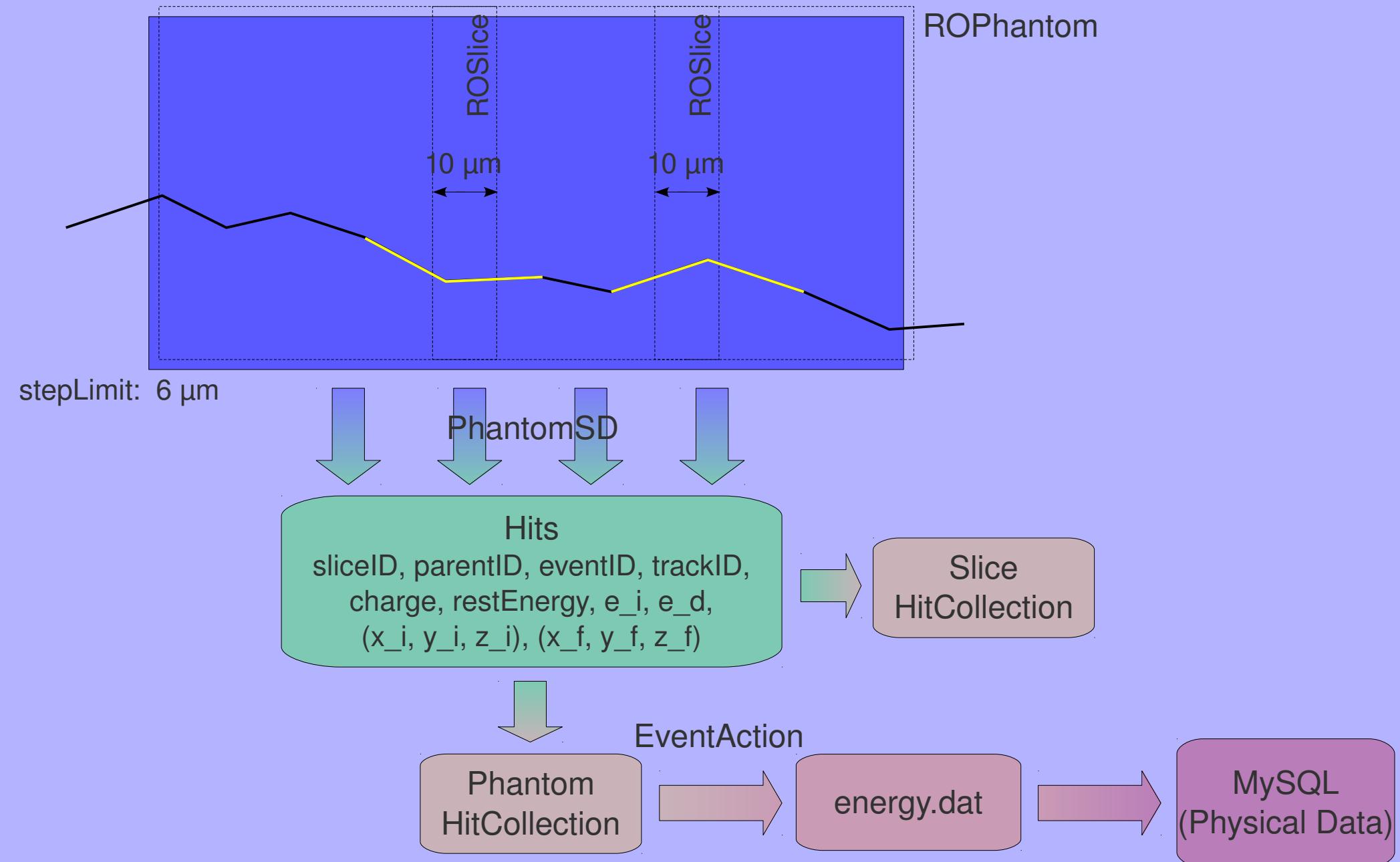


energy.dat

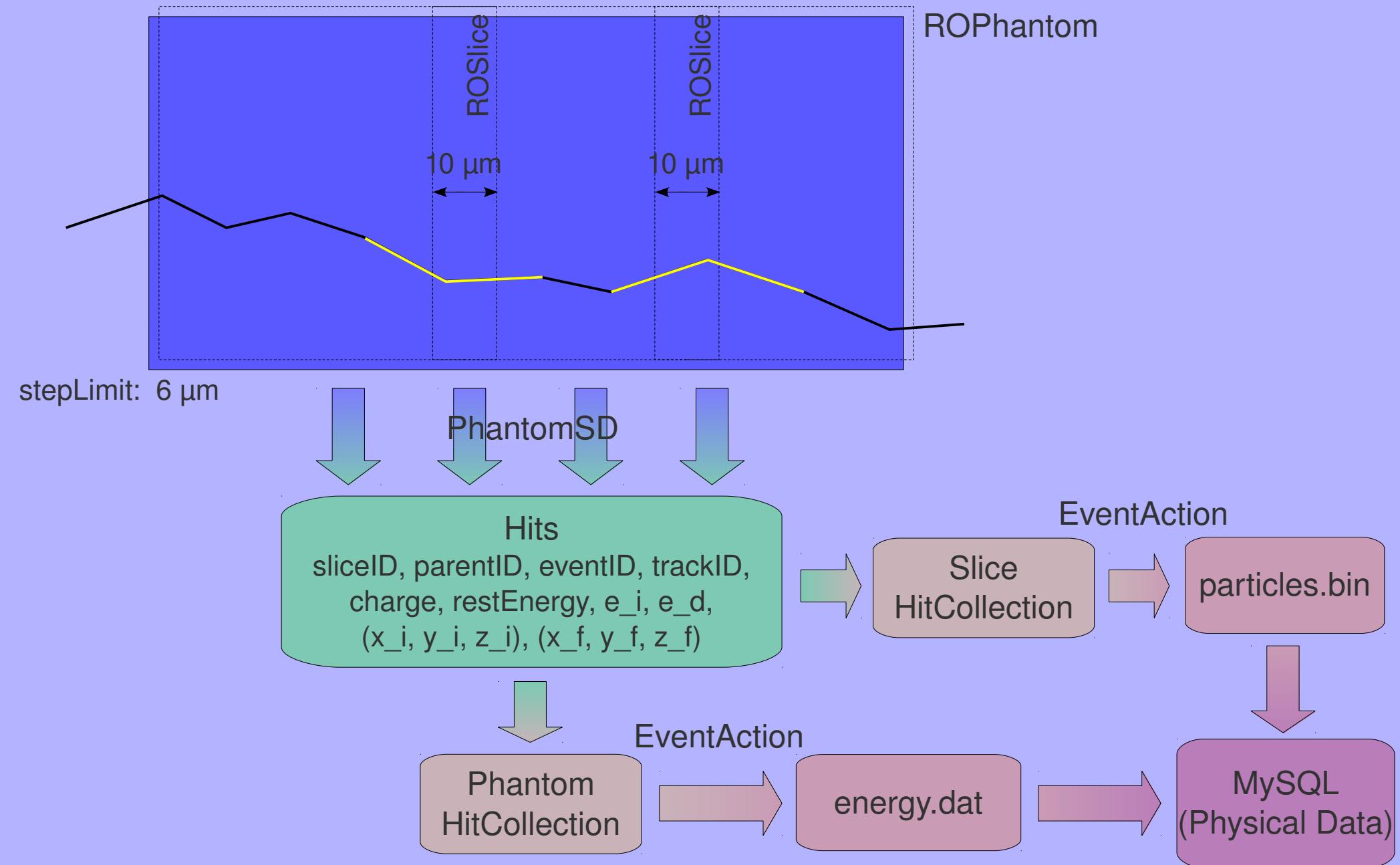
# TPS Physical Data | Geant4 (Fluka) simulation



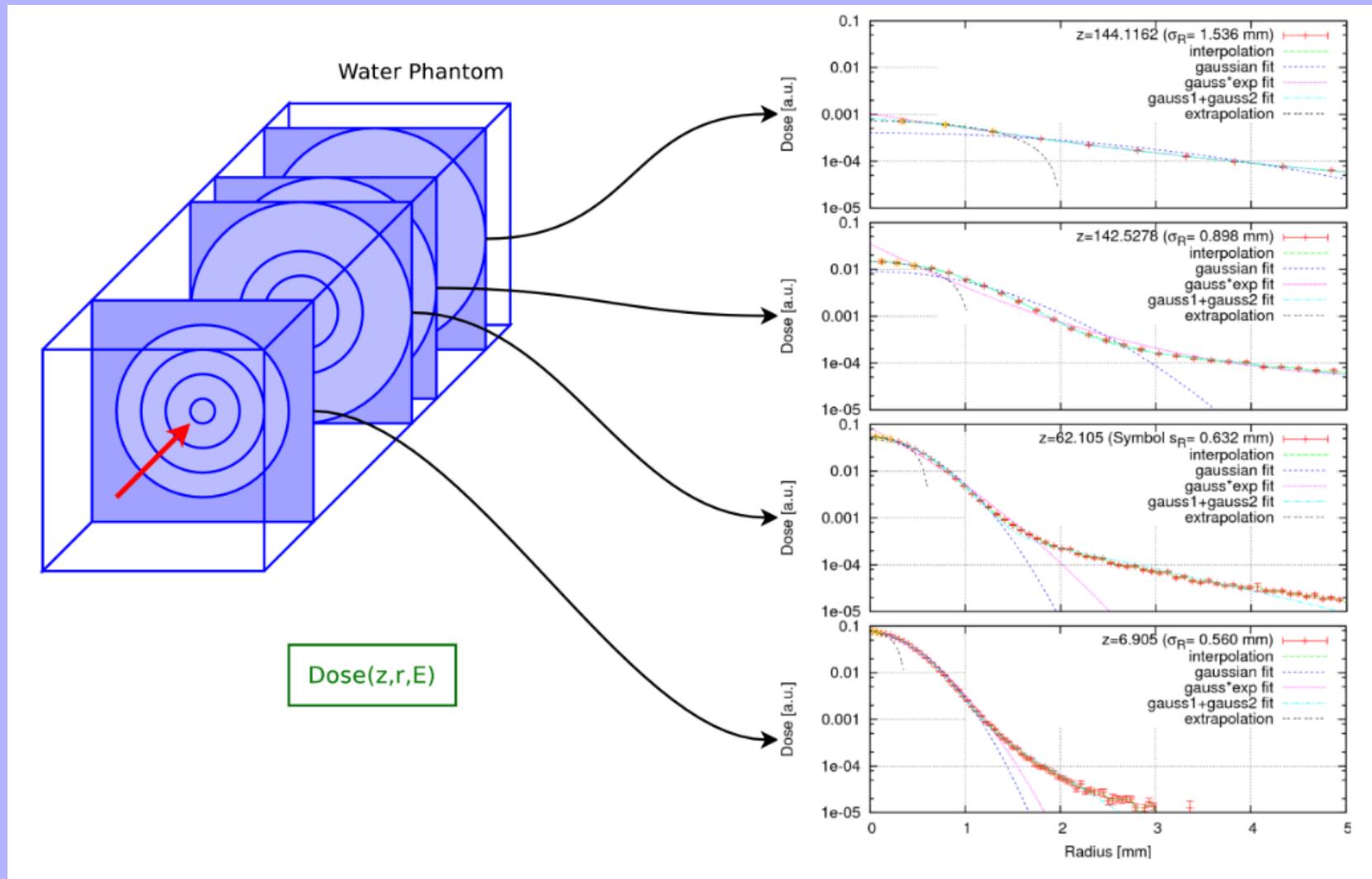
# TPS Physical Data | Geant4 (Fluka) simulation



# TPS Physical Data | Geant4 (Fluka) simulation

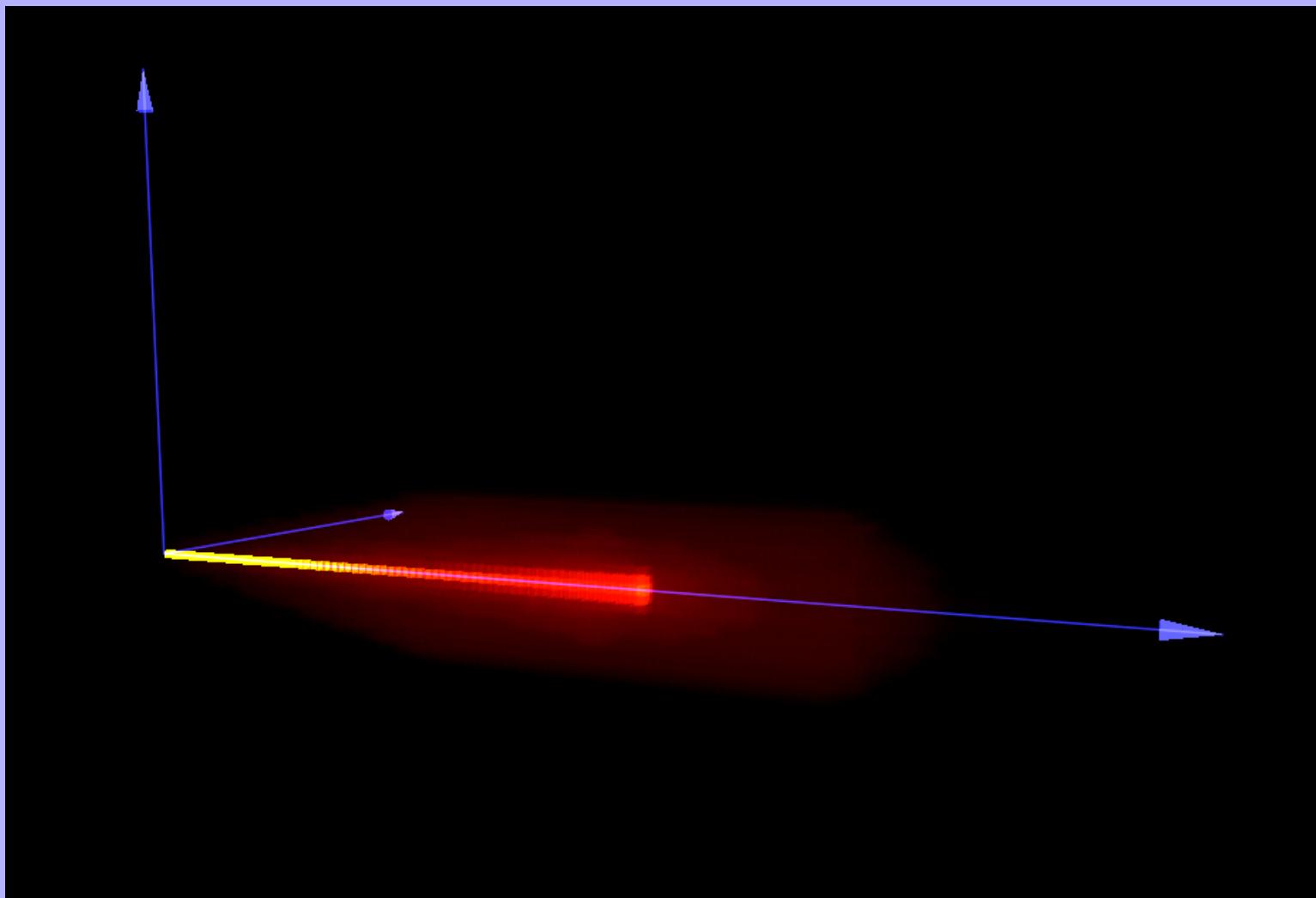


The development of a carbon ion Treatment Planning System  
TPS Physical Data | Data analysis

