



## BNCT 최신동향 소개 Boron Neutron Capture Therapy

**2021. 5. 12.**

서효정  
다원메딕스



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## Neutron

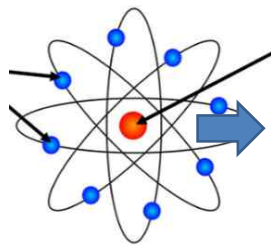
## BNCT

### 1932: James Chadwick's Letter to *Nature* on the Neutron

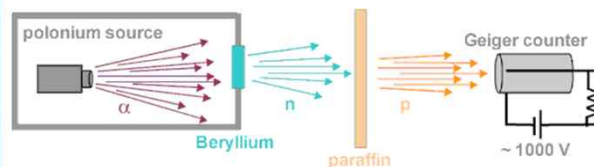
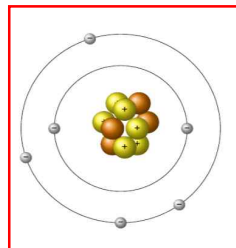
James Chadwick



Rutherford's model



Chadwick's model

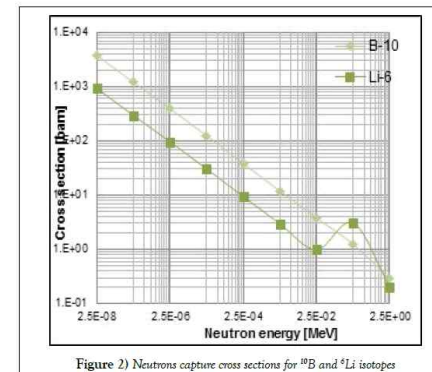


Chadwick, J. (1932) "Possible Existence of a Neutron," *Nature* 129 (3252): 312.

Chadwick, J. (1932) "The Existence of a Neutron," *Proceedings of the Royal Society A: Mathematical, Physical and Engineering Sciences* 136(830): 692.

<https://www.aps.org/publications/apsnews/201402/physicshistory.cfm>

### 1934 : Goldhaber



Capture Cross section  
for slow neutrons

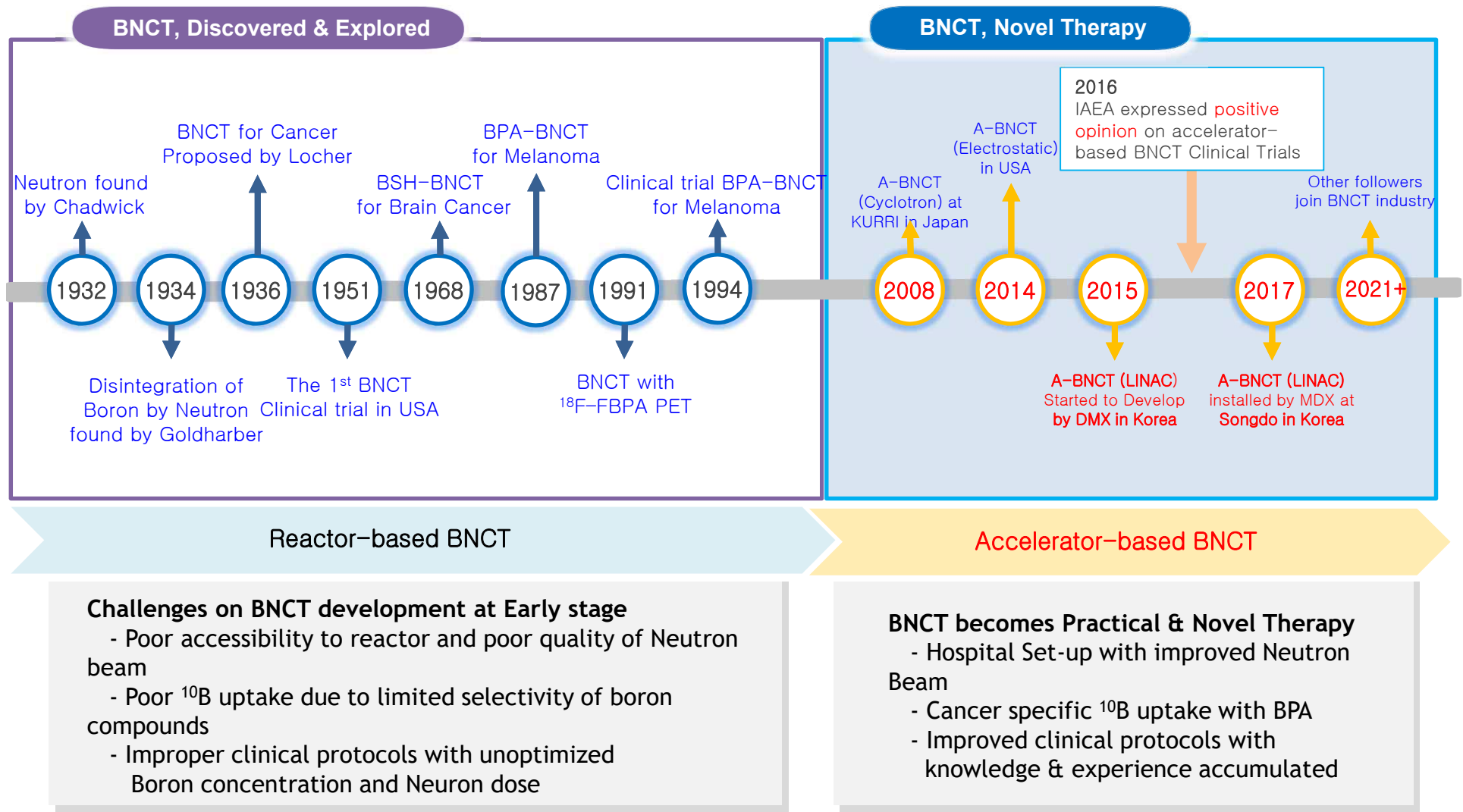
### 1936: Gordon Locher

BNCT in 1936 and hypothesized that if **boron could be selectively concentrated in a tumour mass** and the volume then exposed to **thermal neutrons**, a higher radiation dose to the tumour relative to adjacent normal tissue would be produced

Locher, G. Biological effects and therapeutic possibilities of neutrons. *Am J Roentgenol Radium Ther.* 1936;36(1):1-13



# BNCT 발달 역사



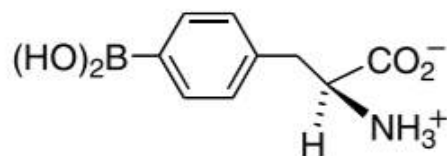


# BNCT 원리

## Neutron

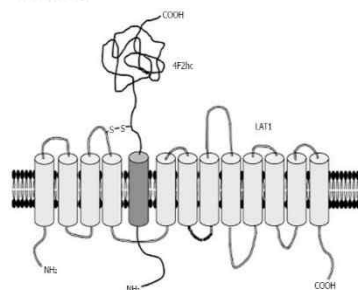
- ✓ Thermal ( $E_n < 0.5$  eV)
- ✓ Epithermal ( $0.5$  eV  $< E_n < 10$  KeV)
- ✓ Fast ( $E_n > 10$  keV)

## $^{10}\text{B}$ enriched Boronophenylalanine (BPA)

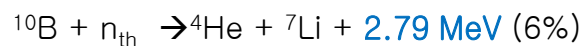


## Tumor cell selectivity

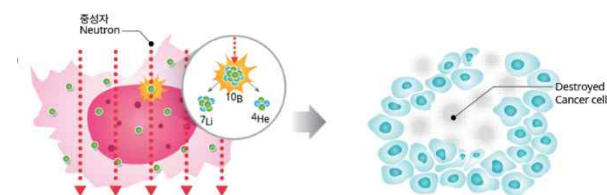
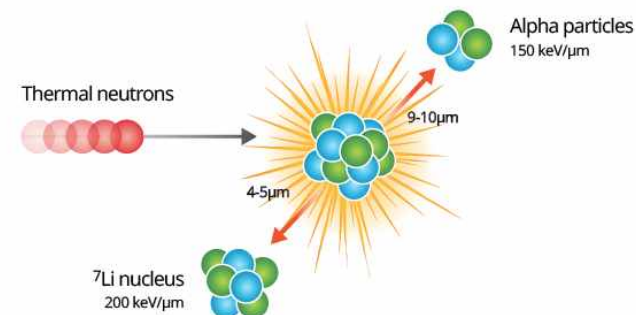
L-type Amino Acid  
Transporter 1 (LAT1)  
High expression