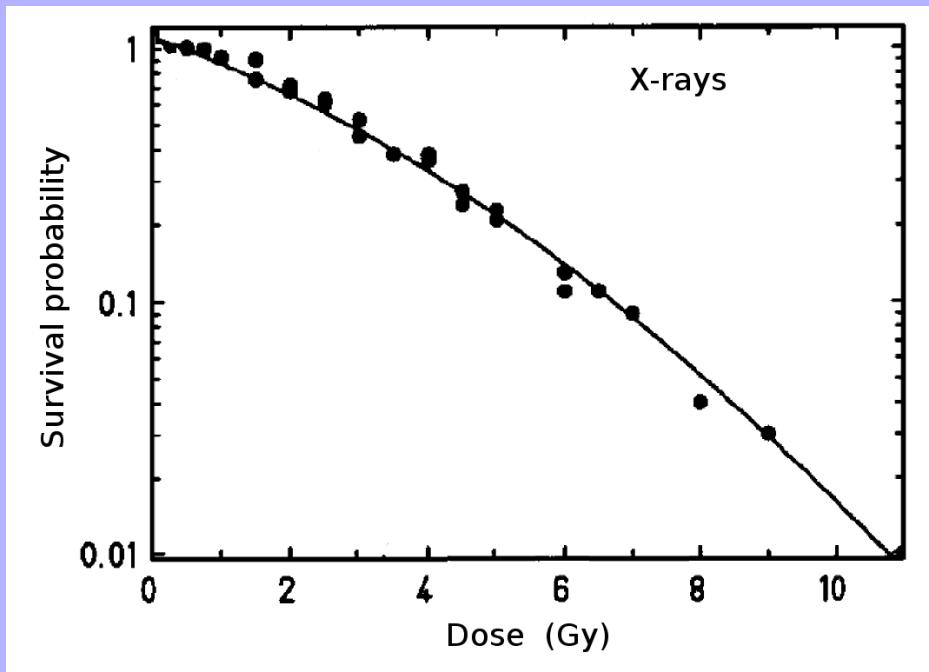


# TPS Physical Data | Pencil beams

Spatial distribution of dose

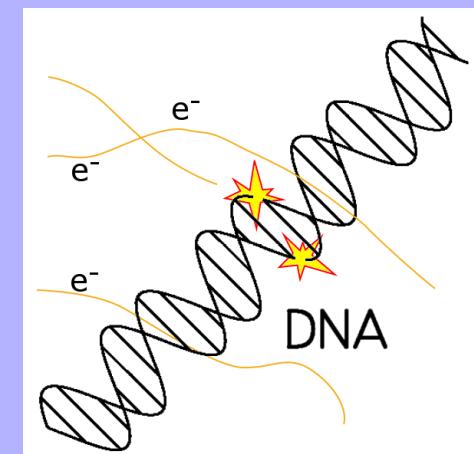
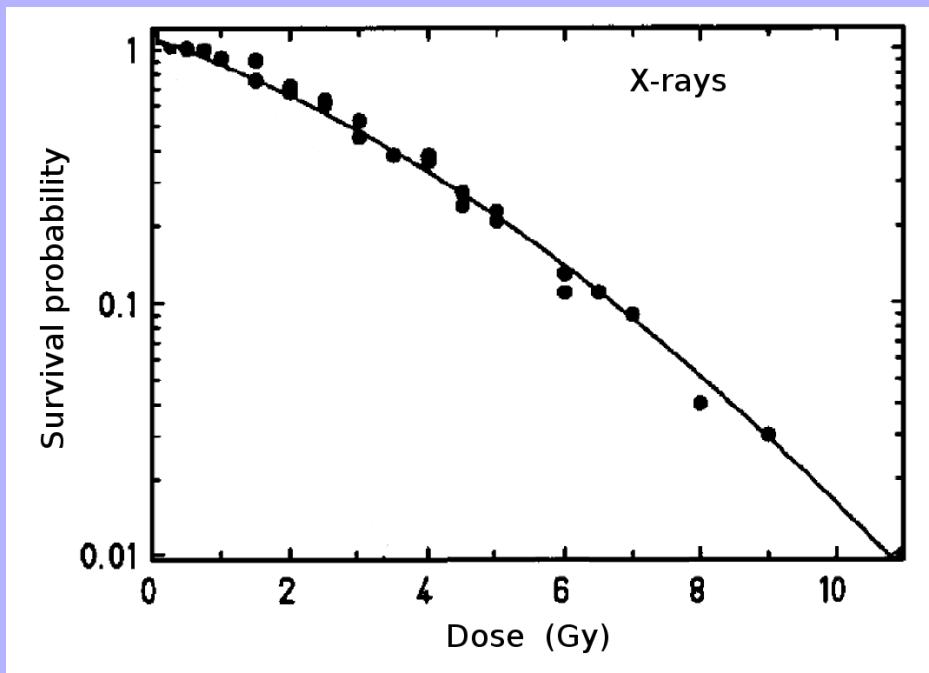


# Implementation of the LEM | Lethal events



$$S_x(D) = e^{-\alpha_x D - \beta_x D^2}$$

# Implementation of the LEM | Lethal events

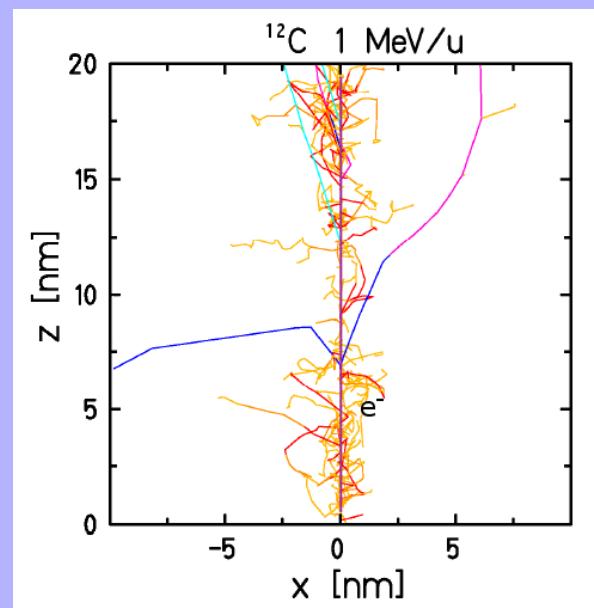
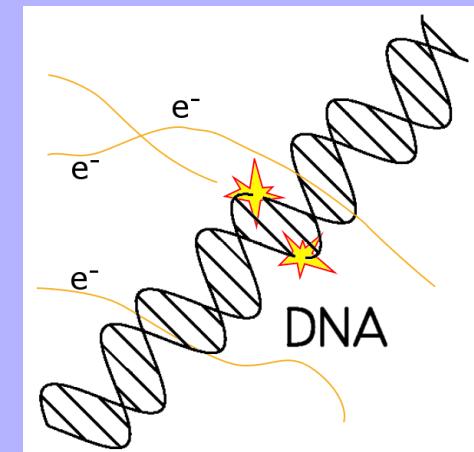
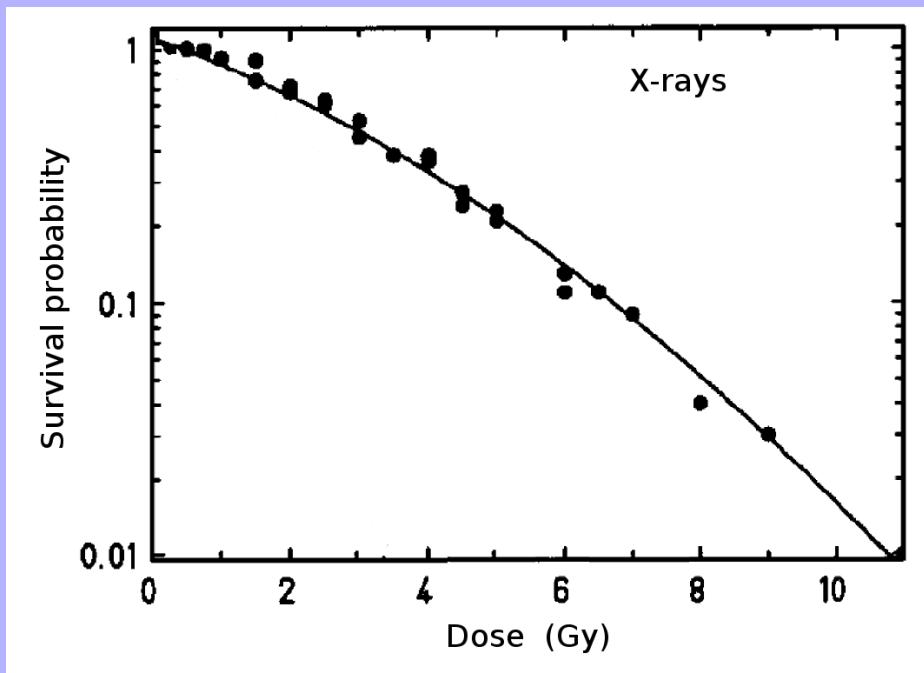


$$S_x(D) = e^{-\alpha_x D - \beta_x D^2}$$

$$N_{\text{leth}} = \text{Pois}(\bar{N}_{\text{leth}})$$

$$S_x = P[N_{\text{leth}} = 0] = e^{-\bar{N}_{\text{leth}}}$$

# Implementation of the LEM | Lethal events



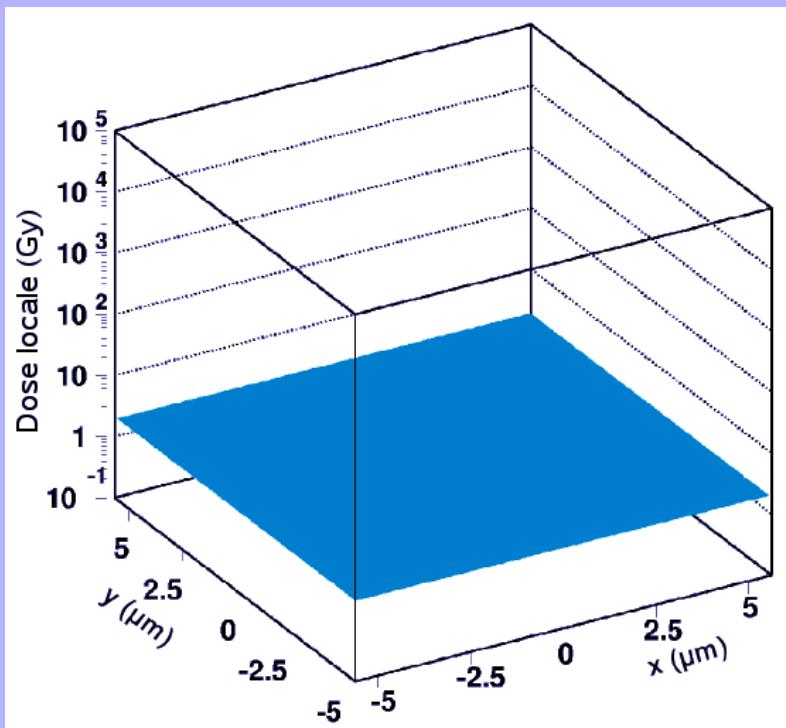
$$S_x(D) = e^{-\alpha_x D - \beta_x D^2}$$

$$N_{\text{leth}} = \text{Pois}(\bar{N}_{\text{leth}})$$

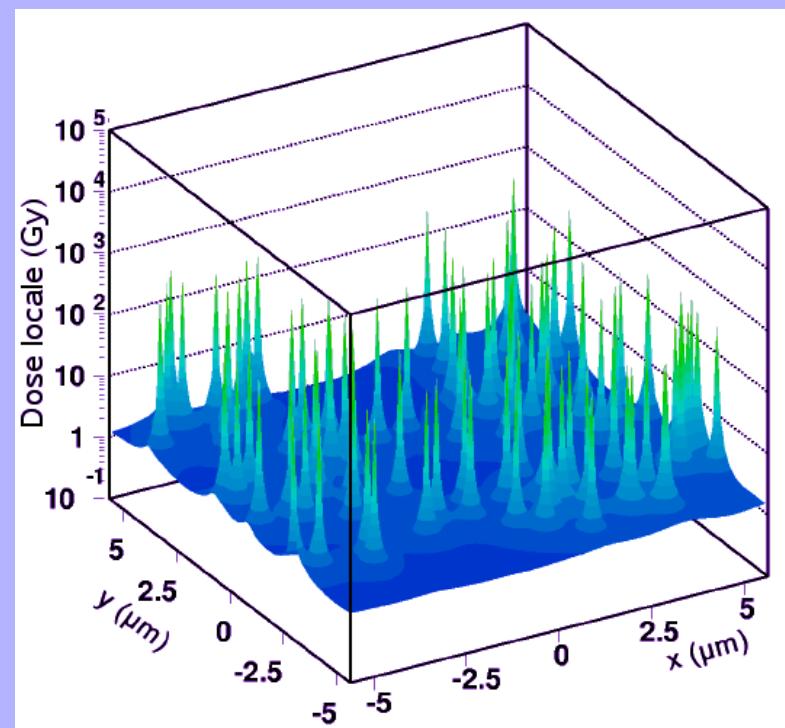
$$S_x = P[N_{\text{leth}} = 0] = e^{-\bar{N}_{\text{leth}}}$$

# Implementation of the LEM | Photons vs ions

Total dose = 2 Gy



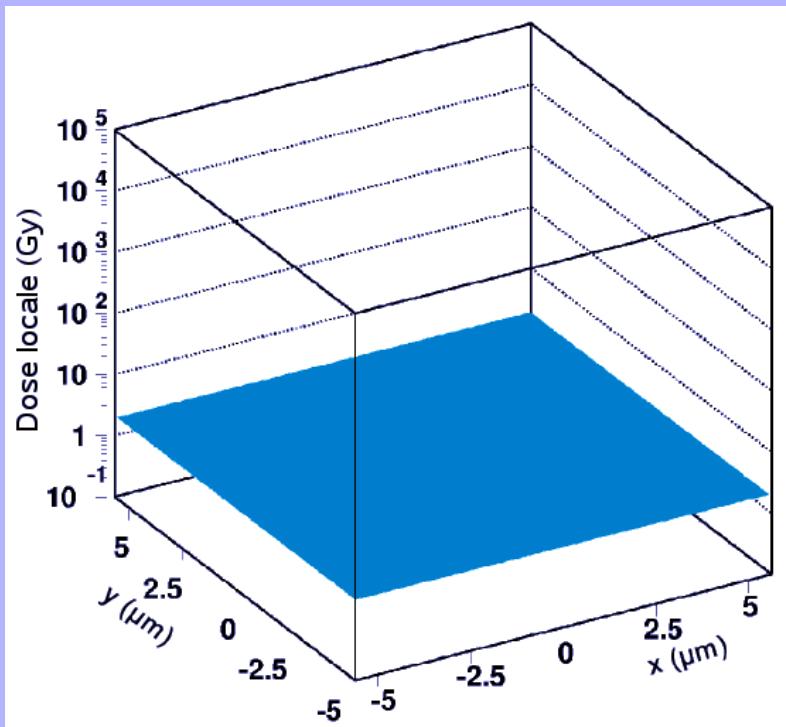
X-rays



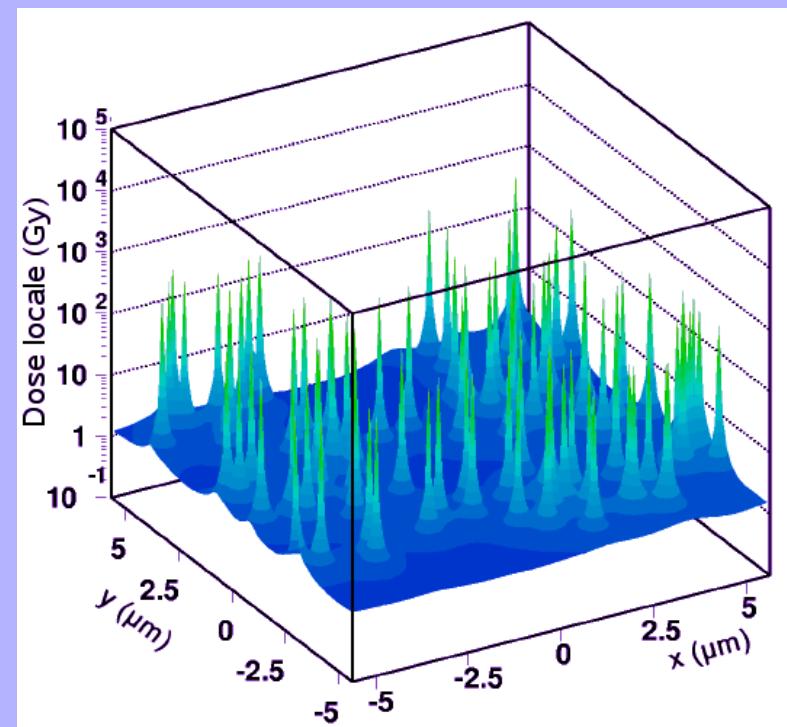
90 MeV/u carbon ions

# Implementation of the LEM | Photons vs ions

Total dose = 2 Gy



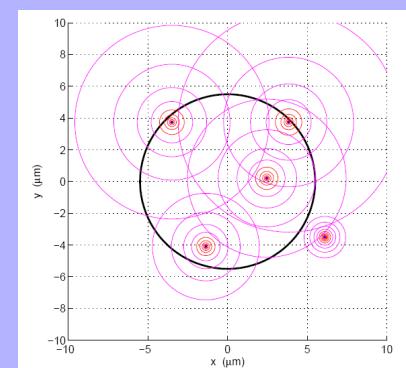
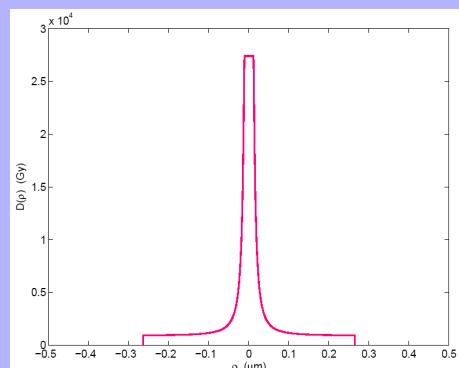
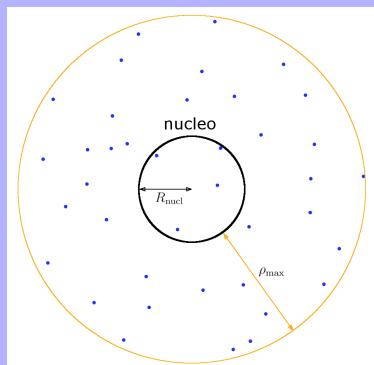
X-rays



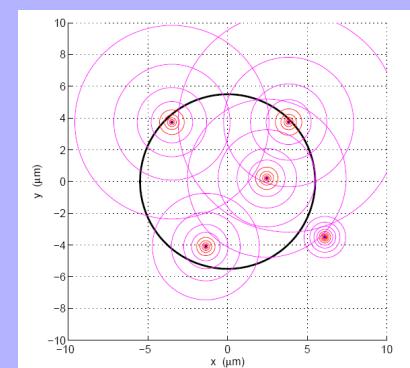
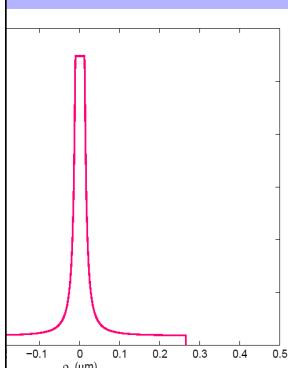
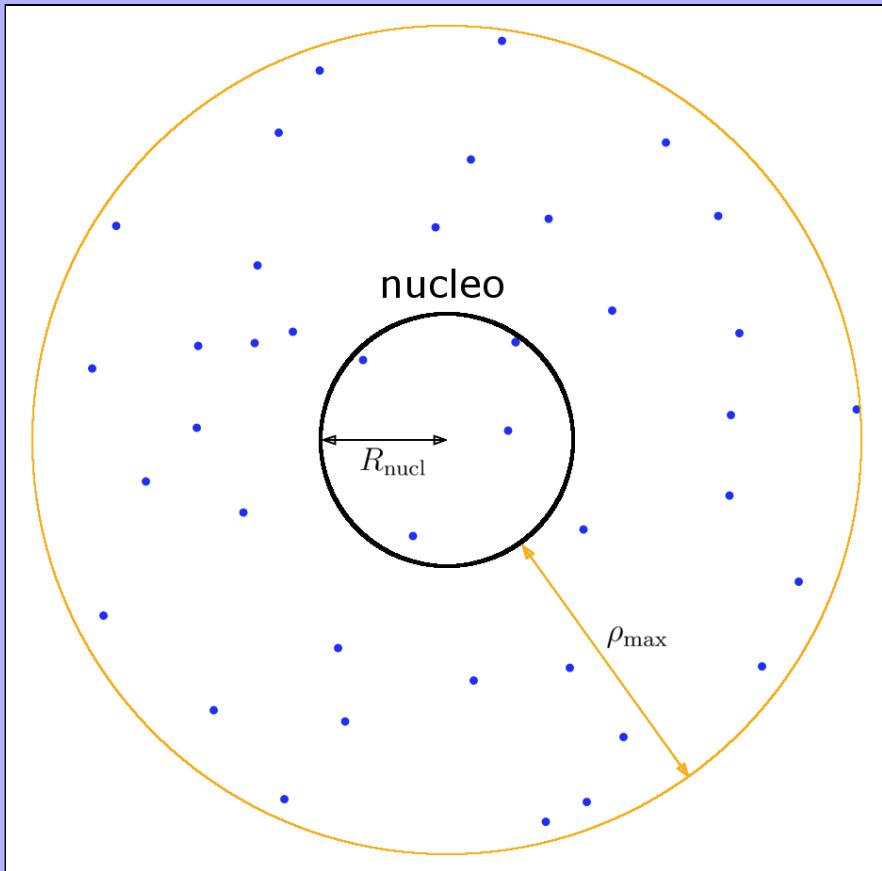
90 MeV/u carbon ions

$$\overline{N}_{\text{leth}} = \alpha_x D + \beta_x D^2 \quad \longrightarrow \quad d\overline{N}_{\text{leth}} = (\alpha_x d(\vec{r}) + \beta_x d(\vec{r})^2) \frac{d\vec{r}}{V_{\text{nucl}}}$$

# Implementation of the LEM | Event generation



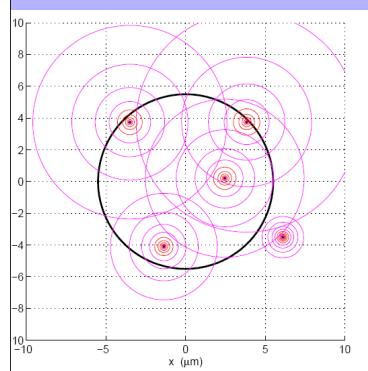
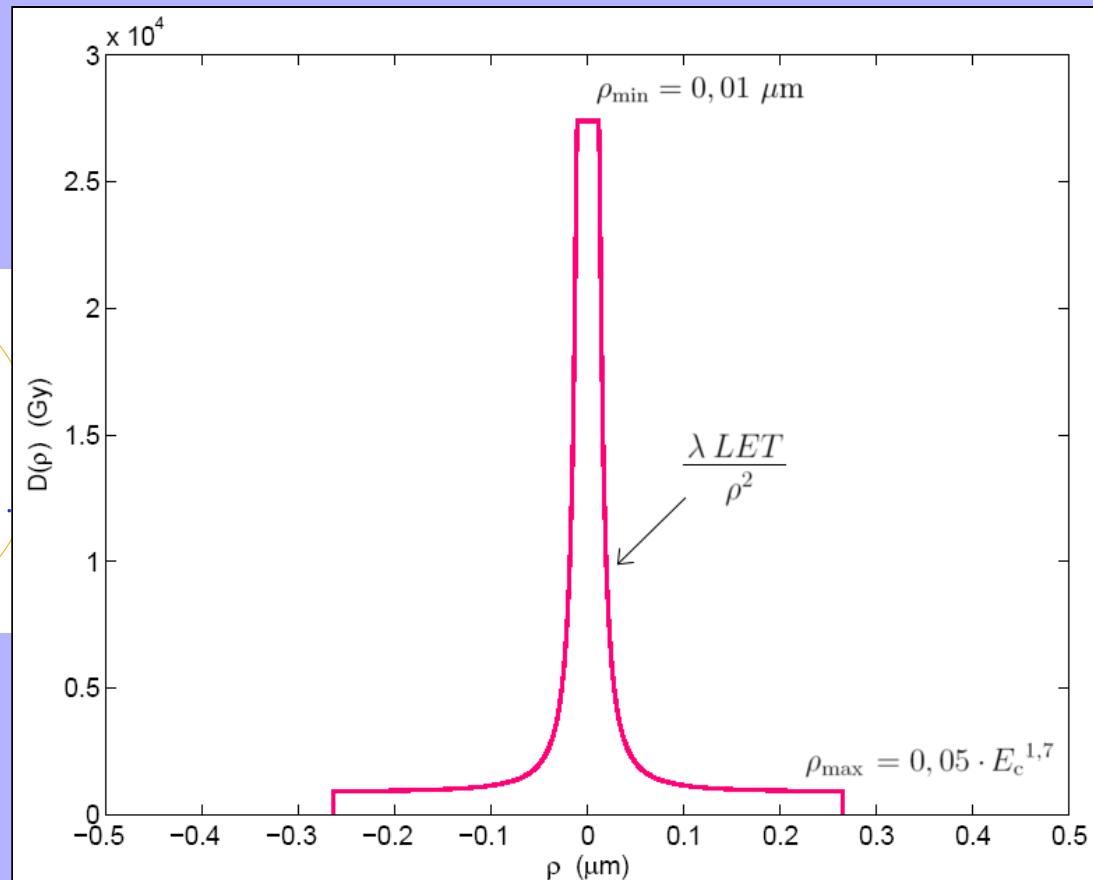
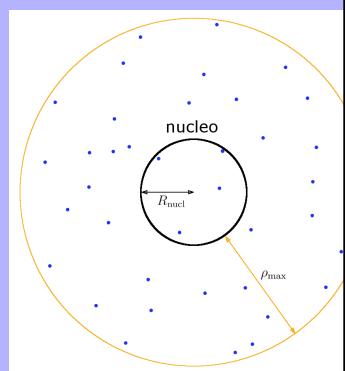
# Implementation of the LEM | Event generation



$$F = \frac{\varrho \langle D \rangle}{\overline{LET}}$$

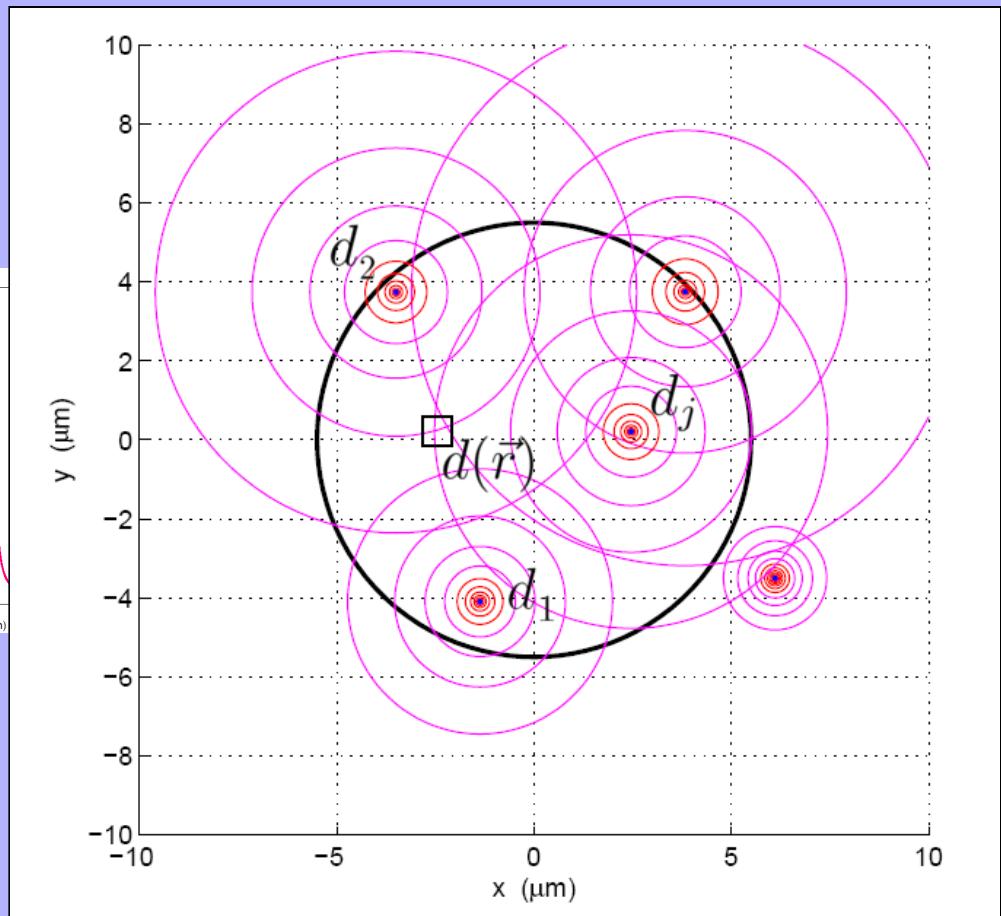
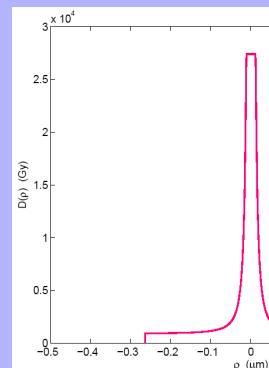
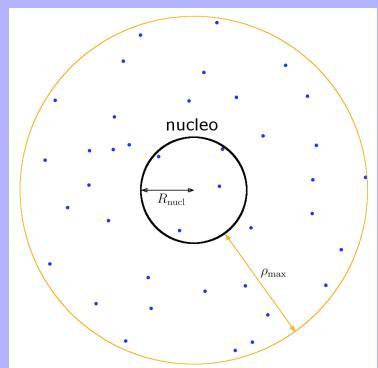
$$\langle n_{\text{ion}} \rangle = F \cdot \pi (R_{\text{nucl}} + \rho_{\text{max}})^2$$

# Implementation of the LEM | Event generation



$$d(\rho) = \begin{cases} \lambda \text{ LET}/\rho_{\min}^2 & \rho < \rho_{\min} \\ \lambda \text{ LET}/\rho^2 & \rho_{\min} \leq \rho \leq \rho_{\max} \\ 0 & \rho > \rho_{\max} \end{cases}$$