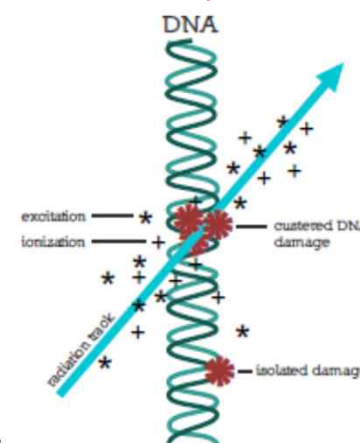
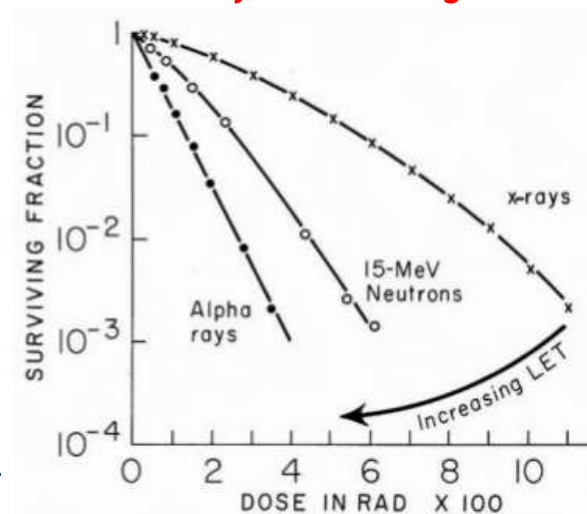
2017 Hayashi K et al. WJGO



$^{10}\text{B}$ : High cross section  
: thermal neutron  
3840 barn

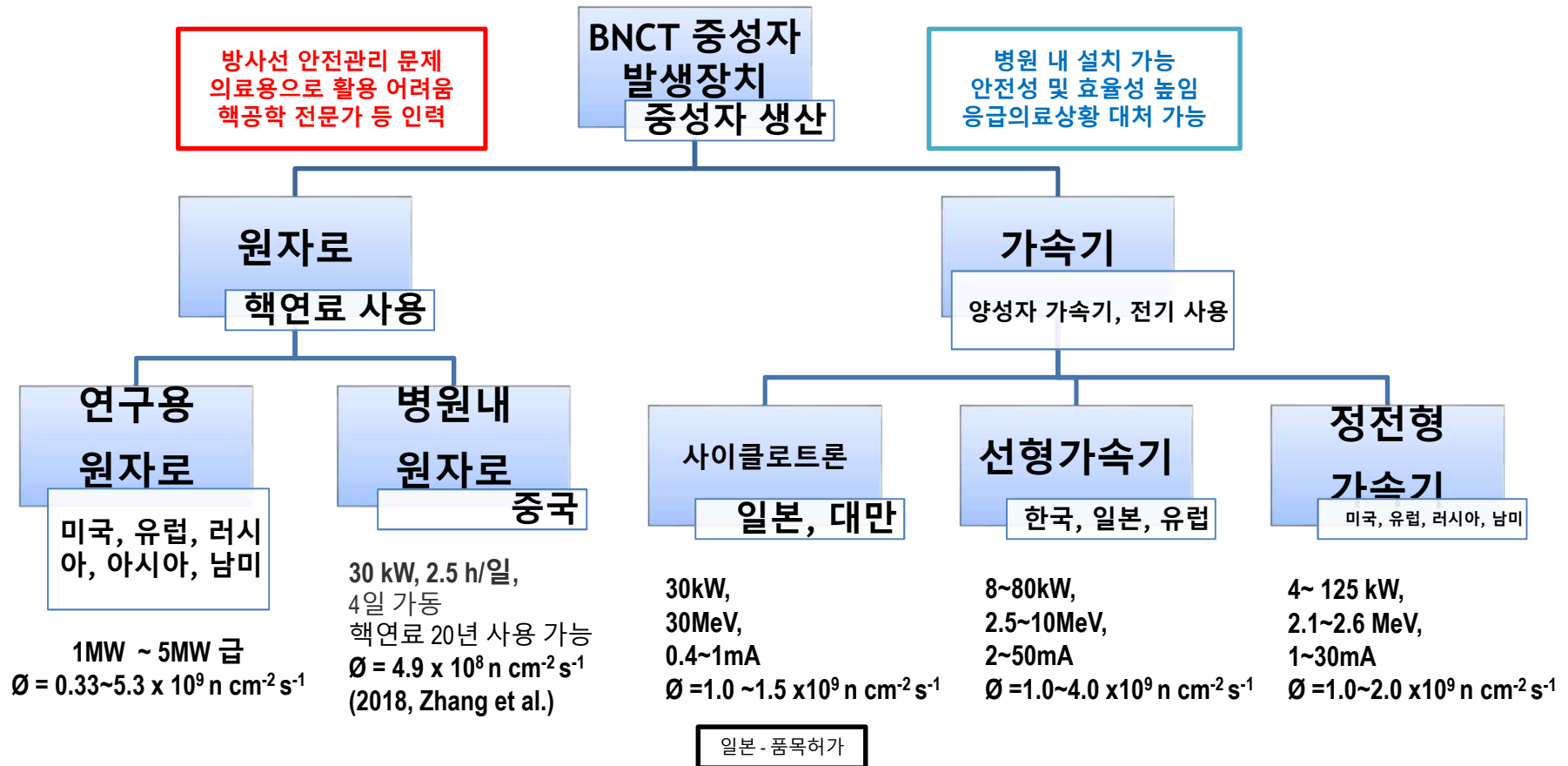


Physical advantage + Biological selectivity



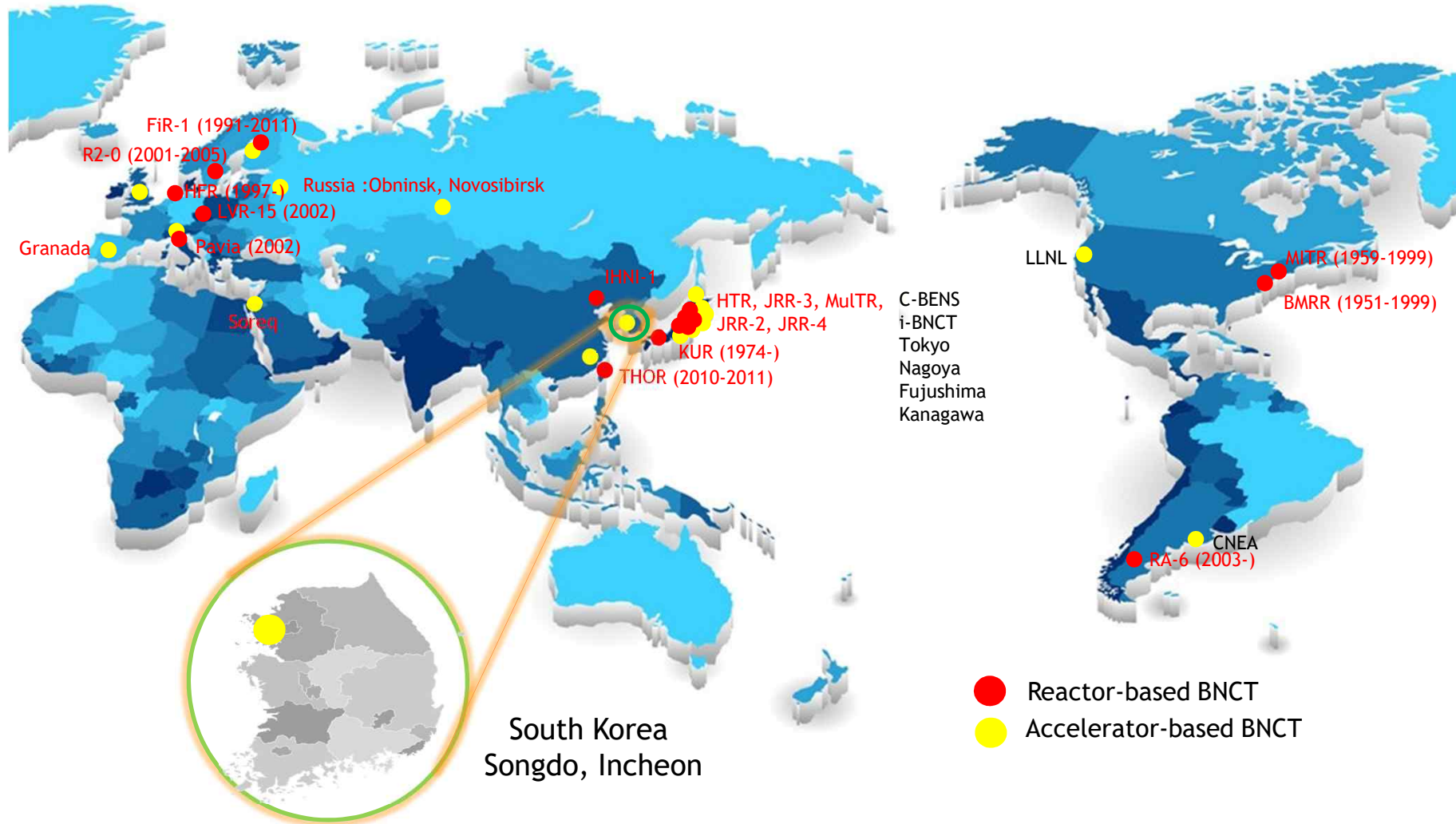
2019 I. Porras







# 전세계 BNCT 센터



Modified from AIP Conference Proceedings (2019)