# Implementation of the LEM | Event generation



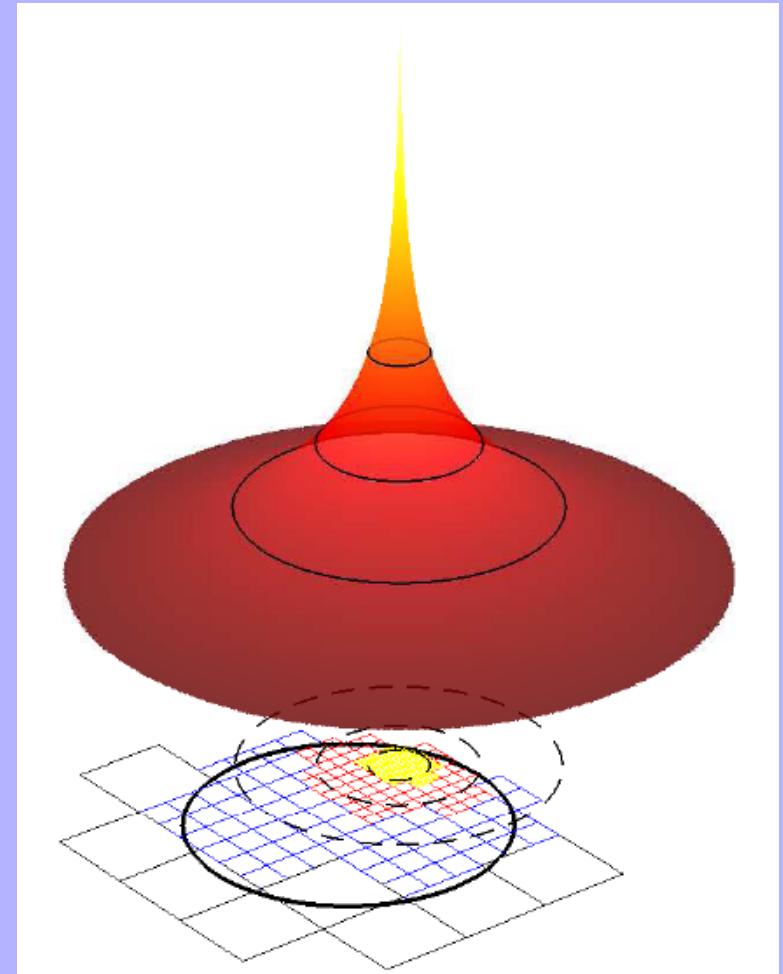
$$d(\vec{r}) = \sum_{j=1}^{n_t} d_j(\vec{r})$$

# Implementation of the LEM | Damage integration

$$d(\vec{r}) \rightarrow d\bar{N}_{\text{leth}} = (\alpha_x d(\vec{r}) + \beta_x d(\vec{r})^2) \frac{d\vec{r}}{V_{\text{nucl}}}$$

$$\bar{N}_{\text{leth}} = \frac{1}{V_{\text{nucl}}} \int_{V_{\text{nucl}}} (\alpha_x d(\vec{r}) + \beta_x d(\vec{r})^2) d\vec{r}$$

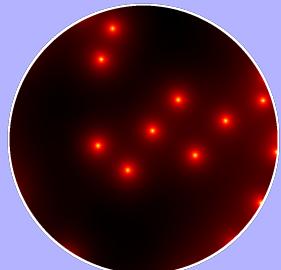
$$S = e^{-\bar{N}_{\text{leth}}}$$



# Implementation of the LEM | Statistical fluctuations

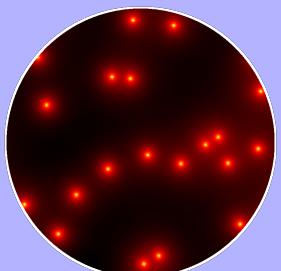
$$\langle D \rangle = 3 \text{ Gy}$$

# Implementation of the LEM | Statistical fluctuations



$$D_1 = 2.02 \text{ Gy}$$

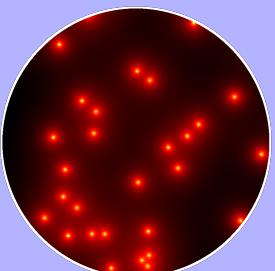
$$S_1 = 0.228$$



$$D_2 = 2.99 \text{ Gy}$$

$$S_2 = 0.13 \quad \langle D \rangle = 3 \text{ Gy}$$

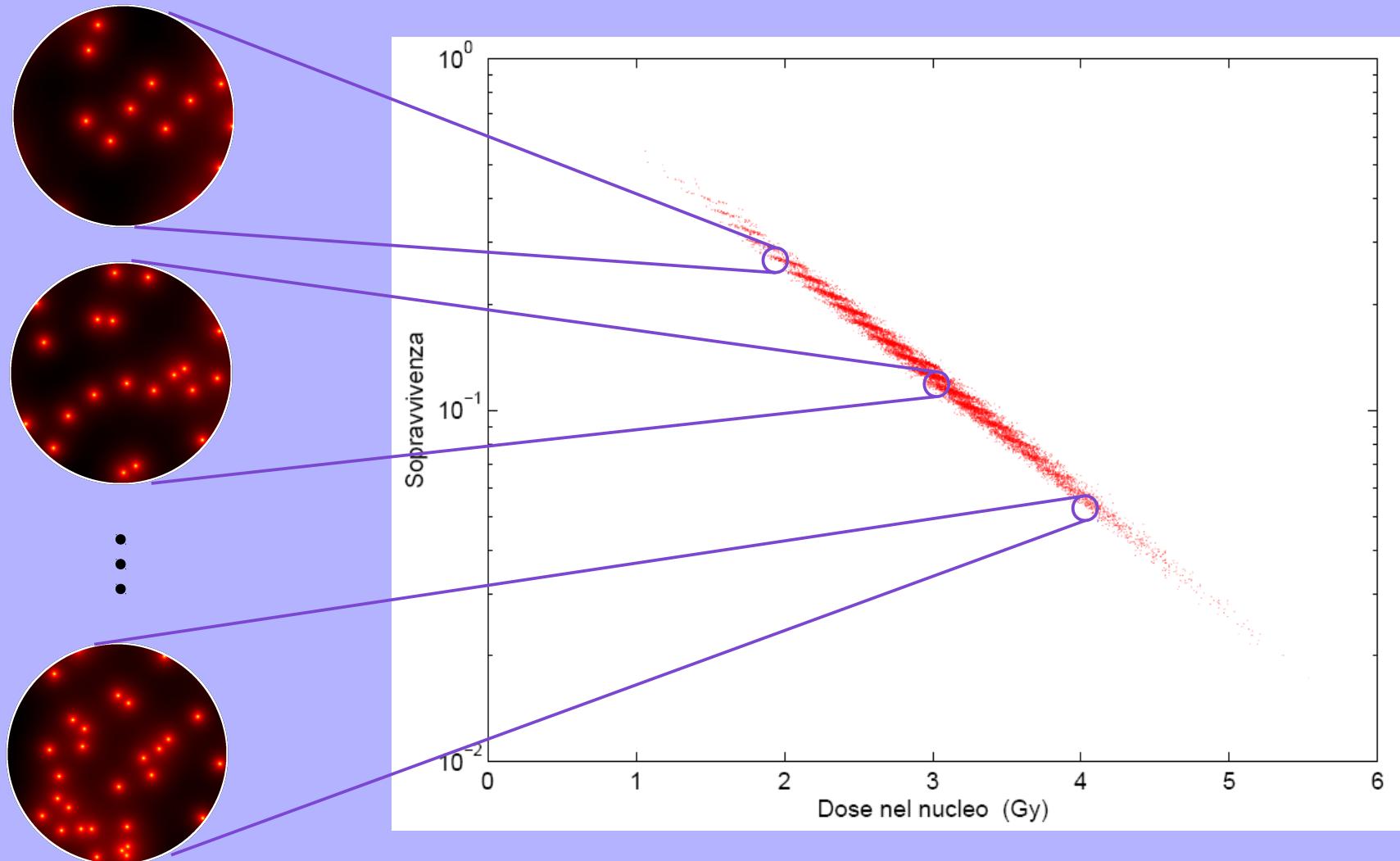
⋮



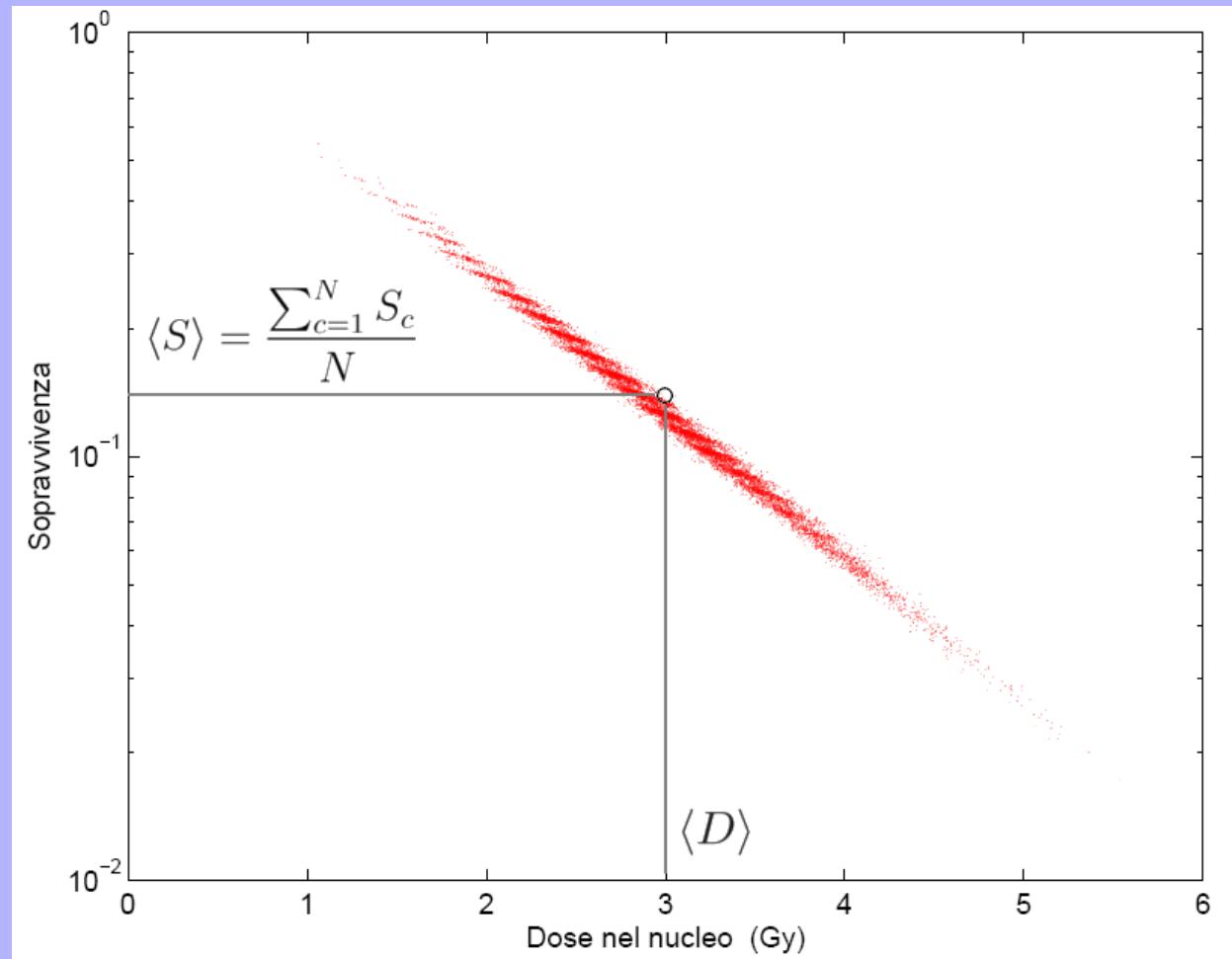
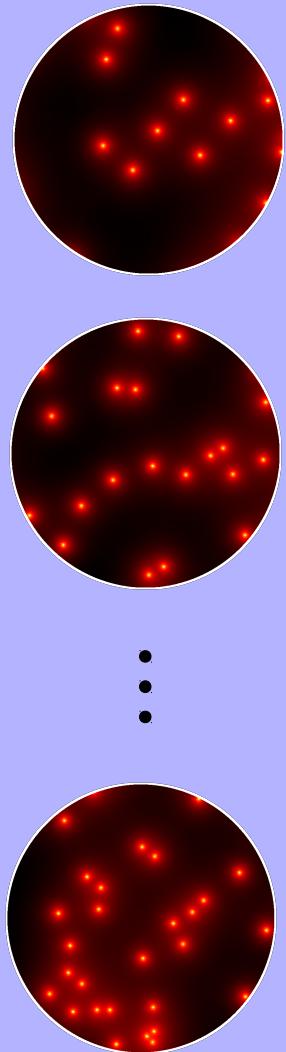
$$D_N = 4.21 \text{ Gy}$$

$$S_N = 0.05$$

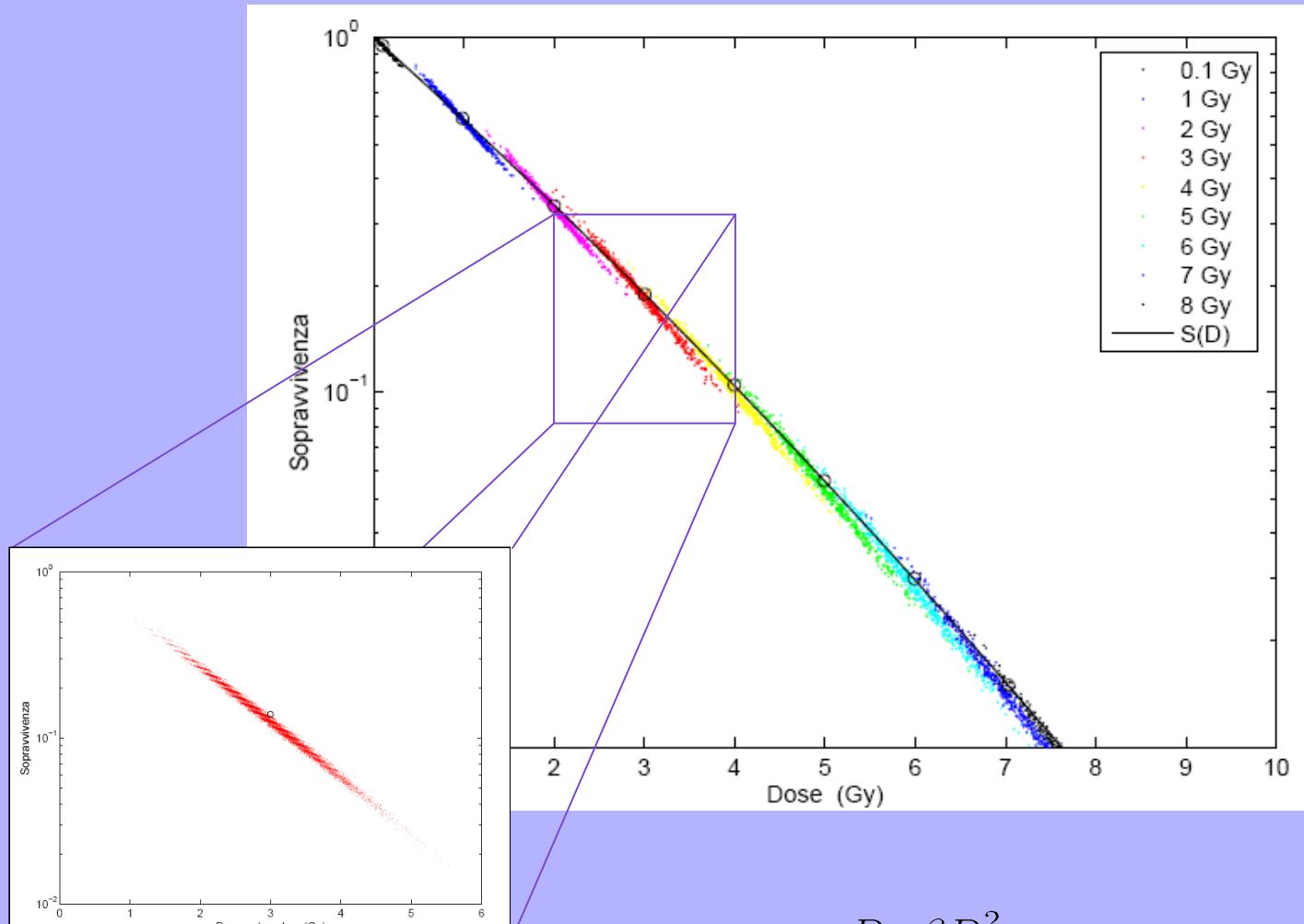
# Implementation of the LEM | Statistical fluctuations