## 가속기 기반 BNCT 사양 및 현황 (2020 IAEA Technical meeting 취합 및 자료 정리)

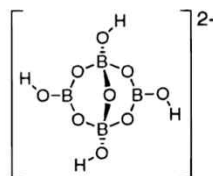
Type	Company	Institute	Accelerator	Beam energy	Intensity	Reaction	Max. n Energy	Current status
Linear	DAWONMEDAX, Korea	Gachon Univ. Gil Med. Center, S.Korea	RFQ-DTL <sup>a</sup>	10 MeV	8 mA	<sup>9</sup> Be(p,n)	8.1 MeV	비임상시험
	Toshiba, MHI, Japan	Tsukuba Univ., Japan	RFQ-DTL <sup>a</sup>	8 MeV	10 mA	<sup>9</sup> Be(p,n)	6.1 MeV	비임상시험
	CICS, Japan	National Cancer Center, Edogawa Hospital BNCT center, Japan	RFQ <sup>a</sup>	2.5 MeV	20 mA	<sup>7</sup> Li(p,n)	0.79 MeV	비임상시험
	-	SOREQ, Israel	RFQ-DTL <sup>a</sup>	4 MeV	2 mA	<sup>7</sup> Li(p,n)	2.3 MeV	개발중
	-	INFN, Italia	RFQ <sup>a</sup>	5 MeV	50 mA	<sup>9</sup> Be(p,n)	3.1 MeV	개발중
Electrostatic	Neutron Therapeutics, US	Helsinki Univ. Cent. Hospital, Finland	Hyperion	2.6 MeV	30 mA	<sup>7</sup> Li(p,n)	0.89 MeV	임상시험 (2021)
	TAE LS, US	Xiamen Humanity Hospital, China	VITA	2.5 MeV	10 mA	<sup>7</sup> Li(p,n)	0.79 MeV	개발중
	-	CNEA Bs. As., Argentina	Tandem Electrostatic Quadropole	1.4 MeV 2.5 MeV	30 mA 30 mA	<sup>9</sup> Be(d,n) <sup>7</sup> Li(p,n)	5.7 MeV 0.79 MeV	건설중
	-	Birmingham Univ., UK	Dynamitron	2.8 MeV	1 mA	<sup>7</sup> Li(p,n)	1.1 MeV	개발중
	-	Nagoya Univ., Japan	Dynamitron	2.8 MeV	15 mA	<sup>7</sup> Li(p,n)	1.1 MeV	커미셔닝
	-	LBNL, USA	Electrostatic	2.5 MeV	50 mA	<sup>7</sup> Li(p,n)	0.79 MeV	NA
	-	Granada Univ., Spain	Hyperion	2.1 MeV	30 mA	<sup>7</sup> Li(p,n)	0.35 MeV	개발중
	-	Budker Institute, Novosibirsk, Russia	Vacuum insulated Tandem	2 MeV	2 mA	<sup>7</sup> Li(p,n)	0.23 MeV	비임상시험
	-	IPPE Obninsk, Russia	Cascade generator KG-2.5	2.3 MeV	3 mA	<sup>7</sup> Li(p,n)	0.57 MeV	개발중
	-	KIRAMS, S. Korea	electrostatic	2.4MeV	15mA	<sup>7</sup> Li(p,n)	0.79 MeV	개발중
Cyclotron	Sumitomo H.I, Japan	Osaka Medical College, Japan	Cyclotron	30 MeV	1 mA	<sup>9</sup> Be(p,n)	28 MeV	품목허가 완료

<sup>a</sup> RFQ stands for Radio Frequency Quadropole and DTL for Drift Tube Linac.

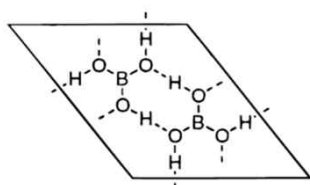


## 1<sup>st</sup> Generation

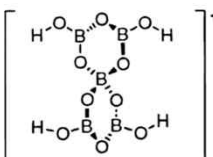
Borax ( $\text{Na}_2\text{B}_4\text{O}_7 \cdot 10\text{H}_2\text{O}$ )



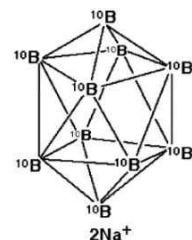
Boric acid  $[\text{B}(\text{OH})_3]$



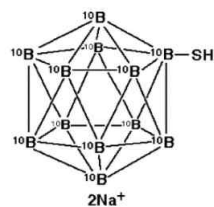
Pentaborate ( $\text{NaB}_5\text{O}_8 \cdot 4\text{H}_2\text{O}$ )



## 2<sup>nd</sup> Generation

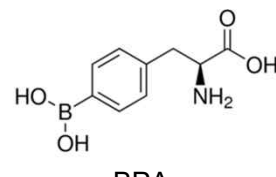


Decahydrodecaborate- $^{10}\text{B}$   
(GB-10,  $\text{Na}_2^{10}\text{B}_{10}\text{H}_{10}$ )



Mercaptoundecahydrodecaborate- $^{10}\text{B}$   
(Sodium borocaptate- $^{10}\text{B}$ , BSH,  
 $\text{Na}_2^{10}\text{B}_{12}\text{H}_{11}\text{SH}$ )

## 3<sup>rd</sup> Generation

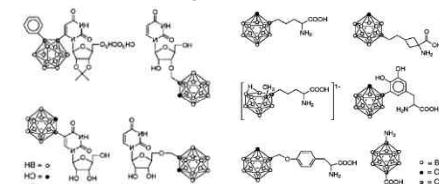


BPA  
(Borono-phenylalanine)

**Cancer-  
Targeted  
Delivery**

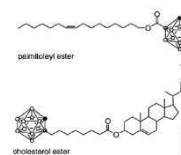
## Candidates of 4<sup>th</sup> Generation

Cellular Building Block

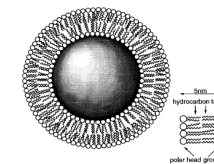


Boron-Containing Nucleic Acid Precursors and Amino Acids

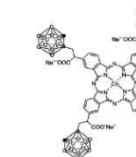
Lipoproteins



Liposomes

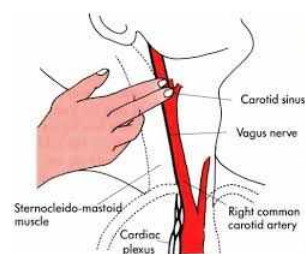


Porphyrins and  
Phthalocyanines

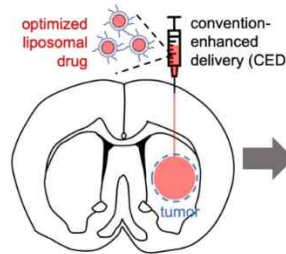


Receptors  
Antigen Binders

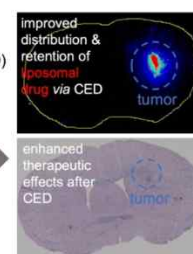
포도당대사  
지질대사  
의약품 개발 등



Intra-arterial injection



Han, Y., et al 2020



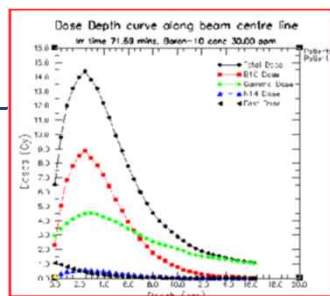
Intravenous injection

**Drug delivery  
system**



# BNCT 선량평가

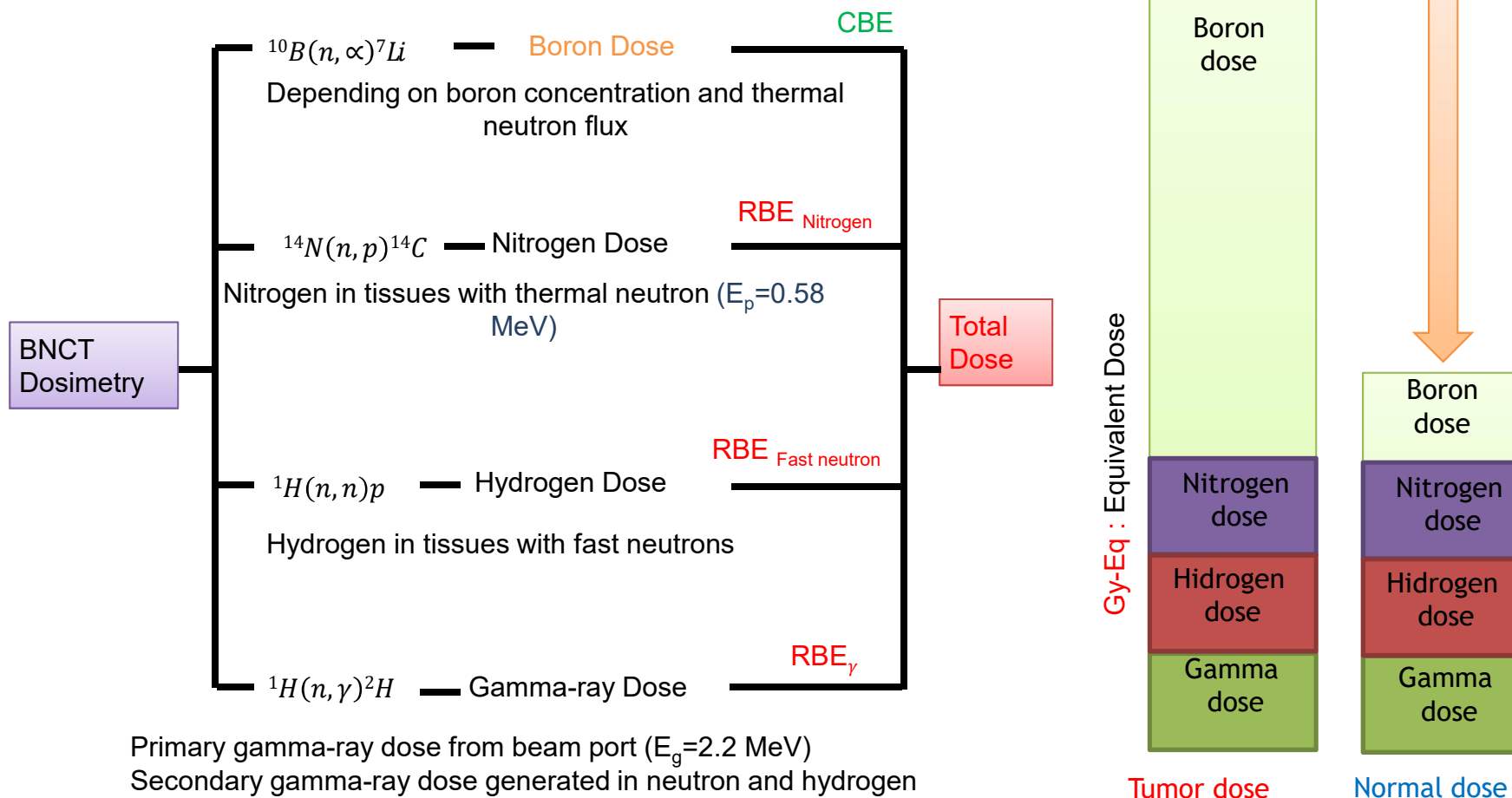
Physical dose



→  
X CBE/RBE

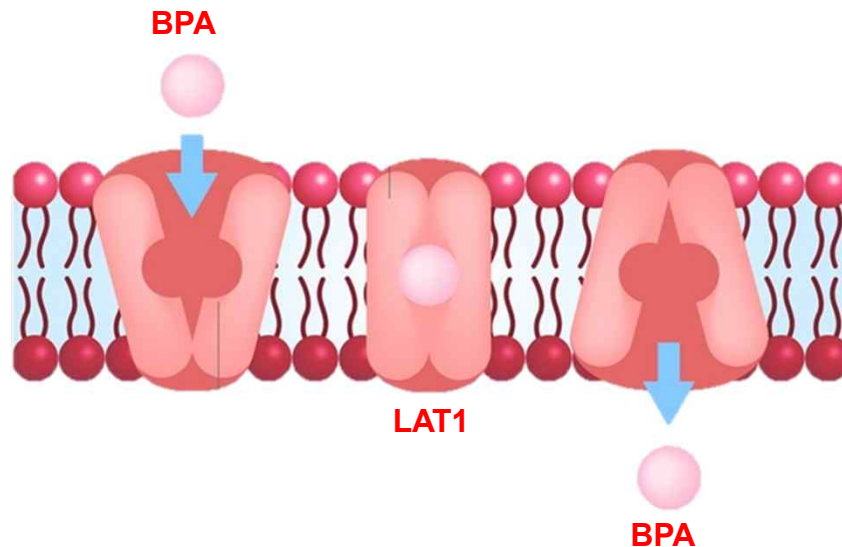
BNCT  
Dosimetry

Gy-Eq : Equivalent Dose



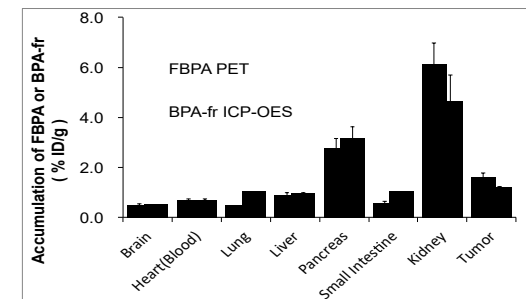


BPA accumulates selectively in cancer cells at much higher levels than normal cells



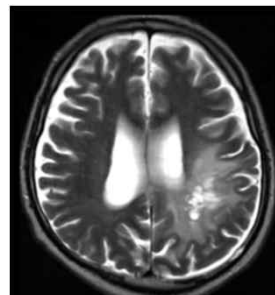
BPA is taken up selectively by LAT1, which is highly expressed in Cancer Cells

$^{18}\text{F}$ -FBPA PET clearly shows location of tumor mass

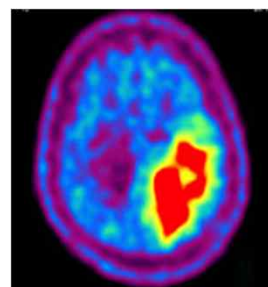


2014 Hanaoka K et al.

MRI Brain Image

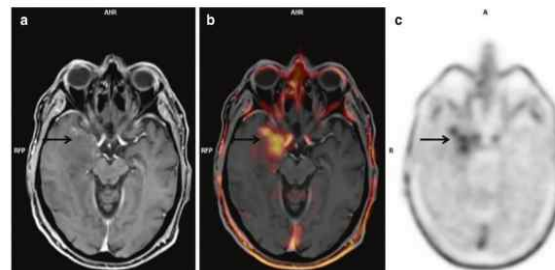


$^{18}\text{F}$ -FBPA PET Image



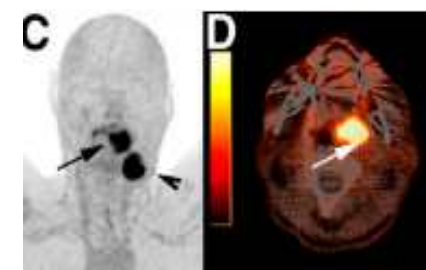
Miyatake et al, 2014, Radiation Oncology 9:6

$^{18}\text{F}$ -FET PET Image



Muoio, B. et al. 2017, Current Medicinal Chemistry.

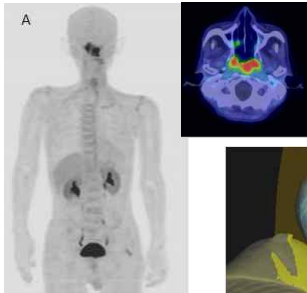
$^{18}\text{F}$ -FMT PET Image



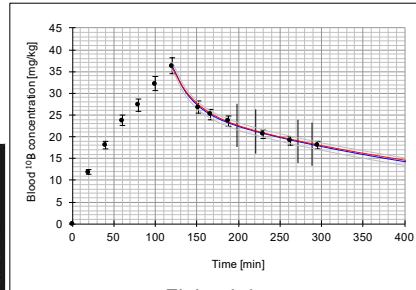
Burger, I. A et al. 2014, JNM



# BNCT 치료방법



H. Tani et al. 2014



Finnish Nuclear Reactor



**Screening  
Initial PET/CT**

**Treatment  
planning &  
simulation**

**BPA IV  
400mg/kg/2hr  
500mg/kg/3hr**

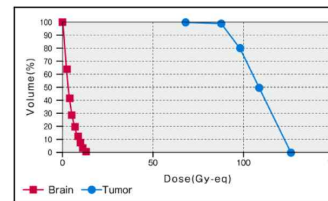
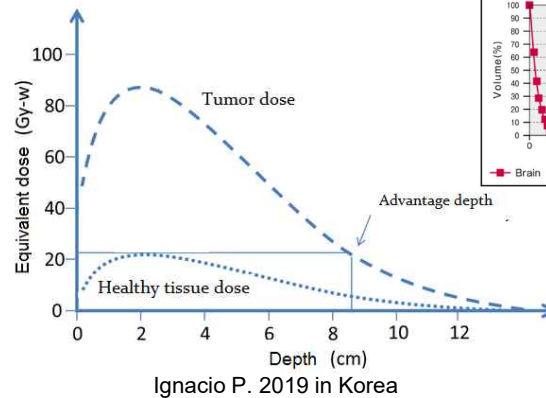
**Neutron  
Irradiation**

**Hydration  
& Monitoring  
in Hospital**

**Follow-up**

**Multidisciplinary  
team**

Physicians  
Radiation oncologists  
Nuclear medicine physicians  
Medical physicists  
Radiation technologists  
Pharmacists  
Nurses  
etc.