# Implementation of the LEM | Statistical fluctuations

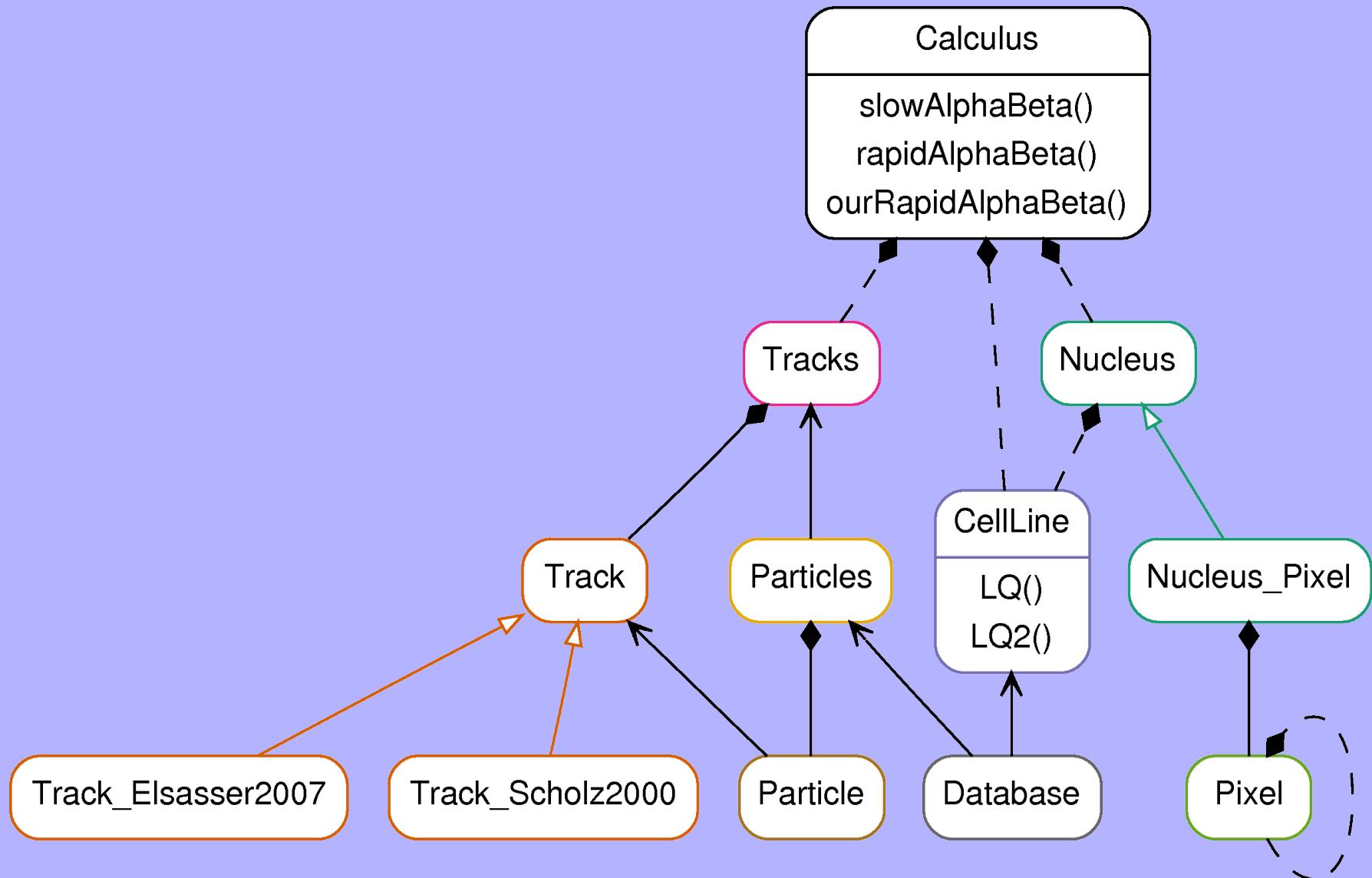


# Implementation of the LEM | Survival curve

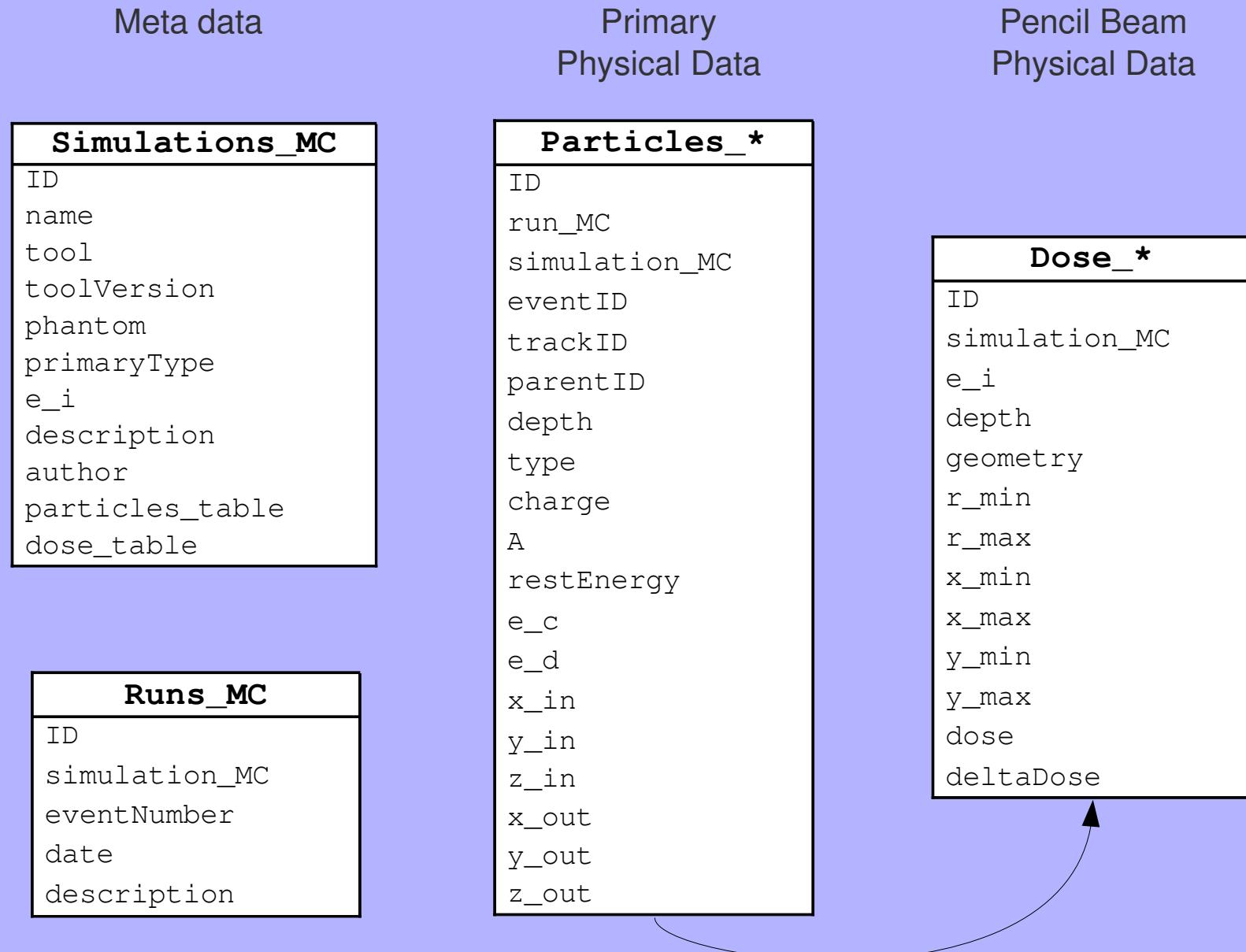


$$S = e^{-\alpha D - \beta D^2}$$

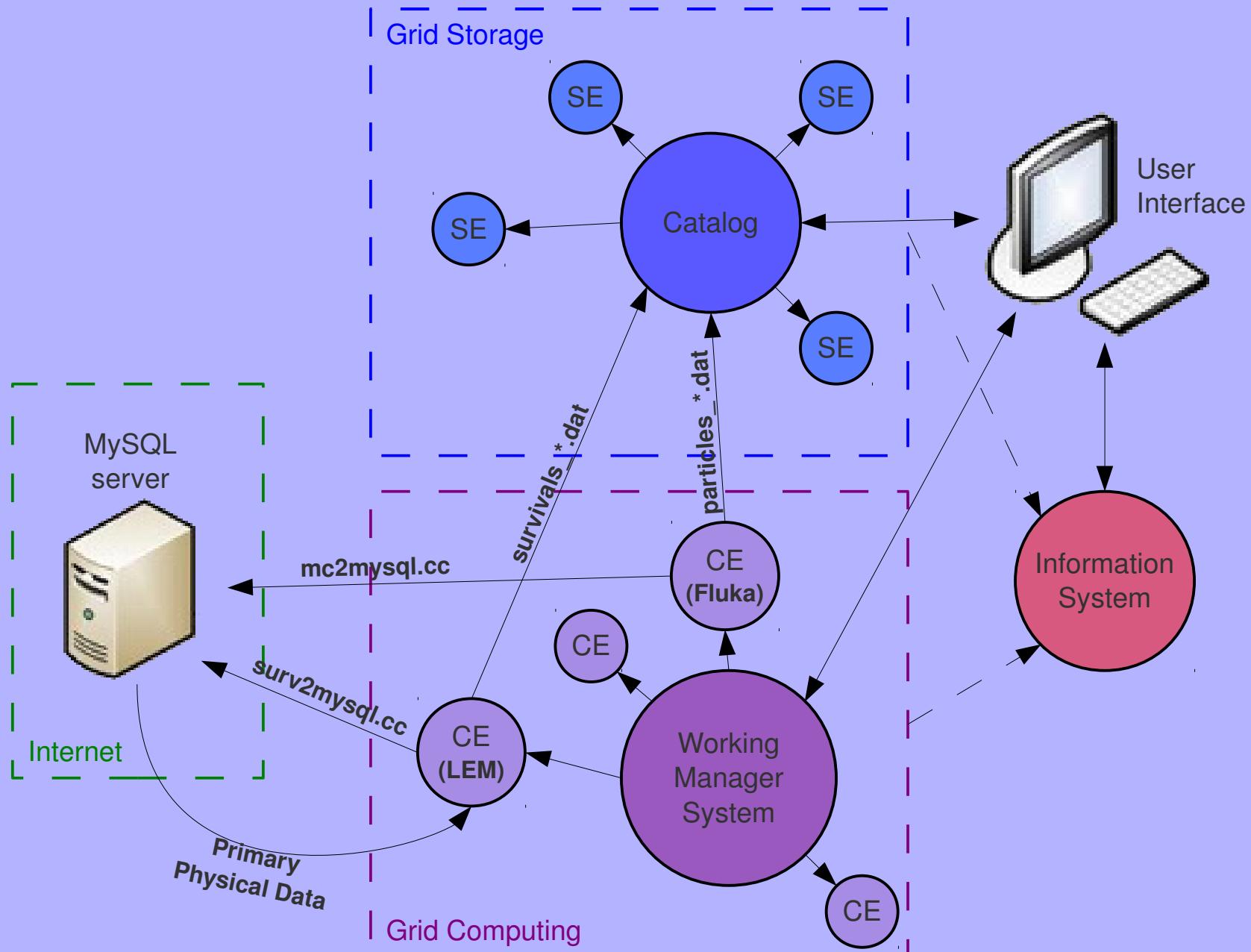
# Implementation of the LEM | C++ classes



# MySQL database structure

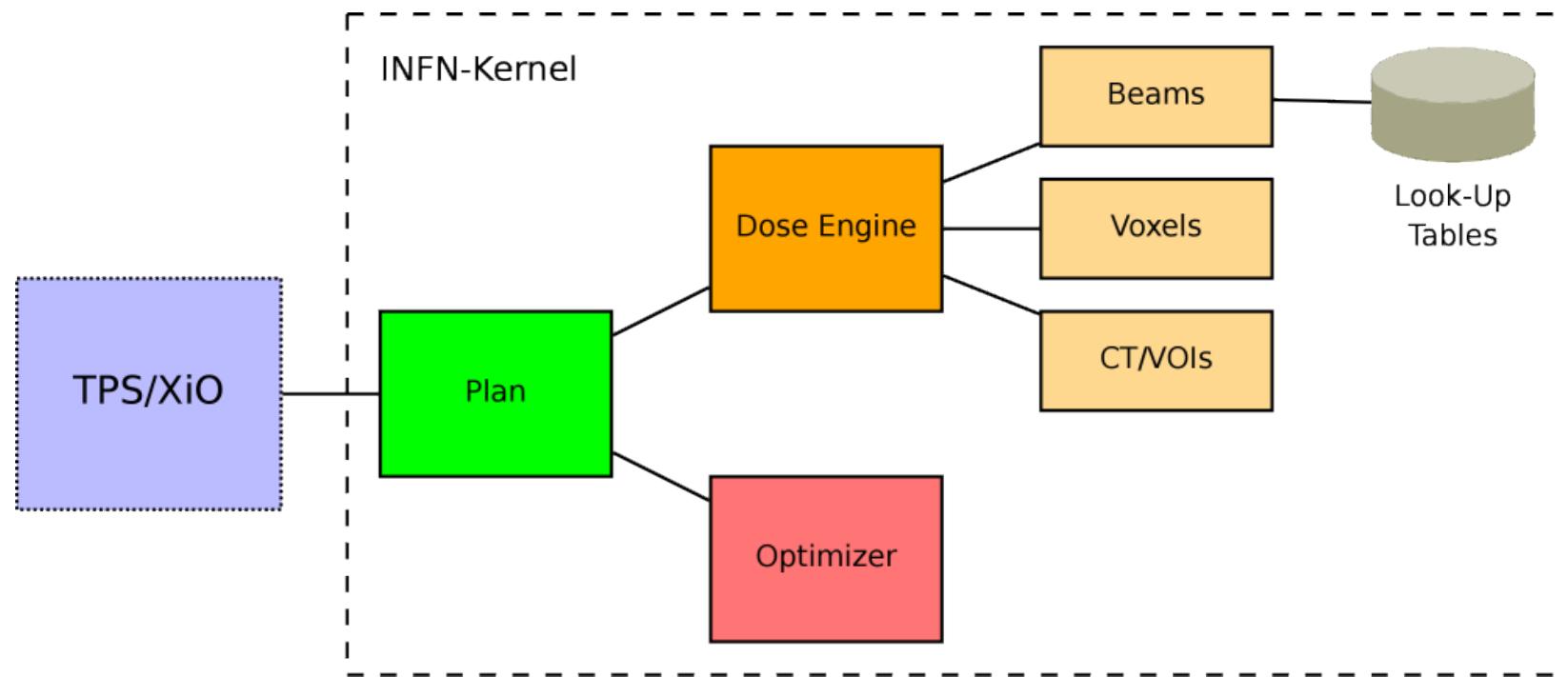


# Grid computations





# TPS Kernel | High level structure



**Look-up Tables:** physical and biological description of elementary beams effectiveness in water;

**Dose Engine:** module responsible of the evaluation of the effect on the patient (in terms of dose and survival levels) for a fully specified irradiation pattern;

**Optimizer:** module in charge of finding the optimal irradiation pattern, in order to satisfy medical doctor's prescription;