*\*Coderre and Morris 1999*

**Dose component**

$D_B$  - boron dose  $^{10}\text{B}(n,\alpha)^7\text{Li}$   
 $D_N$  - nitrogen dose  $^{14}\text{N}(n,p)^{14}\text{C}$   
 $D_{\text{fast}_n}$  - fast neutron dose  $^1\text{H}(n,n')p$   
 $D_g$  - photon dose  $^1\text{H}(n,g)^2\text{H}$

**× CBE/RBE factors**

$D_B$  Cancer 3.8 Brain 1.3  
 Oral mucosa 2.5 (Finland)  
 4.9 (Taiwan, Japan)  
 $D_N$  and  $D_{\text{fast}_n}$  3.2  
 $D_g$  1



# 임상시험 결과의 과거와 현재



BGRR Clinical trial 1951-1959



## MIT Named in Lawsuit Over Radiation Deaths



Adriane Chapman--The Tech

Today, the fourth patient is slated to begin testing a new radiation treatment in this facility at the Nuclear Reactor Laboratory. MIT is named in a lawsuit filed on behalf of brain tumor patients treated with an experimental radiation treatment at the reactor in the 1960s.

Preliminary scanning  
of the cancer patients

Gross calculation of  
tumor size and volume  
from the preliminary  
scanned images

18F-FBPA PET scan  
Image to check the  
uptake of boron  
drug by tumor cells

Epithermal neutron  
beam irradiation

Administration of  
BPA drug

Treatment plan and  
simulation

BNCT : Lysis of tumor cells

## Successful Clinical Trials

**IAEA**  
International Atomic Energy Agency

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### Boron Neutron Capture Therapy Back in Limelight After Successful Trials

Andrew Green, IAEA Office of Public Information and Communication

SEP 27 2016

**BNCT - does it work?**

Glioblastoma treated at Tsukuba University  
Conventional therapy vs. BNCT  
Conclusion: Results BNCT were significantly better.

**Related Stories**

- Reining in Costs and Ensuring Feasibility of Proton Beam Therapy Key to Modern Radiation Oncology
- Reducing Cancer Deaths by a Third in 15 Years: How the IAEA can Help
- Together We Can Do More

**Related Resources**

- IAEA 60th General Conference, 26-30 September 2016
- IAEA General Conference, Photo Gallery
- Scientific Forum, 28-29 September 2016
- Division of Human Health
- Department of Nuclear Sciences and Applications

A cancer treatment involving irradiated boron isotopes has been explored as a therapeutic option for several decades but with very little clinical success. But thanks to recent advances in technology, it is now seeing renewed interest after successful clinical trials to treat certain types of cancer, namely melanoma of the skin, parotid cancer and head and neck cancer. Patients with brain



2021 Hirose et al.

Boron neutron capture therapy using cyclotron-based epithermal neutron source and borofalan ( $^{10}\text{B}$ ) for **recurrent or locally advanced head and neck cancer** (JHN002): An open-label phase II trial

\* 사이클로트론 가속기 + BPA 의약품 사용

Response to BNCT.

Response	SCC (n = 8)	nSCC (n = 13)	Total (n = 21)
Response, No. (%)			
Complete response	4 (50)	1 (8)	5 (24)
Partial response	2 (25)	8 (62)	10 (48)
Stable disease	1 (13)	4 (31)	5 (24)
Progression	0 (0)	0 (0)	0 (0)
Not evaluable	1 (13)	0 (0)	1 (5)
ORR, % (95% CI)	75 (35–97)	69 (39–91)	71 (48–89)
DCR, % (95% CI)	88 (47–100)	100 (79–100)	95 (76–100)
Proportion OS at 2 years, % (95% CI)	58 (18–84)	100 (79–100)	85 (61–95)

The results were from central review at day 90 after BNCT in JHN002 trial. Abbreviations: BNCT, boron neutron capture therapy; SCC, squamous cell carcinoma; nSCC, non-squamous cell carcinoma; ORR, objective response rate; CI, confidential interval; DCR, disease control rate; OS, overall survival.



## 표재성 흑색종 장기추적 임상결과 (원자로)

2020 Hiratsuka et al.  
Long-term outcome of cutaneous melanoma patients treated with boron neutron capture therapy (BNCT)

\* 원자로 (KURRI) + BPA

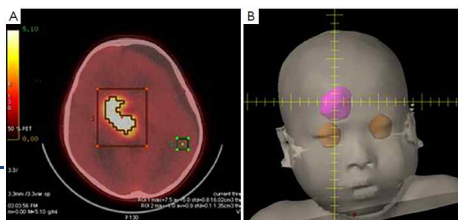
대상 환자군 : 병기 cT1-2N0M0, performance scores < 2.

Table 3. Treatment administered and clinical outcome

Patient No.	Minimum tumor dose (Gy-eq)	Maximum skin dose (Gy-eq)	Adverse reaction	Tumor response	Locoregional control (years)	Survival
1	37	14	Grade 2	CR	12.6	12.6 years (death due to pneumonitis)
2	25	14	Grade 2	CR	6.9	6.9 years (death due to advanced age)
3	25	12	Grade 2	CR	5.5	5.5 years (death due to advanced age)
4	48	15	Grade 1	CR	8.2	8.2 years (alive with NED <sup>a</sup> )
5	50	13.5	Grade 2	PR	7.5	7.5 years (alive with PR)
6	41	12	Grade 2	CR	7.5	7.5 years (alive with NED)
7	33	8	Grade 1	PR	6.0	7.1 years (alive with recurrence in 6 years after NCT)
8	25	8	Grade 1	CR	5.6	5.6 years (alive with NED)

<sup>a</sup>NED = no evidence of disease.





## 재발성 소아뇌종양환자의 구제치료로서 정확한 BNCT 활용 (원자로)



2020 Chen et al. Using precise boron neutron capture therapy as a salvage treatment for pediatric patients with recurrent brain tumors

\* 원자로 (Center of National Tsing-Hua University to use the Tsing-Hua Open Pool Reactor (THOR)) + BPA

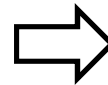
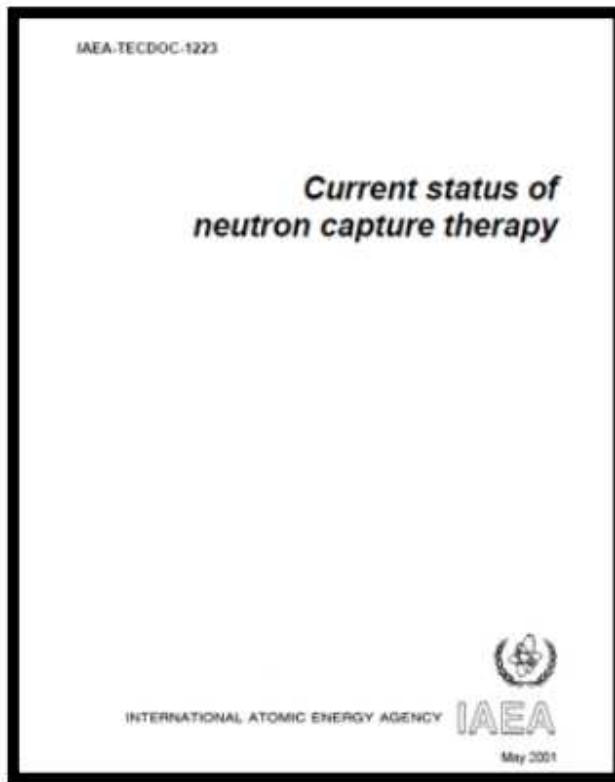
Table 1 Pediatric brain tumor BNCT patients' characteristics and outcomes

Tx serial No.	Pt No.	Sex	Age at initial diagnosis	Diagnosis	Tumor location	Previous Tx history	BNCT age	BNCT date	Response (one month after Tx)	Relapse status	Time from BNCT to progression (months)	Time after BNCT to death (months)	Last status
1	1	M	2	2nd GBM	R't thalamus	Craniotomy for Bx & low dose RT	8	2017/6/30	near CR	Y	5	9	Dead
2	1	M	2	2nd GBM	R't cerebellum (Seeding)	Salvage 1 <sup>st</sup> BNCT	8	2017/11/8	SD	Y	3	4	Dead
3	2	F	6	MB; 2 <sup>nd</sup> GBM	Post fossa; L't frontal	Craniotomy, RT & CHT	11	2017/11/29	PD	Y	5	6	Dead
4	2	F	6	MB; 2 <sup>nd</sup> GBM	Post fossa; L't frontal	Craniotomy, RT & CHT	11	2017/11/29	PD	Y	5	6	Dead
5	3	M	6	GBM	Brainstem	Craniotomy for 3 times	7	2018/3/23	PR	Y	3	4	Dead
6	4	F	3	GBM	Left parietal	Craniotomy & CCRT	5	2019/3/15	PR	Y	3	-	Alive
7	4	F	3	GBM	Left parietal & splenium	Craniotomy & salvage 1 <sup>st</sup> BNCT	5	2019/5/24	PR	Y	3	-	Alive
8	4	F	3	GBM	Splenium	Salvage 2 <sup>nd</sup> BNCT	5	2019/8/14	SD	Y	3	-	Alive
9	5	M	7	HGG (Favor GBM)	Brainstem	Biopsy and CCRT	8	2019/3/15	SD	Y	5	6	Dead
10	5	M	7	HGG (Favor GBM)	Brainstem	Salvage 1 <sup>st</sup> BNCT	8	2019/4/19	SD	Y	4	5	Dead

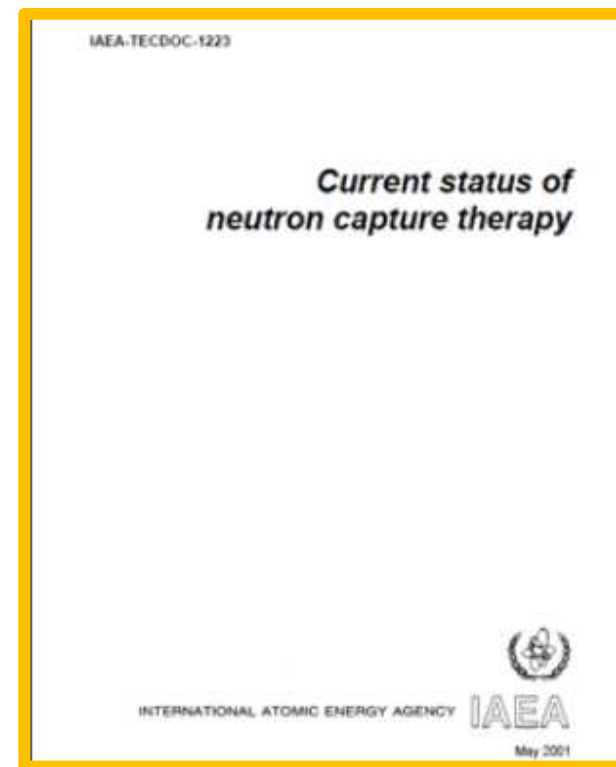
Tx, treatment; Pt, patient; M, male; F, female; 2nd, secondary; GBM, glioblastoma; MB, medulloblastoma; HGG, high grade glioma; R't, right; L't left; Bx, biopsy; RT, radiotherapy; BNCT, boron neutron capture therapy; CHT, chemotherapy; CCRT, concurrent chemoradiotherapy; CR, complete response; SD, stable disease; PD, progressive disease; PR, partial response; Y, yes.



IAEA TECDOC-1223  
May 2001



New Technical document  
2021~2022





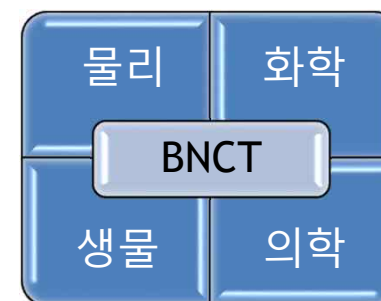
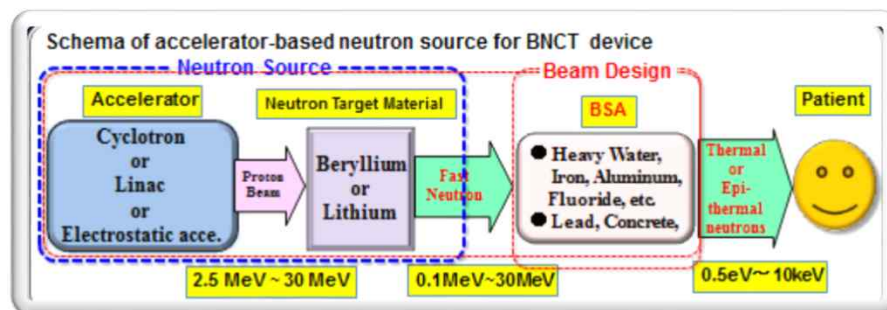
# IAEA BNCT 기술미팅 시행 (27th-31th, July, 2020)



온라인 미팅	주요 논의 주제
월 (7월 27일)	<b>Neutron beam design, desired parameters &amp; measurement</b> Prerequisites for neutron beam parameters: David Nigg, Iiro Auterinen Beam design considerations : Hiroaki Kumada, Jacek Capala Physical dosimetry of BNCT: determination of beam parameters: Hiroki Tanaka, Daniel Santos
화 (7월 28일)	<b>Source and facility design, mgmt, and regulatory aspects</b> Neutron sources for BNCT treatment facilities : Yoshiaki Kiyanagi, Andres Kreiner Organization, operation and management of a BNCT treatment facility : Koji Ono, Yoshihiro Takai Treatment facility design : Liisa Porra, Akira Matsumura Regulatory aspects : Sandro Rossi, Noah Smick
수 (7월 29일)	<b>Boron compounds, BNCT radiobiology &amp; Boron imaging</b> Boron compound : Hiroyuki Nakamura, Eva Hey-Hawkins Radiobiology : Amanda Schwint, Mitsuko Masutani Boron concentration determination and imaging : Saverio Altieri, Sasana Nieves
목 (7월 30일)	Prescribing and treatment planning for BNCT : Hanna Koivunoro, Yoshinori Sakurai Dose reporting in BNCT : Wolfgang Sauerwein, Shin-Ichi Miyatake Clinical trial design and procedures for BNCT : Adrea Wittig, Hiroshi Igaki
금 (7월 31일)	Friday session IAEA TM on Advances in Boron Neutron Capture Therapy : Ignacio Porras, Minoru Suzuki



## New TEC-DOC



1. New TECDOC is devoted to **Accelerator Based** Neutron Sources
2. Radiobiology measurements are key
3. Important a good characterization of the beam
4. Diverse n producing reactions  $7\text{Li}(p,n)$ ,  $9\text{Be}(p,n)$ ,  $13\text{C}(d,n)$ ,  $9\text{Be}(d,n)$
5. Operation & management of facilities: previous TECDOC is not suitable
6. Treatment facility design
7. Radiation protection
8. Cost similar to proton beam therapy but can be reduced in existing hospital
9. There is not much knowledge from authorities about BNCT facilities, longer time for approval, some education is required
10. Dose calculations of BNCT

## New TEC-DOC

set of consensus on

1. recommend solutions and frame of guidance for "BNCT-specific" clinical trial methodology
  - **Ease regulatory procedures**
2. indispensable parameters, which are to be defined in study protocols and which have to be reported in publications
  - **Global exchange**
  - **Quality assurance**
  - **Opening up financing opportunities**
3. preclinical/translational strategies which ease clinical procedures
  - **Effective developments through collaborative research**



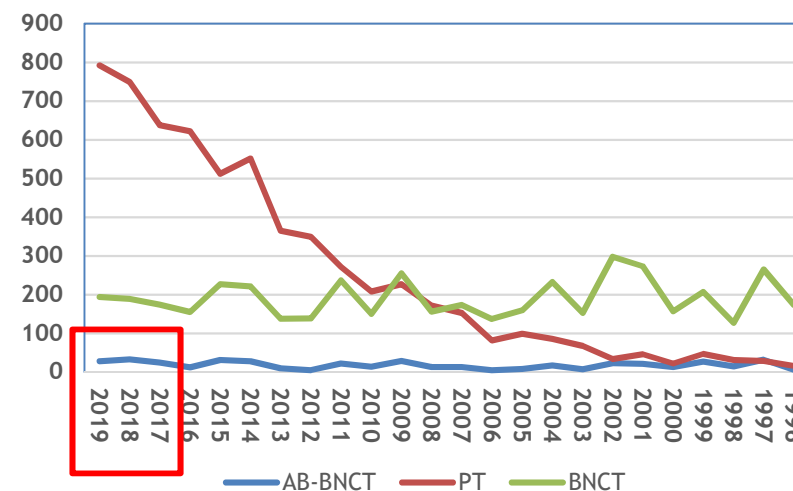
# 연구경향 : “Neutron Capture Therapy” OR “Neutron Therapy” OR “BNCT”