**Plan:** module that manages the interaction with the external world and sets up Dose Engine and Optimizer;

**XiO:** module coded by the Elekta company which connects with the Oncological Information System and provides the GUI.

# TPS Kernel | High level structure

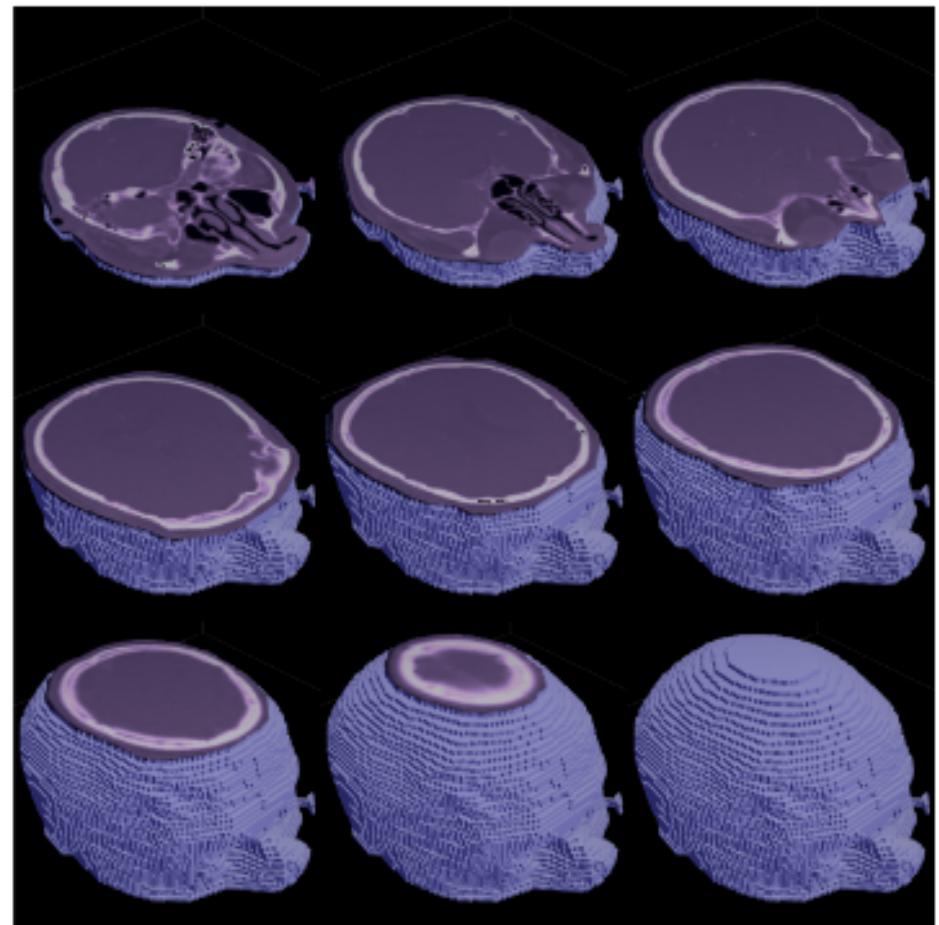


CT meningioma;

```
meningioma.LoadCT(filename);
```

```
meningioma.N'_i {N'_j, N'_k};  
meningioma.dx' {dy', dz'};  
meningioma.x'_0 {y'_0, z'_0};
```

```
meningioma.Hounsfield(i',j',k'); → Hi'j'k'  
meningioma.Density(i',j',k'); → ρi'j'k'
```



# TPS Kernel | High level structure

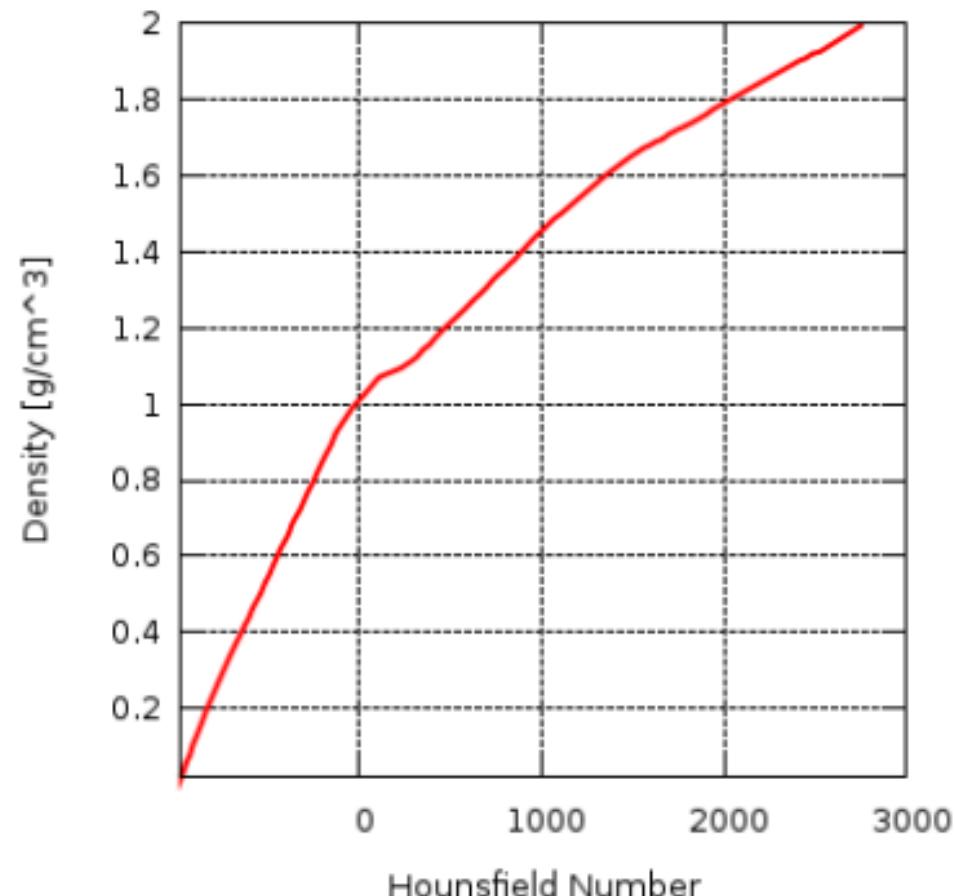


CT meningioma;

```
meningioma.LoadCT(filename);
```

```
meningioma. $N'_i$  { $N'_j$ ,  $N'_k$ };  
meningioma. $dx'$  { $dy'$ ,  $dz'$ };  
meningioma. $x'_0$  { $y'_0$ ,  $z'_0$ };
```

```
meningioma.Hounsfield( $i', j', k'$ );  $\rightarrow H_{i'j'k'}$   
meningioma.Density( $i', j', k'$ );  $\rightarrow \rho_{i'j'k'}$ 
```



# TPS Kernel | High level structure

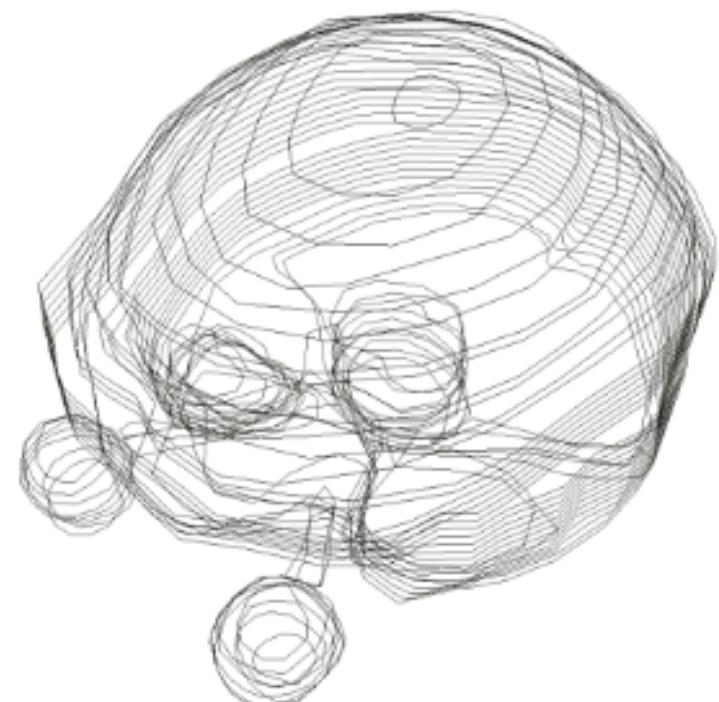


```
meningioma.LoadVOIs(file1, file2);  
memeningioma.NVOI;  
memeningioma.vois[n];
```

```
meningioma.vois[n] -> Name;  
meningioma.vois[n] -> NPoints;  
meningioma.vois[n] -> x[i] {y[i], z[i]};  
meningioma.vois[n] -> Transform(**R, *T);
```

```
meningioma.vois[n] -> indexSlice;  
meningioma.vois[n] -> zSlice;
```

```
meningioma.vois[n] -> IsIn(x', y', z'); → bool
```



# TPS Kernel | High level structure

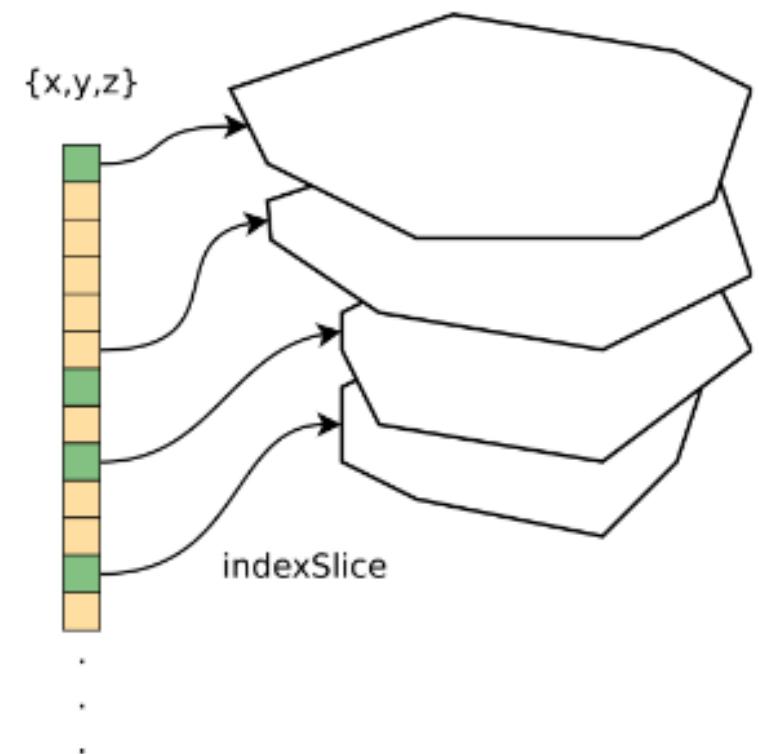


```
meningioma.LoadVOIs(file1, file2);  
memeningioma.NVOI;  
memeningioma.vois[n];
```

```
meningioma.vois[n] -> Name;  
meningioma.vois[n] -> NPoints;  
meningioma.vois[n] -> x[i] {y[i], z[i]};  
meningioma.vois[n] -> Transform(**R, *T);
```

```
meningioma.vois[n] -> indexSlice;  
meningioma.vois[n] -> zSlice;
```

```
meningioma.vois[n] -> IsIn(x', y', z'); → bool
```



# TPS Kernel | High level structure

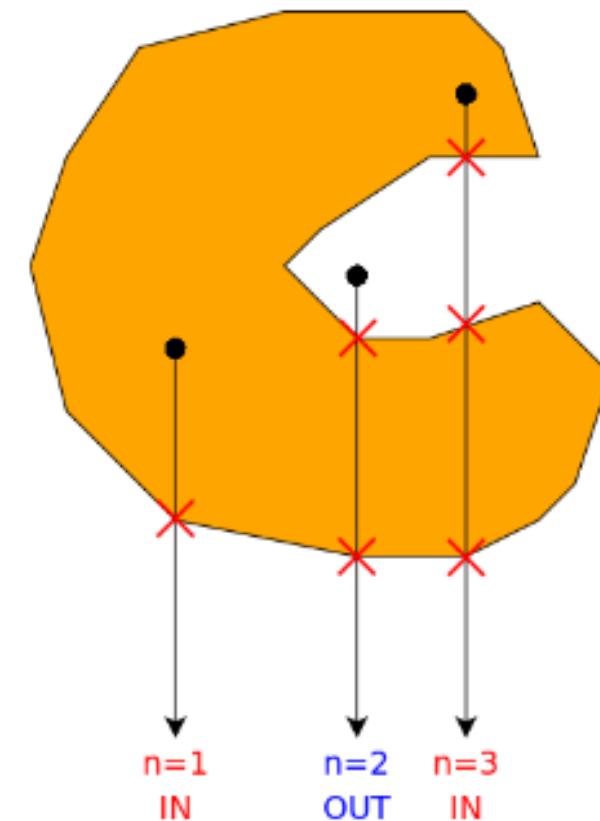


```
meningioma.LoadVOIs(file1, file2);  
memeningioma.NVOI;  
memeningioma.vois[n];
```

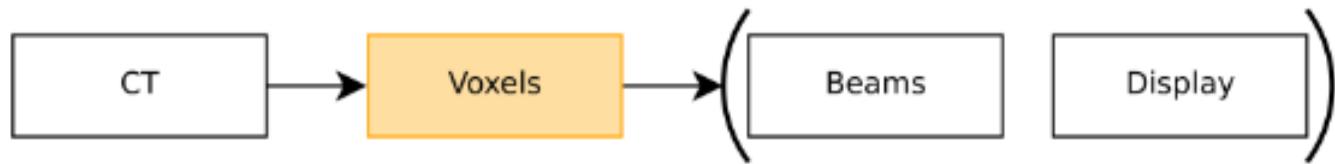
```
meningioma.vois[n] -> Name;  
meningioma.vois[n] -> NPoints;  
meningioma.vois[n] -> x[i] {y[i], z[i]};  
meningioma.vois[n] -> Transform(**R, *T);
```

```
meningioma.vois[n] -> indexSlice;  
meningioma.vois[n] -> zSlice;
```

```
meningioma.vois[n] -> IsIn(x', y', z'); → bool
```



# TPS Kernel | High level structure



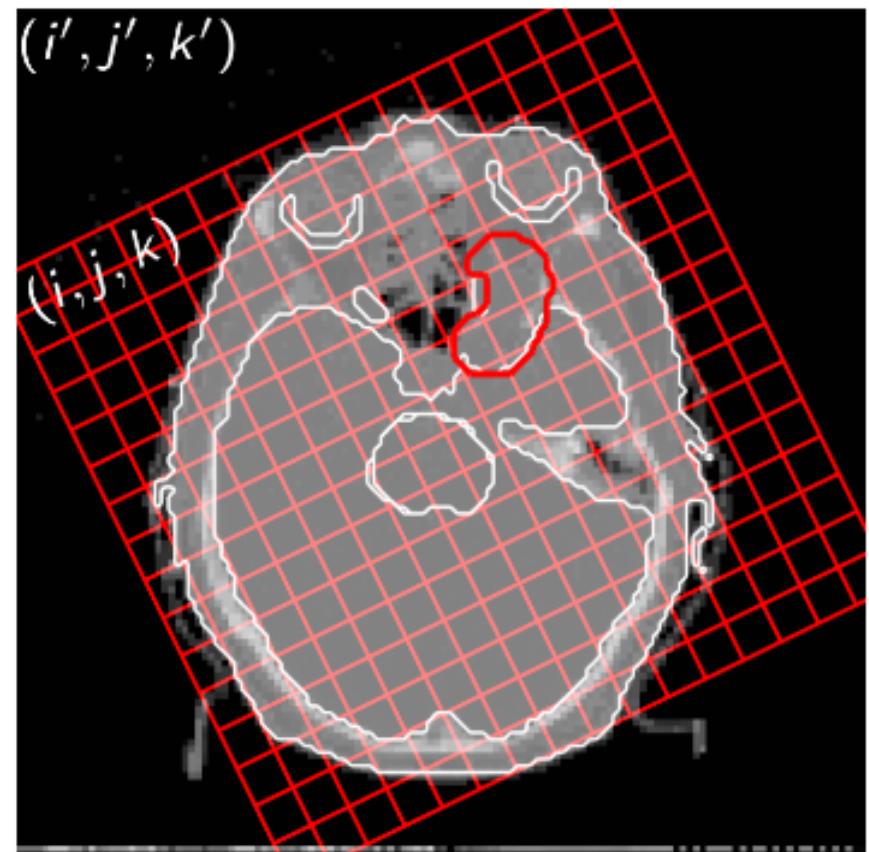
```
Voxels myVoxels;
```

```
myVoxels.CreateArrays( $N_i, N_j, N_k$ );
```