By Countries

Countries with more than 100 publication

country	documents	citations
Argentina	190	1917
Australia	102	2771
England	215	6834
Finland	125	1572
France	139	4033
Germany	363	8980
Iran	102	597
Italy	358	7405
Japan	979	16901
Netherlands	145	5996
Peoples R China	228	3353
Russia	294	3514
South Korea	113	1104
Sweden	165	3663
Taiwan	127	1196
USA	1534	41742



Yaser Kasesaz, Wolfgang Sauerwein, Afsaneh Karami, 2020, IAEA TM Scientometric analysis of BNCT research and development



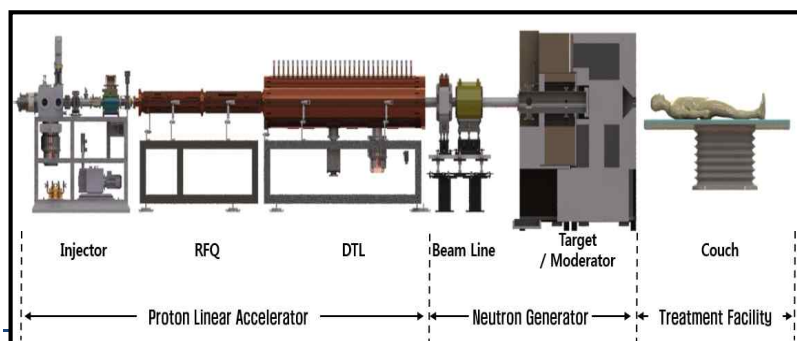
# 국내 A-BNCT 개발 – 다원메딕스



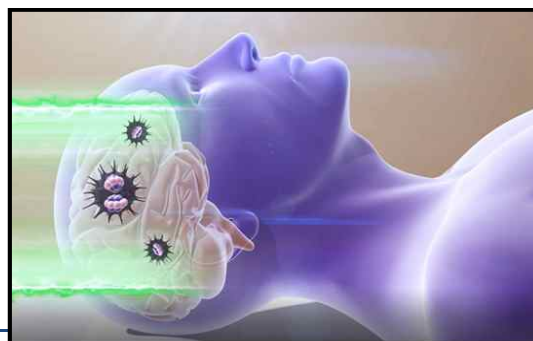
- ❑ **Project Name** : Development of the accelerator based Boron Neutron Capture Therapy system for the cancer treatment within 1 hour therapeutic time
- ❑ **Project Period** : 2016 . 5 ~ 2021 . 6 (MOTIE project) and continuous development
- ❑ **Leading Organization** : Dawonmedax & Dawonsys Inc.
- ❑ **Participating Organizations** : Gachon Univ Gil Medical Center,, PAL, KAERI and KBSI
- ❑ **Developed Items** : Proton Linac, Be Target / Moderator Assembly, Radiation Safety & Licensing, Boron Compounds, TPS, Dosimetry (n& $\gamma$ ), Biological Experiment (cells, animals) Clinical Trials