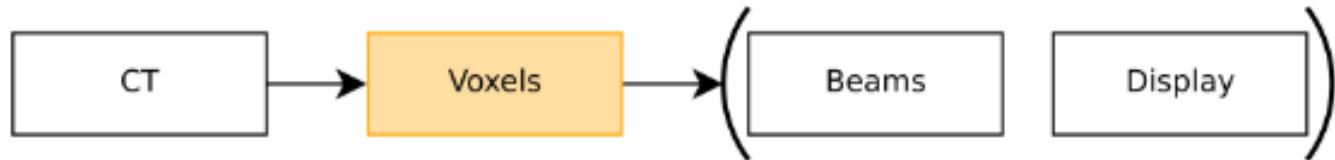
```
myVoxels.Density[i][j][k];  $\rightarrow \rho_{ijk}$   
myVoxels.Dose[i][j][k];  $\rightarrow D_{ijk}$   
myVoxels.Alpha[i][j][k];  $\rightarrow \alpha_{ijk}$   
myVoxels.Beta[i][j][k];  $\rightarrow \beta_{ijk}$   
myVoxels.VOIs[i][j][k];  $\rightarrow \text{binary}$ 
```

```
myVoxels.SetCT(meningioma);  
myVoxels.SetReferenceFrame(**R', *T');  
myVoxels.SetDimensions(dx, dy, dz);  
myVoxels.EvaluateCT(samples);
```

```
myVoxels.EvaluateVOIs;
```



# TPS Kernel | High level structure



`Voxels myVoxels;`

`myVoxels.CreateArrays( $N_i, N_j, N_k$ );`

`myVoxels.Density[i][j][k]; →  $\rho_{ijk}$`   
`myVoxels.Dose[i][j][k]; →  $D_{ijk}$`   
`myVoxels.Alpha[i][j][k]; →  $\alpha_{ijk}$`   
`myVoxels.Beta[i][j][k]; →  $\beta_{ijk}$`   
`myVoxels.VOIs[i][j][k]; → binary`

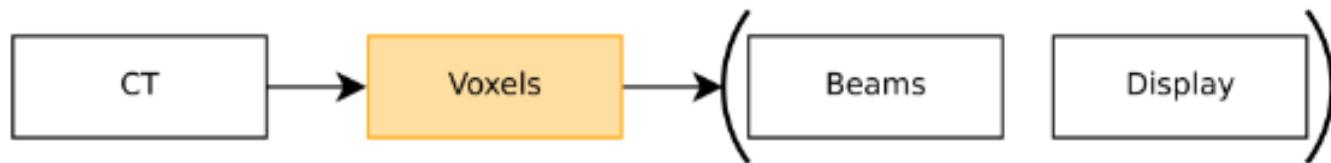
`myVoxels.SetCT(meningioma);`  
`myVoxels.SetReferenceFrame(**R', *T');`  
`myVoxels.SetDimensions(dx, dy, dz);`  
`myVoxels.EvaluateCT(samples);`

`myVoxels.EvaluateVOIs;`

Direct evaluation:

- `Voxels::SetDirectCT(&CT) {`
- `myCT = &CT;`
- `SetDimensions(myCT->dx,`
- `myCT->dy, myCT->dy);`
- `SetReferenceFrame(I, 0);`
- `CreateArrays(myCT-> $N_i$ ,`
- `myCT-> $N_j$ , myCT-> $N_k$ );`
- `EvaluateCT(1);`
- `return;`
- `}`

# TPS Kernel | High level structure



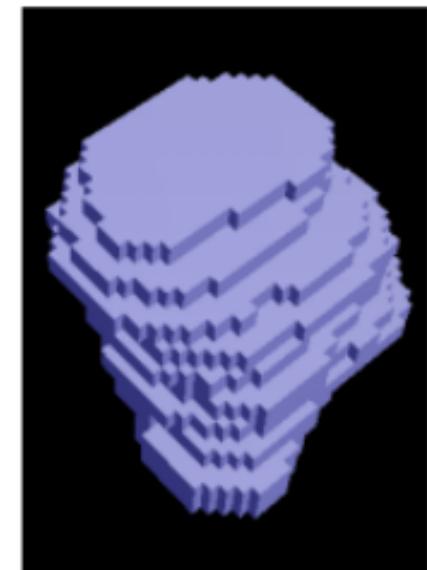
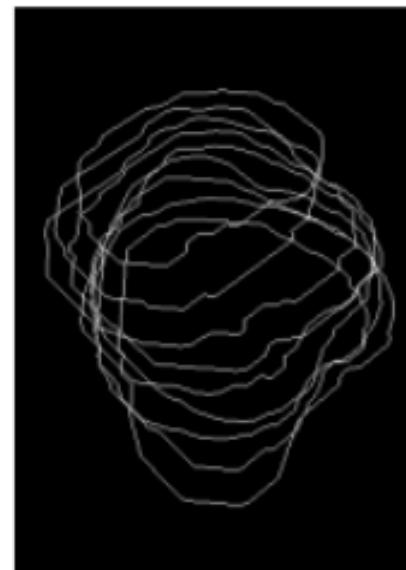
```
Voxels myVoxels;
```

```
myVoxels.CreateArrays( $N_i, N_j, N_k$ );
```

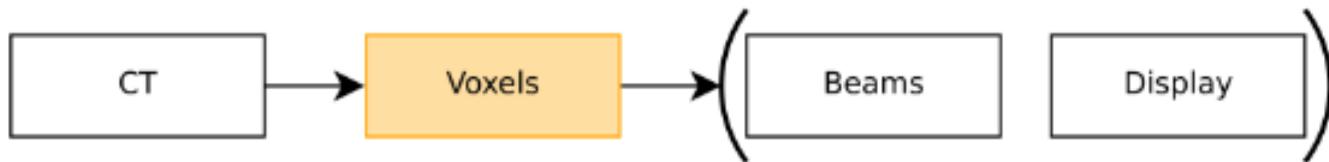
```
myVoxels.Density[i][j][k];  $\rightarrow \rho_{ijk}$   
myVoxels.Dose[i][j][k];  $\rightarrow D_{ijk}$   
myVoxels.Alpha[i][j][k];  $\rightarrow \alpha_{ijk}$   
myVoxels.Beta[i][j][k];  $\rightarrow \beta_{ijk}$   
myVoxels.VOIs[i][j][k];  $\rightarrow$  binary
```

```
myVoxels.SetCT(meningioma);  
myVoxels.SetReferenceFrame(**R', *T');  
myVoxels.SetDimensions(dx, dy, dz);  
myVoxels.EvaluateCT(samples);
```

```
myVoxels.EvaluateVOIs;
```



# TPS Kernel | High level structure



`Voxels myVoxels;`

`myVoxels.CreateArrays( $N_i, N_j, N_k$ );`

`myVoxels.Density[i][j][k]; →  $\rho_{ijk}$`   
`myVoxels.Dose[i][j][k]; →  $D_{ijk}$`   
`myVoxels.Alpha[i][j][k]; →  $\alpha_{ijk}$`   
`myVoxels.Beta[i][j][k]; →  $\beta_{ijk}$`   
`myVoxels.VOIs[i][j][k]; → binary`

`myVoxels.SetCT(meningioma);`  
`myVoxels.SetReferenceFrame(**R', *T');`  
`myVoxels.SetDimensions(dx, dy, dz);`  
`myVoxels.EvaluateCT(samples);`

`myVoxels.EvaluateVOIs;`

## VOIs

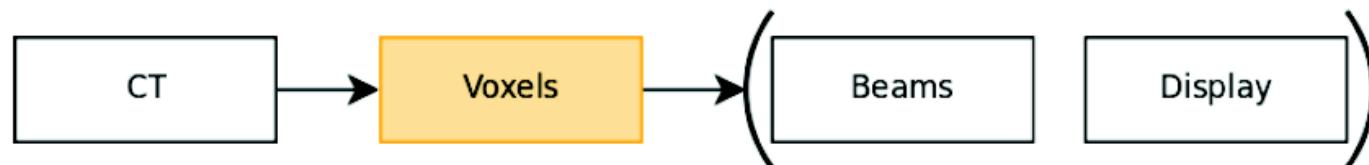
Values:

- `voi[0] = 00000001`
- `voi[1] = 00000010`
- `voi[2] = 00000100`
- [...]

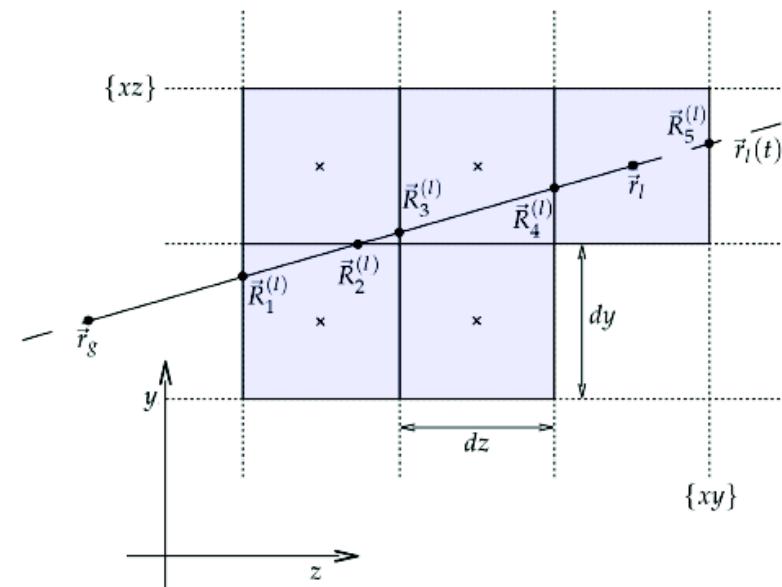
Bitwise functions examples:

- `Voxels::PutVOI(n, i, j, k) {  
 VOIs[i][j][k] |= voi[n];  
}`
- `Voxels::IsVOI(n, i, j, k) {  
 return(VOIs[i][j][k] & voi[n]);  
}`

# TPS Kernel | High level structure



Raytracing:



## Member Functions

Logical Output:

- $\text{Voxel}[i][j][k].\text{Tissue} \rightarrow T_{ijk}$
- $\text{Voxel}[i][j][k].\text{Organs} \rightarrow \text{binary}$

Ray-Tracing:

- $\text{Voxels.SetRay}(\vec{r}_g, \vec{\theta}) \rightarrow n$
- $\text{Voxels.GetIntersections}(n) \rightarrow \{\vec{R}_p^{(n)}\}$
- $\text{Voxels.WEPL}(n, r) \rightarrow WEPL^{(n)}(r)$

$$WEPL^{(n)}(r) = \sum_{p < p_r} |\vec{R}_{p+1}^{(n)} - \vec{R}_p^{(n)}| \rho_{i_p j_p k_p}$$

# TPS Kernel | High level structure



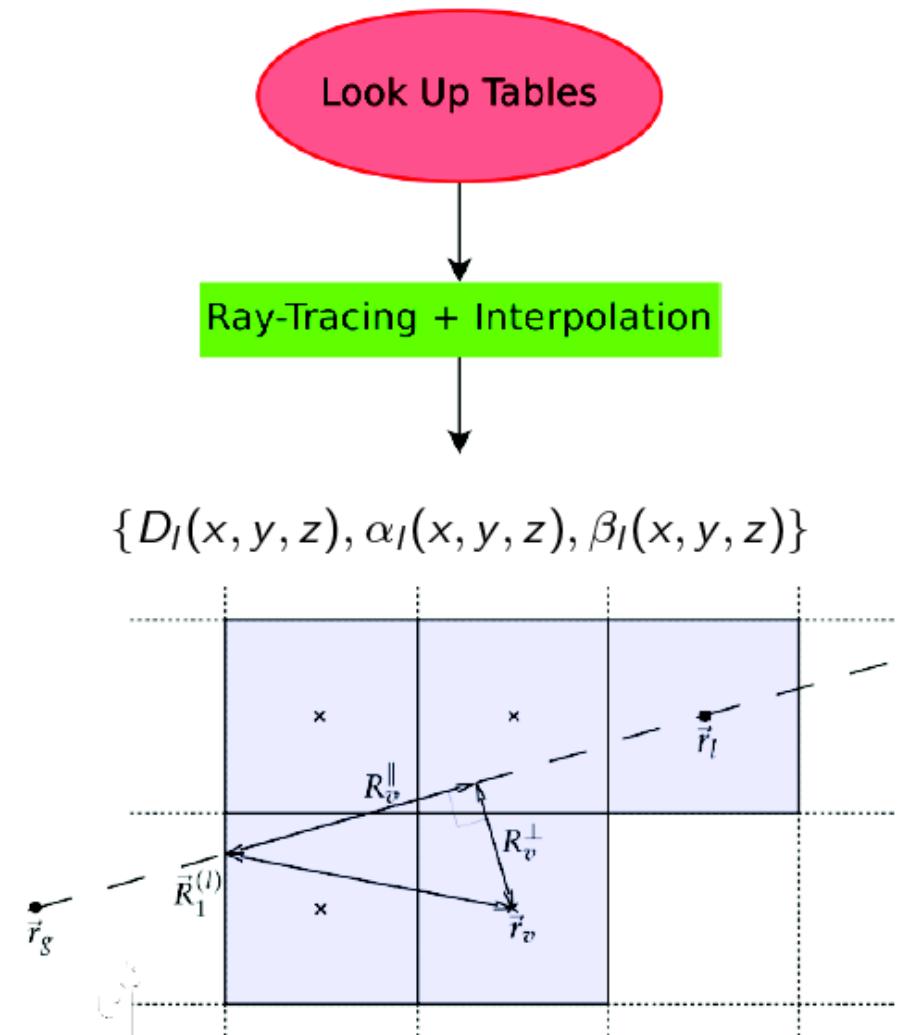
## Member Functions

Setting:

- Beams.SetVoxels(&voxels)
- Beams.CreateBeam() →  $I$
- Beam[ $I$ ].SetEnergy( $E$ )
- Beam[ $I$ ].SetDirection( $\vec{g}, \vec{r}$ )
- Beam[ $I$ ].SetFluence( $\phi$ )

Physical and Biological model (using look-up tables):

- Beam[ $I$ ].Dose( $x, y, z$ ) →  $D_I(x, y, z)$
- Beam[ $I$ ].Alpha( $x, y, z$ ) →  $\alpha_I(x, y, z)$
- Beam[ $I$ ].Beta( $x, y, z$ ) →  $\beta_I(x, y, z)$
- Beam[ $I$ ].SetEnergyForSpot( $\vec{r}_g, \vec{r}_s$ ) →  $E$



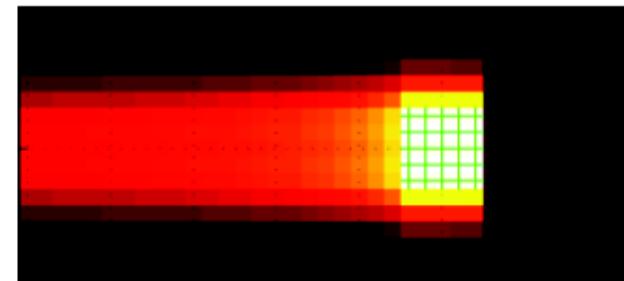
# TPS Kernel | High level structure



## Member Functions

Evaluation on Voxels:

- Beams.SetDoseCutoff( $D_c$ )
- Beams.EvaluateNetDose()
- Beams.EvaluateNetAlpha()
- Beams.EvaluateNetBeta()



## Voxels Data Structure

- Voxel[i][j][k].Dose
- Voxel[i][j][k].Alpha
- Voxel[i][j][k].Beta

$$D_{ijk} = \sum_l D_{ijkl}$$

$$\alpha_{ijk} = \frac{\sum_l \alpha_{ijkl} D_{ijkl}}{D_{ijk}}$$

$$\beta_{ijk} = \frac{(\sum_l \sqrt{\beta_{ijkl}} D_{ijkl})^2}{D_{ijk}^2}$$

# TPS Kernel | High level structure



## Treatment Specifications

VOI	Requirements	
PTV	Prescription dose	80 Gy
	Maximum dose	82 Gy
	Minimum dose	78 Gy
	95% of volume	$\geq 79$ Gy
Rectum	Maximum dose	76 Gy
	70% of volume	$\leq 32$ Gy
Bladder	Maximum dose	78 Gy
	70% of volume	$\leq 32$ Gy



Constraints  
Matrix

# TPS Kernel | High level structure



Treatment  
Specifications



Constraint Matrix

$\lambda$	VOI name	$D_{\lambda}^{\max}$ [Gy]	$v_{\lambda}^{(u)}$ [%]	$w_{\lambda}^{(u)}$	$D_{\lambda}^{\min}$ [Gy]	$v_{\lambda}^{(l)}$ [%]	$w_{\lambda}^{(l)}$
1	PTV	80	100	0.9	80	100	1.0
2	PTV	82	100	0.9	78	100	1.0
3	PTV	-	-	-	79	95	1.0
4	rectum	76	100	1.0	-	-	-
5	rectum	32	70	1.0	-	-	-
6	bladder	78	100	1.0	-	-	-
7	bladder	32	70	1.0	-	-	-

# TPS Kernel | High level structure



Constraints  
Matrix

$$\chi^2(\phi) = \sum_{\lambda} \left( w_{\lambda}^{(u)} \sum_{ijk \in \text{VOI}_{\lambda}(v_{\lambda}^{(u)})} \max(0, D_{ijk} - D_{\lambda}^{\max})^2 + w_{\lambda}^{(l)} \sum_{ijk \in \text{VOI}_{\lambda}(v_{\lambda}^{(l)})} \max(0, D_{\lambda}^{\min} - D_{ijk})^2 \right)$$

“Biological” Cost Function:

$$D_{ijk} \rightarrow D_{ijk}^{\text{bio}} = D_{ijk} \times \text{RBE}_{ijk}, \quad D_{ijk}^{\text{bio}} = \frac{-\alpha_X + \sqrt{\alpha_X^2 + 4\beta_X N_{ijk}^{\text{leth}}}}{2\beta_X}, \quad N_{ijk}^{\text{leth}} = \alpha_{ijk} D_{ijk} + \beta_{ijk} D_{ijk}^2$$

# TPS Kernel | High level structure



## Member Functions

Setting:

- Optimization.SetConstraints(&Constraints)
- Optimization.SetCostFunction(&CostFunction)

Evaluation:

- Optimization.ConjugateGradient() (GSL)
- Optimization.Simplex() (GSL)
- Optimization.SimulatedAnnealing()
- Optimization.ParallelTempering()
- Optimization.GeneticAlgorithm()
- [...]

Minimization:

- Global minimum
- Non-linear
- Multi-dimensional

$$N\{\phi_I\} \sim 10^4$$

( $\phi_I$  := beams fluences)

# TPS Kernel | High level structure



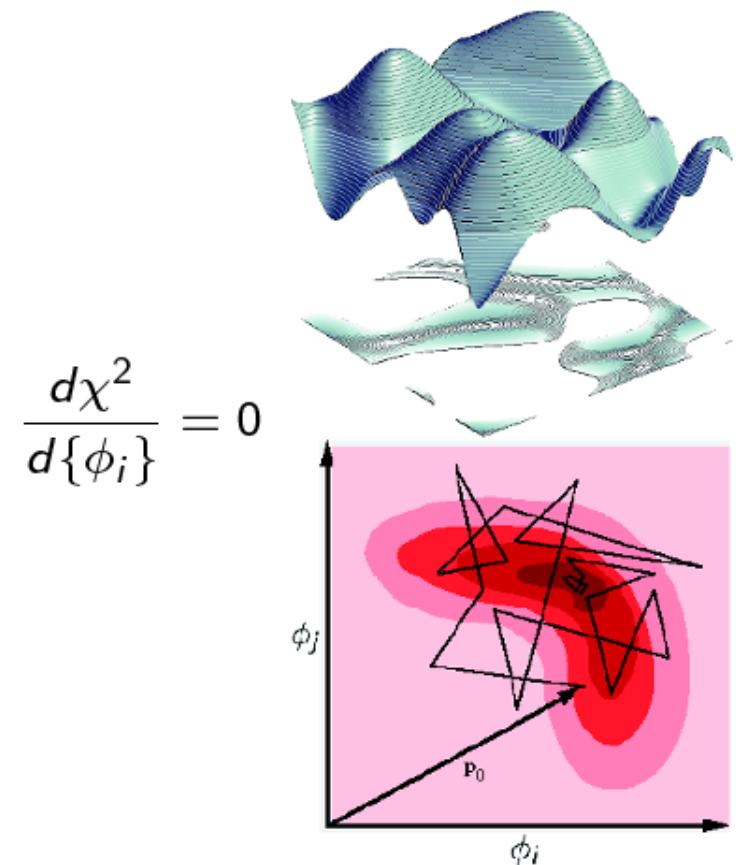
## Member Functions

Setting:

- Optimization.SetConstraints(&Constraints)
- Optimization.SetCostFunction(&CostFunction)

Evaluation:

- Optimization.ConjugateGradient() (GSL)
- Optimization.Simplex() (GSL)
- Optimization.SimulatedAnnealing()
- Optimization.ParallelTempering()
- Optimization.GeneticAlgorithm()
- [...]



# TPS Kernel | High level structure



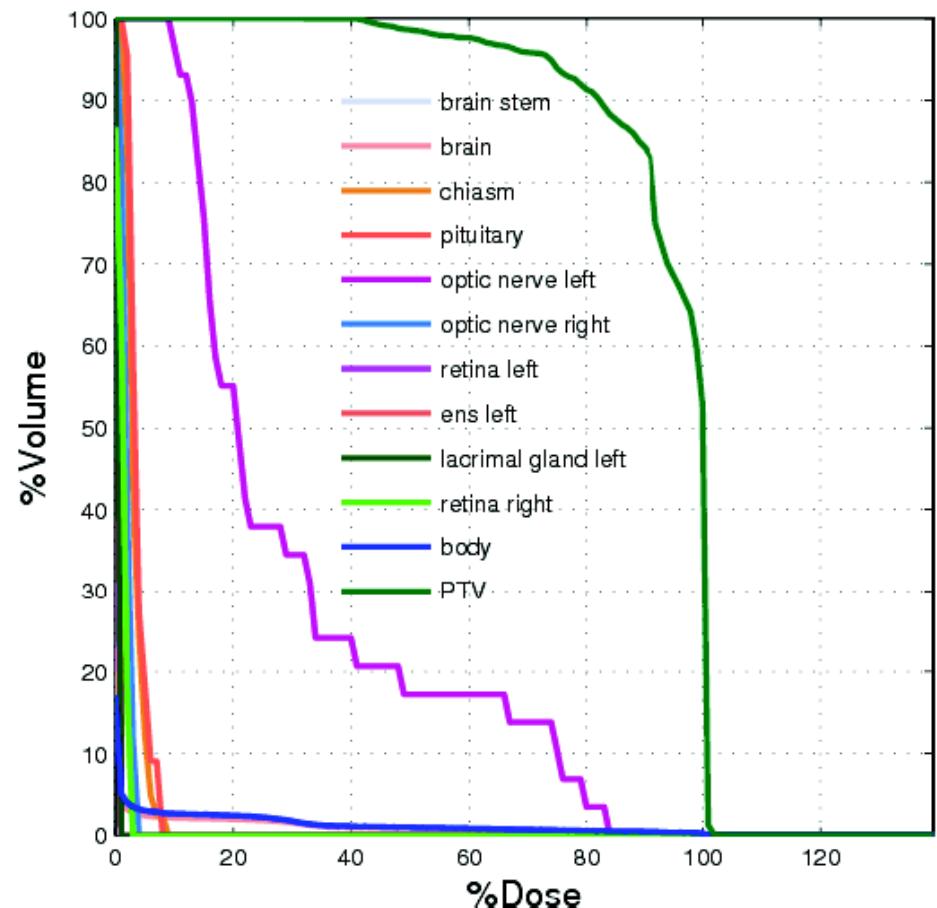
## Member Functions

### Plan Evaluation:

- `Plan.Evaluate()`

### Output:

- `Plan.DVH(%D) → %V`
- `Plan.Dose(i, j, k) → %Dijk`
  - `Voxel[i][j][k].Dose`
- `Plan.Survival(i, j, k) → %Sijk`
  - `Voxel[i][j][k].Survival`
- `Plan.OptimizationInfos()`
- [...]



The development of a carbon ion Treatment Planning System

# TPS Kernel | High level structure

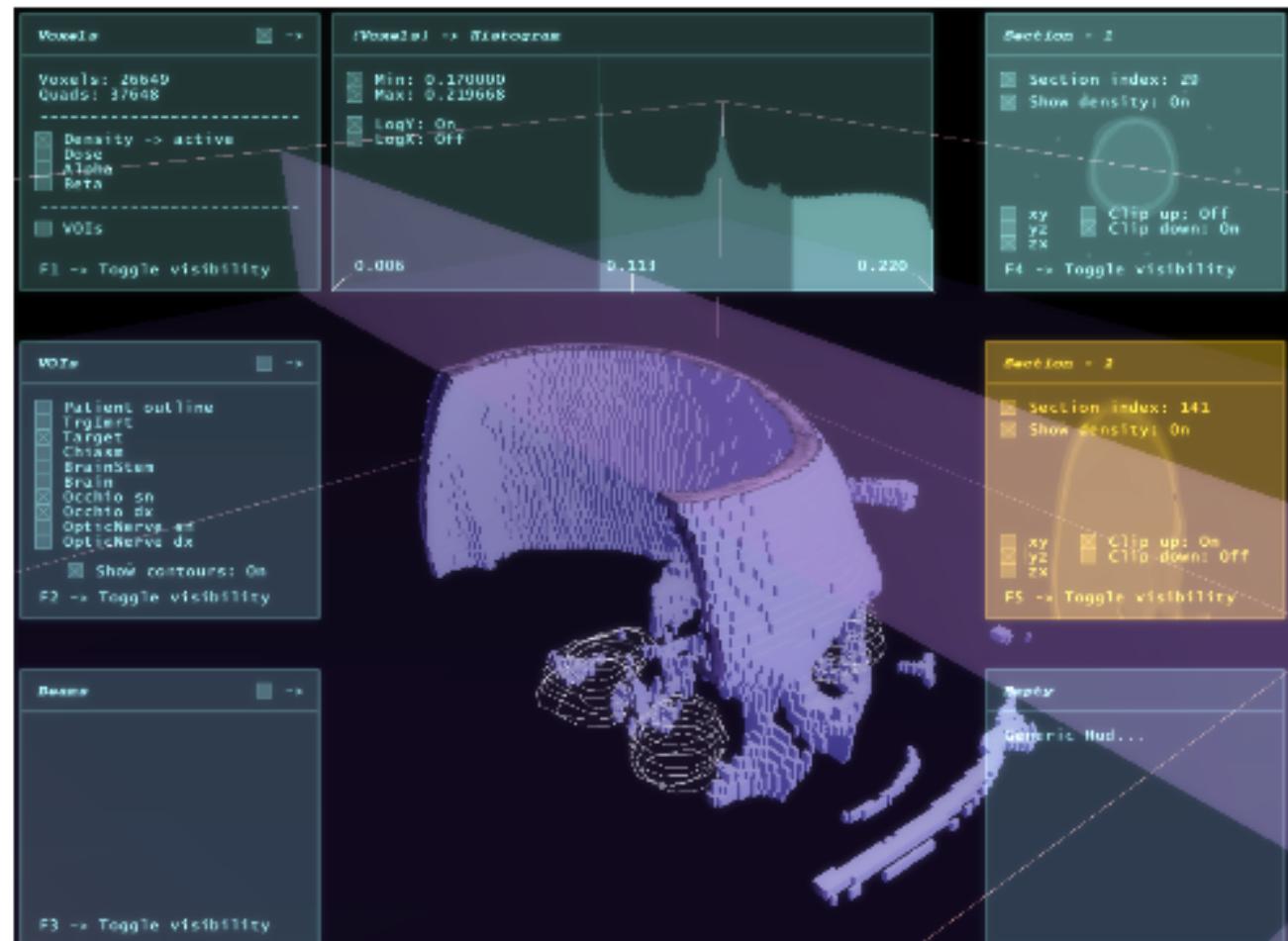


Display myDisplay;

```
myDisplay << meningoia;  
myDisplay << myVoxels;  
myDisplay << myBeams;  
myDisplay << myPlan;
```

```
myDisplay.SetGeometry(s);  
myDisplay.ScreenWidth;  
myDisplay.ScreenHeight;
```

myDisplay.BeginIntSession();



# Quality Assurance

Q-Spin Audit (28 September 2009):

*Quality Management audit for assessing  
compliance of INFN with the ISO13485:2003 for  
the development of the calculation module of the  
Carbon Therapy Treatment Planning calculation  
module to become an EC/92/42 approved  
product for CE marking.*



Corrective Actions

Q-Spin Training workshop (2-4 November 2009):

- Project Life Cycle
- Project Planning
- Risk Management
- Project Monitoring and Control
- Verification and Validation
- Requirement Management
- Configuration Management
- Issue Management
- Unified Modeling Language (UML)
- Unit Testing
- Software Architecture

## Conclusions

Ion therapy represents an alternative to X-ray conventional cancer treatments, particularly suited for treating radio-resistant, deep-seated tumours.

Proton therapy is a well-established technique for treating cancer; its advantages have been demonstrated with clinical trials.

Carbon ion therapy is a promising technique which is expected to provide additional benefits; these benefits have still to be proven, hence the use of carbon ions in the clinical practice is limited.

Italy is doing, together with Germany and Japan, pioneer work with carbon ions, both in the development of a dedicated medical centre and in the realization of a Treatment Planning System.

The work of the INFN-TPS collaboration consists in the development of a commercial TPS, in cooperation with the IBA company.

The TPS has to provide the medical doctor with the evaluation of the effectiveness of different irradiation patterns, allowing him to choose the one to be delivered to the patient.

## Conclusions

In addition, the capability of guiding the medical doctor towards a solution that optimizes the adherence with the stated prescription is required.

In the TPS-INFN project, this complex task is achieved pre-computing the effectiveness of the elementary beams in water and then loading and rescaling them depending on the actual patient morphology.

The TPS is being written in C++ and up to now involves the use of Geant4, Fluka, MySQL, GRID, OpenGL, GNU Scientific Libraries, CppUnit.

The requests in terms of maximum time for the evaluation (in the order of minutes) and of big treatment volumes (more than 1 litre) impose a trade-off between efficiency, memory consumption and precision.

Claiming to become a commercial medical product, the TPS must obtain the EC marking. Therefore it has to fulfill the Q&A rules specified in the appropriate ISO standards.

## Conclusions

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**THANK YOU!**