❖ Supported by Ministry of Trade, Industry and Energy (MOTIE) project

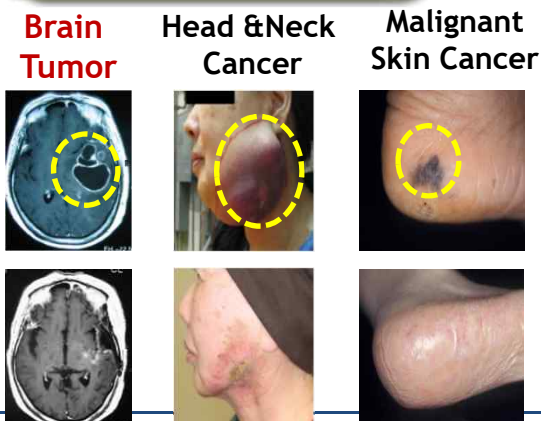
## A-BNCT Facility



## Dosimetry & TPS



## Clinical Trials





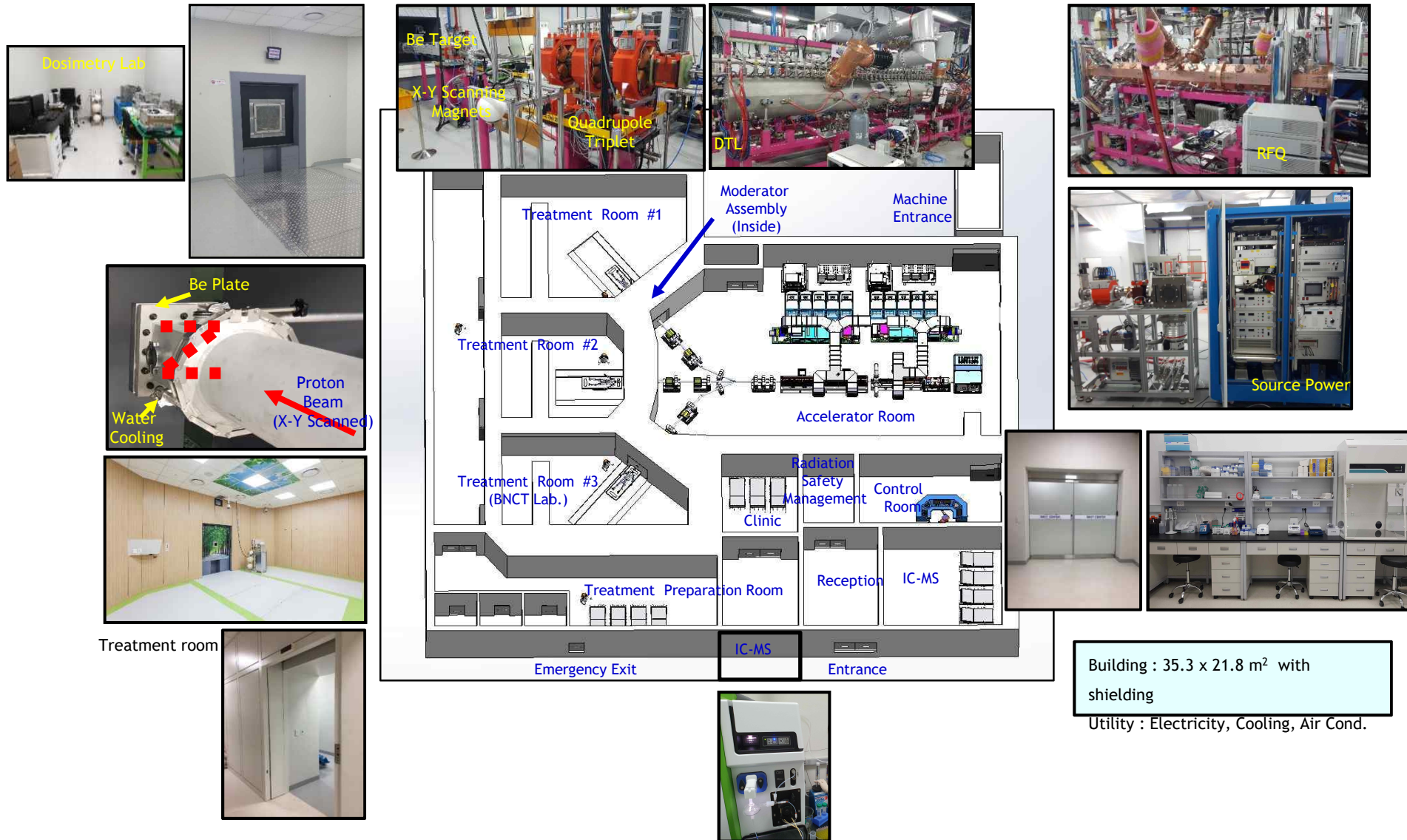
## A-BNCT 센터

Songdo, Incheon



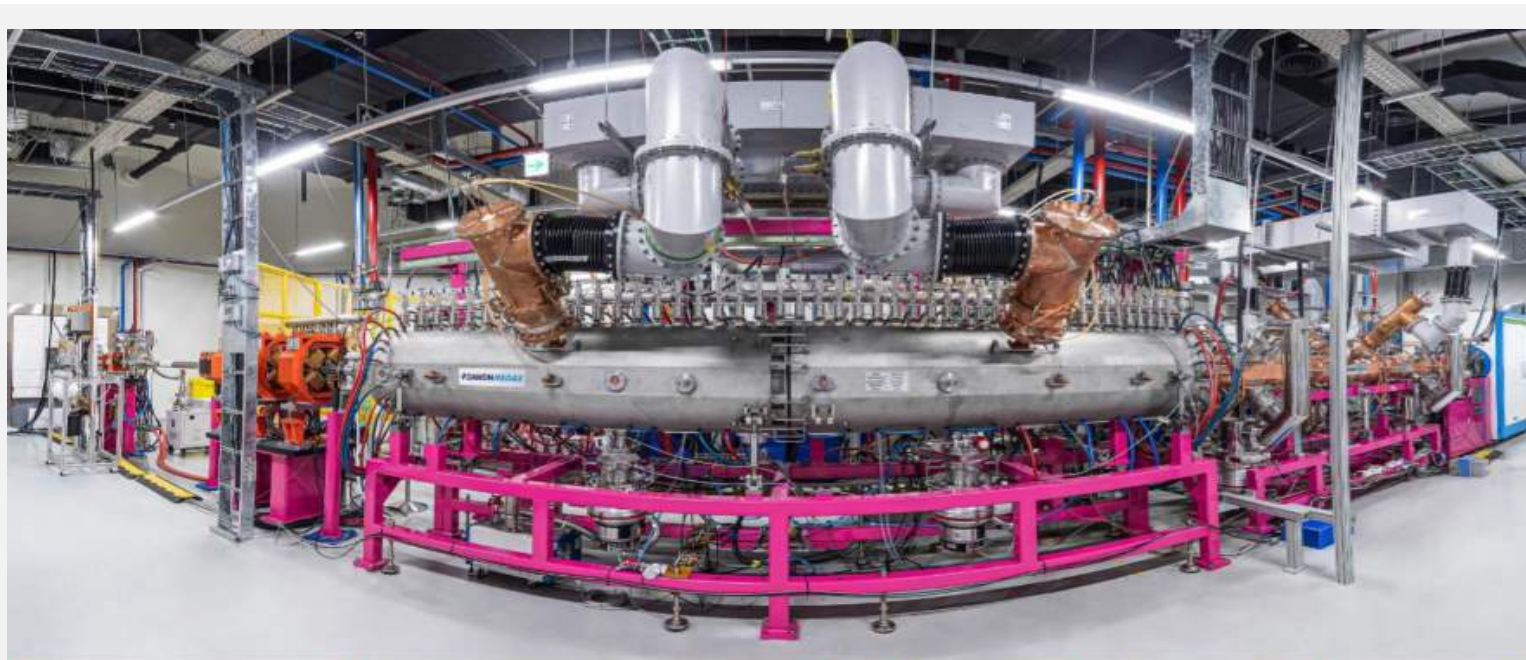


# A-BNCT 센터





## DawonMedax' Linear Accelerator (LINAC)



Beam lines

DTL  
(Drift Tube LINAC)

RFQ  
(Radio Frequency  
Quadrupole)

Ion Source



# 의료기기, 의약품 및 치료계획시스템 인허가 프로세스



[Class III] Medical device

LINAC based BNCT

[Class II] Software

Treatment planning system

MFDS requires the submission of 'Technical Documents' for the certification and approval for BNCT medical devices.

BNCT is categorized as Class III devices.

Test report, comparison data, mode of action, safety & performance process, Clinical study, usage Status at Overseas etc.



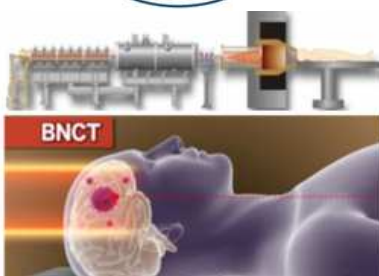
Nuclear Safety and  
Security Commission



Korea Testing  
Laboratory



Ministry of Food and  
Drug Safety



[New drug] Boron Drug

BPA DP

Selected as a High Tech Medical Device and  
Innovative Medical Device Company by Medical device Industry Law

Radiation Safety Approval of facilities LINAC based BNCT  
Selected as a medical device approval guide program of MFDS



Selected as a Pharm Navi guide program of MFDS

MFDS requires the safety & efficacy data, specifications & test methods, Drug Master Files (DMF), certificate of manufacturing and marketing(Imported Pharmaceutical) Data such as name and address of manufacturers of active pharmaceutical ingredients.

Evaluation data of conducting of Good Manufacturing Practice (GMP)



# International Society for Neutron Capture Therapy (ISNCT)



ISNCT: Involves multidisciplinary researchers  
in the field in a spirit of close collaboration  
Promotes the future development of BNCT

[www.isnct.net](http://www.isnct.net)

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- [Silva Bortolussi](#) (Secretary General)
- [Fong-In Chou](#) (Immediate Past President)
- [Javier Praena](#) (ICNCT Chair 2020)
- [Michal Gryzinski](#) (ICNCT Chair 2022)
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- [Leena Kankaanranta](#)
- [Stuart Green](#)



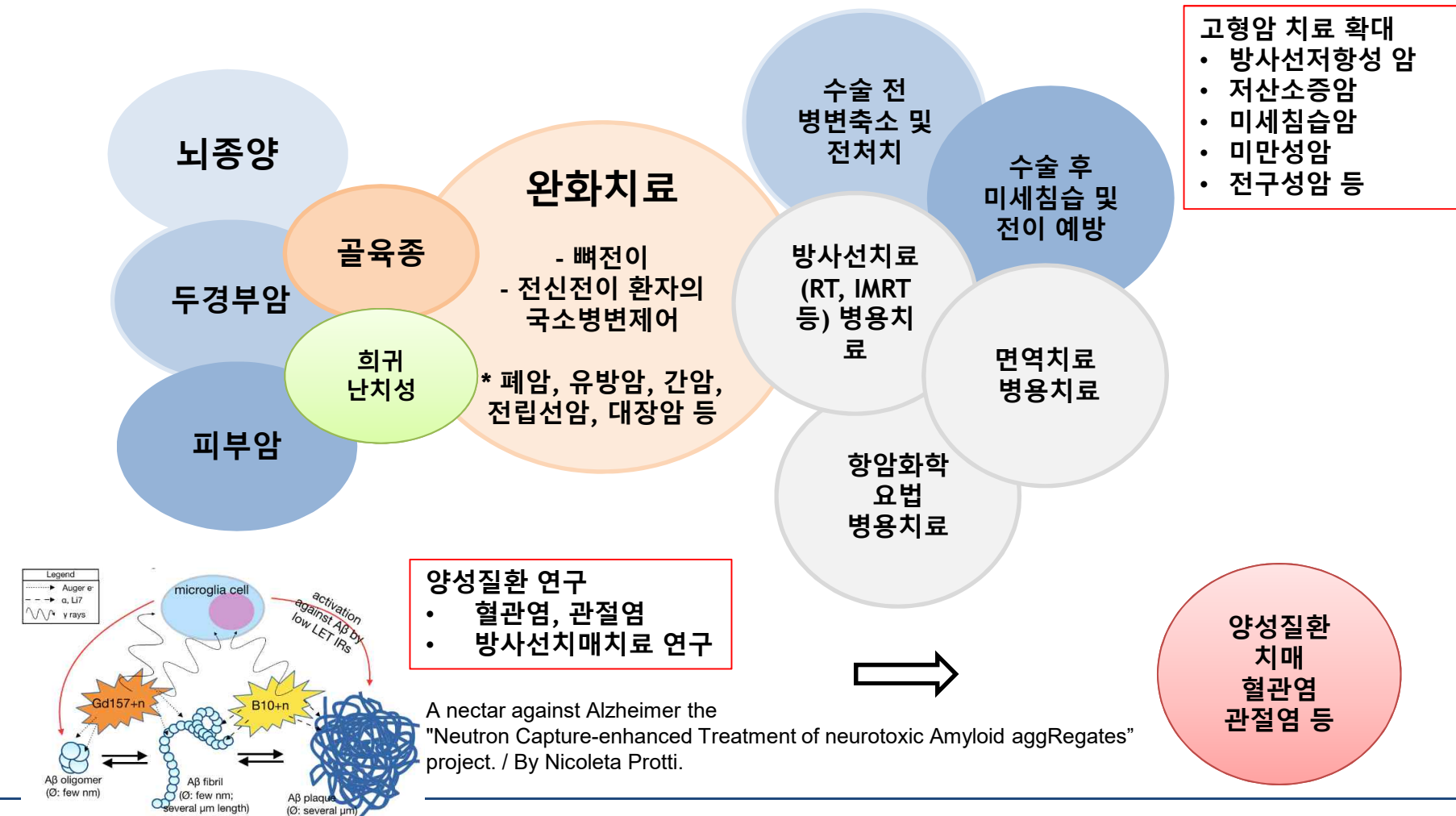
**국내 중성자포획치료 학회 구성 필요**

**Neutron Capture Therapy  
Boron (B) & Gadolinium (Gd)**



## 환자 삶의 질 (QOL)

## 환자 치료효과 증대





감사합니다  
THANK YOU

